Clinical Informatics

Board Review Course

Course Book for Live Meetings

2016
Welcome to AMIA’s Clinical Informatics Board Review Course (CIBRC). By choosing to prepare for this new certification examination in Clinical Informatics (CI), you are a part of the third cohort of healthcare professionals to prepare for ABMS/ABPath Board Certification in this subspecialty. Our goal over the next three days is to prepare you for the high-stakes CI examination offered over a two-week period from October 4 - 14, 2016. But, most importantly, based on our 2013 - 2015 experience of preparing review materials for the examination, we have an even clearer picture of the educational needs of those individuals who are planning to sit for the examination this year.

This course was created thanks to a tremendous (and ongoing) effort by AMIA volunteers, subject matter experts, professional staff, and like-minded partners. It represents more than seven years of concerted efforts to establish the subspecialty of clinical informatics and, at the same time, marks the beginning of an expanded role for AMIA in advancing the subspecialty.

Physicians who achieve a credential in CI are considered pioneers of an exciting area of medical practice. You possess the sheer intellect and talent to collaborate with other health care and information technology professionals to analyze, design, implement and evaluate information and communication systems that enhance individual and population health outcomes, improve patient care, and strengthen the clinician-patient relationship. Through a combination of formal training and professional experience, clinical informaticians such as yourselves are among a group of professionals with the advanced set of core competencies to transform both the delivery and care of patients with your clinical informatics expertise.

On behalf of AMIA, we would like to thank the course faculty and individuals acknowledged in this course book whose efforts have helped to shape the subspecialty and are enabling AMIA to provide resources to individuals who seek assistance in preparing for the board exam. Former AMIA President and CEO, Don E. Detmer, MD, MA, FACMI, and his successor Edward H. Shortliffe, MD, PhD, FACMI, both invested considerable time in this effort and its success is the direct result of their leadership. Doug Fridsma, MD, PhD, FACP, FACMI, AMIA’s current president and CEO, is enthusiastic about supporting the clinical informatics community, particularly as clinical informaticians transition to the diplomate community.

AMIA has invested considerable energy into providing benefits and tools to strengthen the subspecialty of clinical informatics and supporting the professional development of clinical informaticians. In late 2013, we launched a Clinical Informatics Community of Practice (CICOP) for 416 credentialed diplomates who were AMIA members! CICOP now numbers more than 900 participants. AMIA has an MOC program in place, with two live meetings a year – the Annual Symposium and iHealth – that offer MOC-II credit. Plans are underway for additional live and online activities that will offer MOC-II credit for clinical informaticians. Your colleagues in CICOP are now poised to design continuing education resources such as needs assessment exercises, webinars, and sharing of best practices for all health professionals who practice clinical informatics. AMIA is the unique professional society that offers this portfolio of activities for certified clinical informaticians.

Thank you for your leadership in shaping the subspecialty of clinical informatics. Your willingness to take this new exam, your presence at this course, and your commitment to the studying that lies ahead of you require a considerable investment of money and time. By taking this path, you are signaling the importance of the subspecialty to your peers and blazing the trail for those who will follow. The AMIA community welcomes your active participation in further developing the profession of clinical informatics.

On behalf of AMIA’s CIBRC Faculty,

Jeffrey J. Williamson, M.Ed.    Pesha Rubinstein, MPH, CHCP
Vice President of Education & Academic Affairs  Director of Education

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# AMIA Clinical Informatics Board Review Course

## Schedule

- **August 5 – 7, 2016 (Providence)**
- **September 9 – 11, 2016 (Denver)**

### Day 1

<table>
<thead>
<tr>
<th>Total Time</th>
<th>Start Time</th>
<th>Activity</th>
<th>Faculty</th>
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<tbody>
<tr>
<td></td>
<td>7:00 am</td>
<td>Registration</td>
<td></td>
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<tr>
<td></td>
<td>7:00 am</td>
<td>Continental Breakfast</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>7:45 am</td>
<td>Welcome &amp; Course Overview</td>
<td>Hersh</td>
</tr>
<tr>
<td>30</td>
<td>8:00 am</td>
<td>Lecture 1A: History and Current State of Informatics</td>
<td>Hersh</td>
</tr>
<tr>
<td>45</td>
<td>8:30 am</td>
<td>Lecture 1B/4E: Ethical, Legal, and Financial Issues in Informatics</td>
<td>Payne</td>
</tr>
<tr>
<td>60</td>
<td>9:15 am</td>
<td>Lecture 1C: The Health System</td>
<td>Hersh</td>
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<tr>
<td>10</td>
<td>10:15 am</td>
<td>Break</td>
<td></td>
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<tr>
<td>75</td>
<td>10:25 am</td>
<td>Lecture 2A-1: Clinical Decision Making</td>
<td>Desai</td>
</tr>
<tr>
<td>60</td>
<td>11:40 am</td>
<td>Lecture 2A-2: Applied Decision Support</td>
<td>Desai</td>
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<tr>
<td>15</td>
<td>12:40 pm</td>
<td>Break to pick up lunch</td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>12:55 pm</td>
<td>Lunch: How to Approach the Exam</td>
<td>Hersh</td>
</tr>
<tr>
<td>90</td>
<td>1:25 pm</td>
<td>Lecture 2C-1/4F: Clinical Workflow Analysis and Process Redesign; Change Management</td>
<td>Carter</td>
</tr>
<tr>
<td>10</td>
<td>2:55 pm</td>
<td>Break</td>
<td></td>
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<tr>
<td>60</td>
<td>3:05 pm</td>
<td>Lecture 2C-2: Healthcare Quality Improvement</td>
<td>Desai</td>
</tr>
<tr>
<td>10</td>
<td>4:05 pm</td>
<td>Break</td>
<td></td>
</tr>
<tr>
<td>60</td>
<td>4:15 pm</td>
<td>Lecture 3C1: Healthcare Information Systems &amp; Applications</td>
<td>Payne</td>
</tr>
<tr>
<td>60</td>
<td>5:15 pm</td>
<td>Lecture 3C2: Pathology Informatics</td>
<td>Carter</td>
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<tr>
<td>10</td>
<td>6:15 pm</td>
<td>Announcements: Daily evaluation; Overnight exercises</td>
<td>Hersh</td>
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<tr>
<td></td>
<td>6:25 pm</td>
<td>Reception</td>
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<tr>
<td>7:00 am</td>
<td>Registration</td>
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<tr>
<td>7:00 am</td>
<td>Continental Breakfast</td>
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<tr>
<td>7:45 am</td>
<td>Review of Exercises</td>
<td>All Faculty</td>
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<tr>
<td>8:30 am</td>
<td>Lecture 2A-3: Knowledge Acquisition and Use for Clinical Decision Support</td>
<td>Hersh</td>
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<tr>
<td>9:00 am</td>
<td>Lecture 3A-1: Computer Programming and Methods of Software Development</td>
<td>Desai</td>
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<tr>
<td>10:30 am</td>
<td>Break</td>
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<tr>
<td>10:40 am</td>
<td>Lecture 3A-2: Systems, Databases, Networks</td>
<td>Desai</td>
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<tr>
<td>11:55 am</td>
<td>Lecture 3A-3: Security</td>
<td>Payne</td>
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<tr>
<td>12:40 pm</td>
<td>Break to pick up lunch</td>
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<tr>
<td>12:55 pm</td>
<td>Lunch: Lecture 4E-1: Strategic Planning</td>
<td>Carter</td>
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<tr>
<td>1:55 pm</td>
<td>Break</td>
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</tr>
<tr>
<td>2:05 pm</td>
<td>Lecture 3D1-3: Clinical Data Standards</td>
<td>Hersh</td>
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<tr>
<td>3:45 pm</td>
<td>Break</td>
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<tr>
<td>3:55 pm</td>
<td>Lecture 3E1-2: Implementation and Operation of Clinical Information Systems</td>
<td>Payne</td>
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<tr>
<td>4:55 pm</td>
<td>Break</td>
<td></td>
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<tr>
<td>5:05 pm</td>
<td>Lecture 4A: Leadership</td>
<td>Carter</td>
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<tr>
<td>6:05 pm</td>
<td>Announcements: Daily evaluation; Overnight exercises</td>
<td>Hersh</td>
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<tr>
<td>6:15 pm</td>
<td>Adjourn</td>
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### Day 3

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<tr>
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<td>Breakfast</td>
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<tr>
<td>7:45 am</td>
<td>Review of Exercises</td>
<td>All Faculty</td>
</tr>
<tr>
<td>8:15 am</td>
<td>Lecture 3A-4: Healthcare Data Reuse: Challenges and Strategies</td>
<td>Hersh</td>
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<tr>
<td>8:45 am</td>
<td>Lecture 3B: Human Computer Interaction</td>
<td>Desai</td>
</tr>
<tr>
<td>9:30 am</td>
<td>Break</td>
<td></td>
</tr>
<tr>
<td>9:45 am</td>
<td>Lecture 4D: Project Management</td>
<td>Carter</td>
</tr>
<tr>
<td>10:45 am</td>
<td>Lecture 2B-1/2B-2: Evidence-based Medicine; Information Retrieval and Analysis</td>
<td>Hersh</td>
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<tr>
<td>11:30 am</td>
<td>Break to pick up lunch</td>
<td></td>
</tr>
<tr>
<td>11:45 am</td>
<td>Lunch: Lecture 4B/4C: Building Effective Healthcare IT Teams; Communication</td>
<td>Carter</td>
</tr>
<tr>
<td>1:15 pm</td>
<td>Lecture 3E-3: Information System Evaluation</td>
<td>Hersh</td>
</tr>
<tr>
<td>1:45 pm</td>
<td>Daily Evaluation / Closing Remarks</td>
<td>Hersh</td>
</tr>
<tr>
<td>2:00 pm</td>
<td>Adjourn</td>
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CME Information

LIVE ACTIVITY

August 5 - 7, 2016: Providence, RI

September 9 - 11, 2016: Denver, CO

STATEMENT OF PURPOSE

In the past decade health care has radically changed from a paper-based system to one that relies on technology to support all facets of health care delivery. This transformation has given rise to practitioners who need a skill set that goes beyond the clinical specialty in order to provide patients with the right care at the right time in the right place every time. This skill set may include abilities such as collaborating with various stakeholders to implement electronic health record technology in a health care system, managing clinical decision support in the EHR, analyzing “big data” to help determine population health or manage system costs, incorporating telemedicine into everyday practice, and optimizing the appropriate use of technological innovations in patient care. In 2011, the American Board of Medical Specialties recognized clinical informatics as a new subspecialty, with pathways to board certification through either the American Board of Preventive Medicine or the American Board of Pathology. Diplomates from all existing medical specialties are eligible to apply for and pursue this certification. As there is no single path for developing the skill set for the clinical informatician, those physicians desiring this board certification will want to ascertain their competence. A review course focusing on core competencies taught by leaders in the field is a classic component of study preparation for a board exam.

TARGET AUDIENCE

AMIA’s Clinical Informatics Board Review Course is designed to provide an up-to-date review of the core content of the Clinical Informatics subspecialty. It is appropriate for:

Physicians preparing to sit for the board-certification examination in clinical informatics.

LEARNING OBJECTIVES

After participating in this activity, the learner should be better able to:

- Describe the role of data across the health care system, the laws governing use of data, and technical approaches to ensuring quality and protection of data
- Identify the range of clinical decision support tools; explain how to determine which application is appropriate for specific situations; describe how to develop and implement clinical decision support tools
• Describe the processes of developing or selecting a clinical information system, preparing and supporting clinicians for system implementation, and evaluating system effectiveness
• Identify the key types of health information systems and describe how to achieve system interoperability
• Identify the non-technical factors that influence the adoption of clinical information systems by clinicians and describe strategies for promoting effective use of clinical information systems

ACCREDITATION STATEMENT

The American Medical Informatics Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

CREDIT DESIGNATION STATEMENT

The American Medical Informatics Association designates this live activity for a maximum of 25 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

COMMERCIAL SUPPORT

No commercial support was received for this activity.

ADA STATEMENT

Special needs: In accordance with the Americans with Disabilities Act, AMIA seeks to make this live activity accessible to all. If you have a disability which requires special accommodation, please email: Lauren@amia.org.

DISCLOSURE POLICY

As a provider accredited by the ACCME, AMIA requires that everyone who is in a position to control the content of an educational activity disclose all relevant financial relationships with any commercial interest for 12 months prior to the educational activity.

The ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

Faculty and planners who refuse to disclose relevant financial relationships will be disqualified from participating in the CME activity. For an individual with no relevant financial relationship(s), the participants must be informed that no conflicts of interest or financial relationship(s) exist.

AMIA uses a number of methods to resolve potential conflicts of interest, including: limiting content of the presentation to that which has been reviewed by one or more peer reviewers; ensuring that all scientific research referred to conforms to generally accepted standards of experimental design, data
collection, and analysis; undertaking review of the educational activity by a content reviewer to evaluate for potential bias, balance in presentation, evidence-based content or other indicators of integrity, and absence of bias; monitoring the educational activity to evaluate for commercial bias in the presentation; and/or reviewing participant feedback to evaluate for commercial bias in the activity.

DISCLOSURES FOR THIS ACTIVITY

All speakers and members of the planning committee have been asked to disclose any significant relationships they may have with commercial interests. The following report no financial relationships with commercial interests: Faculty Drs. Carter, Desai, Hersh, and Payne; Planners AMIA VP of Education and Academic Affairs Jeffrey J. Williamson; AMIA Director of Education Pesha Rubinstein; AMIA Certification Consultant Ben S. Munger; founding faculty Diane Montella, MD; and consultant Elaine Steen.

CRITERIA FOR SUCCESSFUL COMPLETION

Completion of this activity is demonstrated by engagement in live sessions and completion of an activity evaluation here: https://www.surveymonkey.com/r/CIBRC2016Live

Physicians verify their attendance using instructions below.

INSTRUCTIONS FOR CLAIMING CME CREDIT

CME site works best with IE 8 or above version, Chrome, and Firefox.

- Logon at www.amia.org
- Go to “My Events” under Membership/Activities
- Click “Apply for Credits” link for meeting you attended.
- Be sure both drop-down boxes say “Physician”
- Click the radio button next to the meeting name; continue; submit
- Download your certificate under My AMIA Activities
- Other attendees: if you require a certificate of participation, please contact pesha@amia.org

CONTACT INFORMATION

For questions regarding the content of this activity, contact info@amia.org.
Evaluation

Please provide your feedback about the lectures at the conclusion of each day. The link to the evaluation is at:

https://www.surveymonkey.com/r/CIBRC2016Live

Please use the same device each day to provide your feedback so that previously input clicks and comments are preserved.
Faculty

William (Bill) Hersh, MD, FACP, FACMI Course Director, Clinical Informatics Board Review Course
Professor and Chair, Department of Medical Informatics and Clinical Epidemiology, School of Medicine,
Oregon Health & Science University

William Hersh is Professor and Chair of the Department of Medical Informatics & Clinical Epidemiology in the School of Medicine at Oregon Health & Science University (OHSU) in Portland, Oregon, USA. Dr. Hersh is a leader and innovator in biomedical informatics both in education and research.

In education, he developed and serves as Director of all of OHSU’s graduate biomedical informatics education programs, including the Master of Science, the Master of Biomedical Informatics, the Graduate Certificate, and the Doctor of Philosophy. Dr. Hersh also spearheaded OHSU’s efforts in distance learning for biomedical informatics, which are available up to the master’s degree level. He also conceptualized and implemented the first offering of the American Medical Informatics Association (AMIA) 10x10 (“ten by ten”) program, which aims to educate 10,000 health care professionals and others in biomedical informatics.

Dr. Hersh also serves as Director of the OHSU Clinical Informatics Fellowship, which was accredited by ACGME in 2014 (http://www.ohsu.edu/CIFellowship). In addition, he serves as Director of OHSU’s National Library of Medicine-funded Biomedical Informatics Research Training Grant.

Dr. Hersh obtained his B.S. in Biology from the University of Illinois at Champaign-Urbana in 1980 and his M.D. from the University of Illinois at Chicago in 1984. After finishing a residency in Internal Medicine at University of Illinois Hospital in Chicago in 1987, he completed a Fellowship in Medical Informatics at Harvard University in 1990. Dr. Hersh became board-certified in the clinical informatics subspecialty in 2013 with the initial cohort of physicians who took the board exam.

Dr. Hersh also maintains the Informatics Professor blog (http://informaticsprofessor.blogspot.com/).

Alexis B. Carter, MD, Physician Informaticist, Department of Pathology and Laboratory Medicine,
Children’s Healthcare of Atlanta

Alexis B. Carter, MD, is the Physician Informaticist for the Laboratory at Children’s Healthcare of Atlanta. She is the first chair of the new Informatics Subdivision in the Association of Molecular Pathology and also serves as Test Directory Editor and a member of the AMP Governing Board and Publications Committee.

Dr. Carter is a past-president of the Association of Pathology Informatics and is a member of the Informatics Committee and Clinical Informatics Steering Committee of the College of American
Pathologists. She is the immediate past-chair of the International Pathology and Laboratory Medicine Special Interest Group (IPaLM SIG) of SNOMED CT International which is the governing body for SNOMED CT Terminology. She is the secretary for the working group on two-dimensional barcoding for the Clinical and Laboratory Standards Institute, is a section editor for informatics for *Archives of Pathology and Laboratory Medicine* and is on the editorial board of the *Journal of Pathology Informatics*. Dr. Carter is a faculty member for the Clinical Informatics Board Review Course presented through the American Medical Informatics Association.

Dr. Carter is board-certified in Anatomic Pathology, Clinical Pathology, Molecular Genetic Pathology and Clinical Informatics, and her clinical practice is in both clinical informatics and molecular genetic pathology.

**Bimal Desai**, MD, MBI, FAAP, CMIO *Children’s Hospital of Philadelphia, Assistant Professor of Pediatrics, Perelman School of Medicine, University of Pennsylvania*

Bimal Desai is Chief Medical Information Officer at The Children’s Hospital of Philadelphia and an Assistant Professor of Clinical Pediatrics at the University of Pennsylvania Perelman School of Medicine. He is a board certified pediatrician with a Masters degree in Biomedical Informatics from Oregon Health & Sciences University, and he is a board-certified clinical informatician. He has ten years of experience working with software developers, database analysts, and healthcare analytics teams to develop novel clinical applications that support clinical quality and efficiency. He has worked since 2009 on The Children’s Hospital of Philadelphia electronic health record project, working with teams of healthcare providers and information technologists to implement a commercial EHR across a multi-specialty pediatric healthcare network and an urban tertiary care academic hospital. His informatics interests include studying patterns of alert fatigue, using web-based tools for collaboration, and teaching pediatric trainees how to more effectively integrate web-based clinical resources such as PubMed into patient care. He lives with his wife and twin children in Philadelphia and enjoys choral singing, cooking, and electronic gadgets.

**Thomas Payne**, MD, FACP, FACMI *Medical Director of IT Services, University of Washington*

Dr. Payne is Board Chair of AMIA and has been the Medical Director of UW Medicine IT Services since 2000. He is Professor of Medicine, and Adjunct Professor in Health Services, and Biomedical Informatics & Medical Education. He is Attending Physician in Medicine at the University of Washington Medical Center and Harborview Medical Center. Prior to his current position, he led the installation of the Veterans Administration CPRS electronic medical record at VA Puget Sound in Seattle for which VA
Puget Sound was awarded the 2000 Nicholas E. Davies CPR Recognition Award. He has been elected twice to the Board of Directors. He served on the Editorial Board of the *Journal of the American Medical Informatics Association*, is a fellow of the American College of Medical Informatics, the American College of Physicians and the Royal College of Physicians (Edinburgh) and as Chair of the AMIA EHR-2020 Task Force. He is the author of over 60 articles in the field, and edits a book on Operating Clinical Computing Systems in a Medical Center now in its second edition. His research interests include natural language processing and electronic documentation in EMRs.

Dr. Payne attended Stanford University, the University of Washington School of Medicine, completed his internal medicine residency at the University of Colorado, and completed a fellowship at Massachusetts General Hospital in the Harvard Medical Informatics Fellowship program. He is board certified in Internal Medicine, and, since 2013, in Clinical Informatics.

**Diane Montella, MD, Clinical Informaticist, Knowledge Based Systems, Office of Informatics and Analytics, U.S. Department of Veterans Affairs; Visiting Research Fellow, Vanderbilt University**

Dr. Diane Montella is a Physician Informaticist within the Office of Informatics and Analytics of the U.S. Department of Veterans Affairs (VA) with a focus on Clinical Decision Support (CDS). Diane also provides support in Informatics Education and VA Informatics workforce development efforts, and facilitates communication and training opportunities among Informatics Fellows and Fellowship Directors in the eight VA Advanced Special Fellowships in Medical Informatics nationally.

Dr. Montella was in VA’s legacy Health and Medical Informatics Office and is a key member of the team that developed and produced the “VA Health Informatics Lecture Series 301,” a 41-lecture series available to VA staff nationally in a distance learning format, and the VA Health Informatics-AMIA 10x10 Certificate Program that launched during fiscal year 2012. Diane currently serves as a faculty moderator for the VA 10x10 course. Currently, she is a Visiting Research Fellow in the Department of Biomedical Informatics at Vanderbilt University and is completing the thesis research for her Master’s Degree in Biomedical Informatics.

She has more than 15 years’ experience as a Physician Leader/Physician Executive in medical administration, healthcare quality management, and oversight of healthcare delivery to special populations. Dr. Montella received her undergraduate degree in Public Health from University of Massachusetts at Amherst, and her medical degree from George Washington University School of Medicine in Washington, D.C.
About AMIA

AMIA, the American Medical Informatics Association, is the center of action for more than 5,000 healthcare professionals, informatics researchers, and thought leaders in biomedicine, health care and science. AMIA is an unbiased, authoritative source within the informatics community and the health care industry. AMIA and its members are transforming healthcare through trusted science, education, and practice in biomedical and health informatics.

AMIA is the professional home of leading informaticians: clinicians, scientists, researchers, educators, students, and other informatics professionals who rely on data to connect people, information, and technology.

AMIA supports a broad community for interdisciplinary professionals and students interested in informatics. AMIA actively supports five domains across a continuum from basic and applied research, into clinical practice, and out to the consumer and public health arena. AMIA bridges the knowledge and collaboration in each of five domains: translational bioinformatics, clinical research informatics, clinical informatics, consumer health informatics, and public health informatics.

Members include world-class scholars and practitioners, subject matter experts dedicated to expanding the role informaticians play in patient care, public health, teaching, research, administration and related policy. They play a leading role in moving research findings from bench to bedside, evaluating interventions across communities, and assessing the affect of health innovations on health policy.

Individual members include:

- Physicians, nurses, dentists, pharmacists and other clinicians
- Researchers and educators
- Biomedical and health science librarians
- Advanced degree and undergraduate students pursuing a career in informatics
- Scientists and developers
- Government officials and policy makers
- Consultants and industry professionals

As the voice of the nation’s top biomedical and health informatics professionals, AMIA members play a leading role in:

- Moving basic research findings from bench to bedside;
- Evaluating interventions across communities;
- Assessing the impact of health innovations on health policy; and
- Advancing the field of informatics.

www.amia.org
About the Subspecialty of Clinical Informatics

In March 2007, with financial support from the Robert Wood Johnson Foundation, AMIA launched an 18-month process to define the core content of the subspecialty of clinical informatics and the training requirements for proposed clinical informatics fellowships. Upon approval of these documents by the AMIA Board in November 2008, AMIA contacted several medical specialty boards to assess their interest in, and willingness to sponsor, an application to the American Board of Medical Specialty (ABMS) to create an approved certification process for the clinical informatics subspecialty. In July 2009, the American Board of Preventive Medicine (ABPM) agreed to sponsor the application for a new subspecialty examination, and, in March 2010, ABPM submitted a formal application to ABMS to create the subspecialty certification. After an extensive review by the ABMS specialty boards and the ABMS Committee on Certification (COCERT), the proposal was approved by the ABMS Board in a vote on September 21, 2011.

ABPM opened the application period for board certification in the subspecialty of Clinical Informatics in March 2013. Diplomates of the American Board of Pathology must apply though the American Board of Pathology. Physicians certified through all other ABMS member Boards can apply through ABPM. See the ABPM website for information on specific eligibility requirements:

http://www.theabpm.org/ABPM_Clinical_Informatics.pdf

The Clinical Informatics subspecialty certification process is the sole responsibility of the ABPM and cosponsoring boards. AMIA has offered assistance and expertise, but has no direct responsibility for the exam or for defining the certification criteria. AMIA refers all questions regarding the exam and eligibility to the ABPM.
About the Clinical Informatics Board Review Course

AMIA’s Clinical Informatics Board Review Course is designed for American Board of Medical Specialties (ABMS) Board certified physicians who seek certification in Clinical Informatics. It provides a high-level review of the Core Content of Clinical Informatics on which the exam will be based and helps participants develop a learning map that highlights where they need to spend additional preparation time.

The course includes sample test questions, references for further study, and test-taking strategies. While the primary goal of the course is to assist participants in preparing for the certification exam, we also anticipate that participants will find the course beneficial in their clinical informatics practice. Two options are available: live courses and an online course. Both course types are based on the Core Content for Clinical Informatics which, in turn, is the basis for the Board Exam. The face-to-face course provides over twenty hours of lectures, opportunities to interact with Clinical Informatics subject matter experts, and informal sessions where course participants can learn from their peers.

The fourth edition of the online course released on May 15, 2016. The online version of the course is designed for those learners who either prefer online learning or who are unable to travel to the face-to-face activities. The online version of the course includes lecture slides, downloadable audio files per lecture, hyperlinks to cited literature, posttests with answer feedback, and additional readings.

Both the live and online courses are complemented by an online simulated exam which is also available through learn.amia.org. The simulated examination can be purchased only in conjunction with the face-to-face and/or online course. A team of clinical informatics subject matter experts has developed 200 multiple-choice questions similar in format to what physicians expect from high-stakes exams. The simulated exam was designed to offer content distribution of test items similar to that of the board exam:

- Fundamentals = 10%
- Clinical Decision Making and Care Process Improvement = 30%
- Health Information Systems = 40%
- Leading & Managing Change = 20%
Acknowledgements

The following individuals have contributed and continue to contribute to AMIA’s efforts to define and advance the subspecialty of clinical informatics.

Clinical Informatics Core Content Team*
(August 2007 - January 2008)

Reed M. Gardner, PhD, FACMI (Chair)
J. Marc Overhage, MD, PhD, FACMI (Vice Chair)
Joan S. Ash, PhD, MLS, MBA, FACMI
James J. Cimino, MD, FACMI
H. Dominic J. Covvey, MSc, FACMI
Don E. Detmer, MD, MA, FACMI
John H. Holmes, PhD, FACMI
Nancy C. Nelson, RN, MS
Charles Safran, MD, FACMI
Richard N. Shiffman, MD, MCIS
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*Funding for initial development provided by the Robert Wood Johnson Foundation.

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## Course Syllabus

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<tr>
<th>#</th>
<th>LECTURE TITLE</th>
<th>KEY TOPICS</th>
<th>CORE CONTENT AREAS COVERED</th>
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<tbody>
<tr>
<td></td>
<td>WELCOME AND OVERVIEW</td>
<td>• The clinical informatics subspecialty</td>
<td>1.1. Clinical Informatics</td>
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<td></td>
<td>• What to expect on the Board Exam</td>
<td>1.1.1 The discipline of informatics</td>
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<td></td>
<td>• What to expect from this course</td>
<td>1.1.1.1 Definitions of informatics</td>
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<td>1.1.1.2 History of informatics (e.g., evolution of health records)</td>
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<td>1.1.1.3 Domains/subspecialties of informatics</td>
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<td>1.1.1.4 Careers in informatics</td>
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<td>1A</td>
<td>HISTORY AND CURRENT STATE OF INFORMATICS</td>
<td>• Terminology surrounding informatics and related disciplines and professions</td>
<td>1.1.1.5 Professional organizations</td>
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<td></td>
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<td>• Major milestones in history of informatics</td>
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<td>• Evolution of the medical record (e.g., SOAP, EHR, PHR)</td>
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<td>• Major people and organizations in informatics</td>
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<tr>
<td>1B/</td>
<td>ETHICS, LEGAL, AND FINANCIAL ISSUES</td>
<td>• International codes of practice and ethical codes relevant to clinical</td>
<td>1.1 Clinical Informatics</td>
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<td>4E-2</td>
<td>IN INFORMATICS</td>
<td>informatics.</td>
<td>1.1.5 Ethics and professionalism</td>
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<td></td>
<td>• US legal and regulatory rulings most relevant to clinical informatics.</td>
<td>1.1.6 Legal and regulatory issues</td>
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<td>• Oversight of clinical computing activities by local bylaws and</td>
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<td>compliance groups.</td>
<td>4.5 Strategic and Financial Planning for Clinical Information Systems</td>
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<td>• General principles of capital and operating budgeting as they pertain</td>
<td>4.5.5 Capital and operating budgeting</td>
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<td>to clinical information systems</td>
<td>4.5.6 Principles of managerial accounting</td>
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<td>• General principles of managerial accounting</td>
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<td>• Key financial concepts used in financial</td>
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<td>planning for clinical information systems</td>
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<td>1C</td>
<td>THE HEALTH SYSTEM</td>
<td>• Structure and function of the US healthcare system</td>
<td>1.2. The Health System</td>
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<td>• Current problems and proposed solutions for the US healthcare system</td>
<td>1.2.1 Determinants of individual and population health</td>
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|    |                     | • Key Institute of Medicine reports over the last two decades and the context they set for informatics  
• Spurring adoption of health information technology                                                                                     | 1.2.2 Primary domains, organizational structures, cultures, and processes  
1.2.2.1 Health care delivery  
1.2.2.2 Public health  
1.2.2.3 Clinical research  
1.2.2.4 Education of health professionals  
1.2.2.5 Personal health  
1.2.3 The flow of data, information, and knowledge within the health system  
1.2.4 Policy & regulatory framework  
1.2.5 Health economics and financing  
1.2.6 Forces shaping health care delivery  
1.2.7 Institute of Medicine quality components  
1.2.7.1 Safety  
1.2.7.2 Effectiveness  
1.2.7.3 Efficiency  
1.2.7.4 Patient-centeredness  
1.2.7.5 Timeliness  
1.2.7.6 Equity |
| 2A-1| CLINICAL DECISION-MAKING | • Everyday techniques of decision-making and potential biases.  
• Relevance of “choice under uncertainty” to medical decisions.  
• Using decision analysis to model complex decisions  
• Understanding how definitions of utility and patient preference impact the value of an outcome.  
• Using cost effectiveness analysis to make decisions about allocation of constrained healthcare resources.  
• Sensitivity, specificity, PPV, and NPV using the syntax “the probability of X given Y”.  
• The applicability and limitations of sensitivity, specificity, PPV, and NPV to clinical decision-making, disease screening, and diagnostic testing. | 2.1 Clinical Decision Support  
2.1.1 The nature and cognitive aspects of human decision making  
2.1.1.1 General  
2.1.1.2 Medical  
2.1.2 Decision science  
2.1.2.1 Decision analysis  
2.1.2.2 Probability theory  
2.1.2.3 Utility and preference assessment  
2.1.2.4 Cost effectiveness analysis  
2.1.2.5 Test characteristics |
| 2A-2| APPLIED DECISION-SUPPORT | • The difference between interruptive/modal and non-interruptive/modeless alerts  
• CDS intervention classifications                                                                                                               | 2.1.3 Application of clinical decision support |

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<td></td>
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<td>- by function (alerting, reminding, critiquing, etc)</td>
<td>2.1.3.1 Types of decision support (e.g., alerts, reminders, prompts)</td>
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<td>- by area of clinical care (prevention, diagnosis, treatment, follow-up, care planning).</td>
<td>2.1.3.2 Users of decision support (including clinicians and patients)</td>
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<td>- by intended audience.</td>
<td>2.1.3.3 Implementing, evaluating, and maintaining CDS tools</td>
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<td>• The “five rights” and “10 commandments” of an effective CDS intervention.</td>
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<td>• Review of current state of CDS effectiveness</td>
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<td>• Common limitations of evaluations of CDS interventions and ways to overcome these limitations.</td>
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<td>• Facilitating broader adoption of CDS tools through interoperability, clinical terminology, and guideline representation standards</td>
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<td>• Common strategies for maintaining and updating decision support tools, and the risks of not having these strategies in place.</td>
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<td>• Approaches for guideline representation and sharing of CDS content</td>
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<td>2A-3</td>
<td>KNOWLEDGE ACQUISITION AND USE FOR CLINICAL DECISION SUPPORT</td>
<td>• Approaches to representing knowledge in clinical decision support systems from the past and present</td>
<td>2.1.4. Transformation of knowledge into clinical decision support tools</td>
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<td>• Known problems of safety with health IT systems and how they can be minimized</td>
<td>2.1.4.1 Knowledge generation</td>
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<td>• Current legal and regulatory framework for clinical decision support</td>
<td>2.1.4.2 Knowledge acquisition</td>
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<td>2B-1/2B-2</td>
<td>EVIDENCE-BASED MEDICINE; INFORMATION RETRIEVAL AND ANALYSIS</td>
<td>• Formulating an appropriate clinical question to finding and applying evidence</td>
<td>2.2. Evidence-based Patient Care</td>
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<td>• Critical appraisal of a study addressing one of the fundamental clinical evidence</td>
<td>2.2.1 Evidence sources</td>
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<td>2.2.2 Evidence grading</td>
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<td>2.2.3 Clinical guidelines</td>
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<td>question types: treatment, diagnosis, harm, and prognosis • Evidence grading schemes • Structure, function, and limitations of clinical practice guidelines • Content, indexing, retrieval, and evaluation of information retrieval (search) systems</td>
<td>2.2.4 Implementation of guidelines as clinical algorithms 2.2.5. Information retrieval and analysis 2.2.5.1 Search skills 2.2.5.2 Critical analysis of biomedical literature</td>
</tr>
<tr>
<td>2C-1/4F</td>
<td>CLINICAL WORKFLOW ANALYSIS AND PROCESS REDESIGN/ CHANGE MANAGEMENT</td>
<td>Workflow: • Design, Theory and Components of - Workflow - Workflow analysis - Process redesign - Data Collection Methods • Tools to visually represent workflow • Process redesign: steps • Relationship of process redesign and change management Change Management • Change is more rapid now than ever before which can increase resistance to further change • Successful process redesign requires good change management skills • Effecting change requires knowing your audience • Theories provide a framework for change management activities • Tailor your strategy to the affected culture and user group(s)</td>
<td>2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement 2.3.1 Methods of Workflow Analysis 2.3.2 Principles of Workflow Re-engineering</td>
</tr>
<tr>
<td>2C-2</td>
<td>HEALTHCARE QUALITY IMPROVEMENT</td>
<td>• Define healthcare quality from the standpoint of a patient, a healthcare provider, a society/community, and a payor; understand that these definitions are sometimes challenging to reconcile. • Distinguish healthcare quality indicators – structure, process, and outcomes • Understand that there are numerous well-established quality improvement (QI) frameworks in use in healthcare, such as Toyota Lean, Six Sigma, and Associates for Process Improvement (API); describe high-level concepts associated with each.</td>
<td>2.3.3 Quality improvement principles and practice</td>
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<td>Describe how Ishikawa/fishbone diagrams and Pareto charts can be used to identify targets for QI efforts.</td>
<td>3.1 Information Technology Systems 3.1.1 Computer Systems 3.1.1.1 Programming 3.1.1.2 Data and control structures 3.1.1.3 Software development methods (e.g., agile, waterfall, spiral, rapid prototyping) 3.1.1.4 System integration 3.1.1.5 Quality</td>
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<td>Describe a Plan-Do-Study-Act cycle</td>
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<td>Understand the applicability of Control Charts to evaluation of healthcare QI efforts</td>
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<td>Distinguish Control Charts from evaluation methods based on hypothesis testing, such as randomized trials.</td>
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<td>3A-1</td>
<td>COMPUTER PROGRAMMING AND METHODS OF SOFTWARE DEVELOPMENT</td>
<td>Understand binary representation, simple examples of Boolean algebra, and how these can be used to perform calculation.</td>
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<td>Distinguish low-level and high-level programming languages, distinguish RISC and CISC instructions</td>
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<td>Understand differences between imperative, procedural, and object-oriented programming languages.</td>
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<td>Give examples of common data structures; use the example of date representations to illustrate how choice of data structure influences its use.</td>
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<td>Using pseudo-code, be able to define a clinical rule using each of the following control structures: “IF-THEN-ELSE”, “CASE”, “FOR loop”, and “WHILE loop”.</td>
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<td>Recognize that different software development methodologies exist and that each has different approaches to requirement gathering, scope definition, and risk mitigation.</td>
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<td>Understand how software systems may be integrated through interfaces, messaging standards, and web services.</td>
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<td>Distinguish “black-box” and “white-box” software testing; software verification and software validation.</td>
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<td>Give clinical examples of software testing strategies such as beta testing, testing, and regression testing following system enhancement.</td>
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<td>3A-2</td>
<td>SYSTEMS, DATABASES, NETWORKS</td>
<td>• Distinguish hierarchical, relational, and object-oriented databases; advantages and disadvantages of each.</td>
<td>3.1.1.6 Information systems design and analysis</td>
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<td>• Describe the logical schema of a database using a UML Entity Relationship (ER) diagram.</td>
<td>3.1.2 Architecture</td>
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<td>• Understand how the suite of UML diagrams are used to model a process and assist in software development and maintenance.</td>
<td>3.1.2.1 Systems</td>
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<td>• Understand how update, insert, and deletion anomalies in databases are prevented through database normalization.</td>
<td>3.1.2.2 Networks</td>
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<td>• Understand how denormalization of a database can be used to optimize certain queries, for example, in a clinical datamart.</td>
<td>3.1.2.3 Data/database</td>
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<td>• Describe some of the common network topologies, such as star, tree, and bus networks.</td>
<td>3.1.3 Networks</td>
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<td>• Recognize the names and uses of common telecommunications standards.</td>
<td>3.1.3.1 Topologies</td>
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<td>3.1.3.2 Telecommunications</td>
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<td>3A-3</td>
<td>SECURITY</td>
<td>• Key elements of the HIPAA Security Rule.</td>
<td>3.1.4 Security</td>
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<td>• Policy, and technical measures to protect the security of identified patient health information.</td>
<td>3.1.4.1 The HIPAA Security Rule and other government regulations</td>
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<td>• Three technical measures (firewalls, VPNs, and encryption) and the security context in which they are used.</td>
<td>3.1.4.2 Firewalls</td>
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<td>3.1.4.3 Virtual private networks</td>
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<td>3.1.4.4 Encryption</td>
</tr>
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<td>3A-4</td>
<td>HEALTHCARE DATA REUSE: CHALLENGES AND STRATEGIES</td>
<td>• Use and limitations of clinical data for patient care and other purposes</td>
<td>3.1.5 Data</td>
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<td>• Flow of data in clinical systems from collection to storage to analysis.</td>
<td>3.1.5.1 Integrity</td>
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<td>• Use and challenges for identification and anonymization of patient data</td>
<td>3.1.5.2 Mapping</td>
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<td>3.1.5.3 Manipulation (e.g., querying, SQL, reporting)</td>
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<td>3.1.5.4 Representation and types</td>
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<td>3.1.5.5 Warehousing</td>
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<td>3.1.5.6 Data mining and knowledge discovery</td>
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<td>3.1.6 Technical approaches that enable sharing data</td>
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<td>3.1.6.1 Integration versus interfacing</td>
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<td>3.1.6.2 Dealing with multiple identifiers</td>
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<td>3B</td>
<td>HUMAN COMPUTER INTERACTION</td>
<td>• Examples of clinical errors that can be prevented through the application of human factors engineering principles.</td>
<td>3.1.6.3 Anonymization of data</td>
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<td>• Contrast usability inspection, usability testing and usability inquiry</td>
<td>3.2 Human Factors Engineering</td>
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<td>• The three components of discount usability engineering: prototypes, simplified think-aloud exercise, and heuristic evaluation</td>
<td>3.2.1 Models, theories, and practices of human-computer (machine) interaction (HCI)</td>
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<td>• Commonly accepted standards of good interface design</td>
<td>3.2.2 HCI Evaluation, usability testing, study design and methods</td>
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<td>3.2.3 Interface design standards and design principles</td>
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<td>3.2.4 Usability engineering</td>
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<td>3C-1</td>
<td>HEALTH INFORMATION SYSTEMS AND APPLICATIONS</td>
<td>• Architecture, technical and computing infrastructure underlying health information systems (HIS).</td>
<td>3.3 Health Information Systems and Applications</td>
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<tr>
<td></td>
<td></td>
<td>• Breadth of HIS functionality and topics historically challenging to physicians.</td>
<td>3.3.1 Types and functions offered by systems</td>
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<td>• Telemedicine application areas and types.</td>
<td>3.3.2 Types of settings where systems are used</td>
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<td>3.3.3 Electronic health/medical records systems as the foundational tool</td>
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<td>3.3.4 Telemedicine</td>
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<td>3C-2</td>
<td>PATHOLOGY INFORMATICS</td>
<td>• The EHR-LIS relationship</td>
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<td>- EHR-LIS Architectures</td>
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<td>- Support Models for LISs</td>
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<td>- Laboratory Regulations and Standards that may impact EHRs</td>
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<td>• The Laboratory as an Automation Driver</td>
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<td>- Interfaces and automation lines</td>
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<td>- Barcodes</td>
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<td>- Radiofrequency Identification Tags (RFID)</td>
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<td></td>
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<td>• Basics of digital imaging</td>
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<td>- Telepathology</td>
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<td></td>
<td>• Genomic data</td>
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<td>- Impact on clinical informatics</td>
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<td>- Next-generation sequencing and bioinformatics</td>
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<td>- Genomic data privacy</td>
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<td>• Big data</td>
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<td>• Computational pathology</td>
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<tr>
<td>3D1-3</td>
<td>CLINICAL DATA STANDARDS</td>
<td>• Importance and limitations of standards in clinical information systems</td>
<td>3.4 Clinical Data Standards</td>
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<td></td>
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<td>3.4.1 Standards development history and current process</td>
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<td>LECTURE TITLE</td>
<td>KEY TOPICS</td>
<td>CORE CONTENT AREAS COVERED</td>
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<tr>
<td>3E</td>
<td>IMPLEMENTATION AND OPERATION OF CLINICAL INFORMATION SYSTEMS</td>
<td>• Institutional governance models for clinical information systems</td>
<td>3.5 Information System Lifecycle</td>
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<tr>
<td></td>
<td></td>
<td>• Formal and informal methods to define and specify system requirements, and solicit vendor proposals</td>
<td>3.5.1 Institutional governance of clinical information systems</td>
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<td></td>
<td></td>
<td>• System conversion strategies and their relative merits</td>
<td>3.5.2 Clinical information systems needs analysis and system selection</td>
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<td>• Elements of a system implementation plan</td>
<td>3.5.3 Clinical information system implementation</td>
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<td>• Key elements of clinical system operations and maintenance program</td>
<td>3.5.4 Clinical information system testing</td>
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<td>3.5.5 Clinical information system maintenance</td>
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<td>3E</td>
<td>EVALUATION OF CLINICAL INFORMATION SYSTEMS</td>
<td>• Measurement of usage, outcomes, and cost of clinical information systems</td>
<td>3.5.6. Clinical information system evaluation</td>
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<td>• Quantitative research methods</td>
<td>3.5.6.1 Outcomes relevant to the clinical goals and quality measures</td>
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<td>• Qualitative research methods</td>
<td>3.5.6.2 Qualitative and quantitative methods for evaluating clinical information systems</td>
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<td>• Actionable evaluation research in operational settings</td>
<td>3.5.6.3 Evaluation plan design</td>
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<td>4A</td>
<td>LEADERSHIP MODELS, PROCESSES, AND PRACTICES</td>
<td>• Enable and support effective technology adoption in healthcare through:</td>
<td>4. 1. Leadership Models, Processes, and Practices</td>
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<td>- Dimensions of effective leadership</td>
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<td></td>
<td>- Organizational governance</td>
<td>4.1.1 Dimensions of effective leadership</td>
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<td></td>
<td></td>
<td>- Effective techniques in Negotiation, Conflict Management, Collaboration, Motivation, and Decision Making</td>
<td>4.1.2 Governance (e.g., processes; responsibility versus authority)</td>
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<td></td>
<td>• How to recruit and retain employees and team members</td>
<td>4.1.3 Negotiation</td>
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<td>• Human resource factors for healthcare IT teams</td>
<td>4.1.4 Conflict management</td>
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<td>• Factors critical for team effectiveness</td>
<td>4.1.5 Collaboration</td>
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<td>• Structuring Team Goals to promote team effectiveness</td>
<td>4.1.6 Motivation</td>
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<td>4.1.7 Decision making</td>
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<tr>
<td>4B/4C</td>
<td>BUILDING EFFECTIVE HEALTHCARE IT TEAMS; COMMUNICATION STRATEGIES</td>
<td>• How to recruit and retain employees and team members</td>
<td>4.2 Effective Interdisciplinary Teams</td>
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<td>• Human resource factors for healthcare IT teams</td>
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<td>• Factors critical for team effectiveness</td>
<td>4.2.1 Human resources management (e.g., hiring, performance reviews and feedback, professional development, termination)</td>
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<td>• Structuring Team Goals to promote team effectiveness</td>
<td>4.2.2 Team productivity and effectiveness (e.g., articulating team</td>
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<tr>
<td>#</td>
<td>LECTURE TITLE</td>
<td>KEY TOPICS</td>
<td>CORE CONTENT AREAS COVERED</td>
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<td></td>
<td>• Processes commonly employed in Group Management</td>
<td>goals, defining rules of operation, clarifying individual roles)</td>
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<td>• Successful management of team meetings, and techniques for management of group deliberations</td>
<td>4.2.3 Group management processes (e.g., nominal group, consensus mapping, Delphi method)</td>
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<td></td>
<td></td>
<td>• Communication method depends on audience and other factors</td>
<td>4.2.4 Managing meetings</td>
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<td>• A comprehensive <strong>communication plan</strong> is a critical element in any successful information management project plan</td>
<td>4.2.5 Managing group deliberations</td>
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<td>4.3 Effective Communications</td>
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<td></td>
<td></td>
<td>4.3.1 Effective presentations to groups</td>
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<td>4.3.2 Effective one-on-one communication</td>
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<td>4.3.3 Writing effectively for various audiences and goals</td>
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<td>4.3.4 Developing effective communications program to support system implementation</td>
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<td>4D</td>
<td>PROJECT MANAGEMENT</td>
<td>• Basic Principles of Project Management</td>
<td>4. 4 Project Management</td>
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<td>• Common constraints in Project Management planning</td>
<td>4.4.1 Basic principles</td>
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<td>• The Project Management Lifecycle</td>
<td>4.4.2 Identifying resources</td>
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<td>• Project Process Groups</td>
<td>4.4.3 Resource allocation</td>
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<td>• Components of an effective Project Plan</td>
<td>4.4.4 Project management tools (non-software specific)</td>
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<td>• Tools useful in Project Planning</td>
<td>4.4.5 Informatics project challenges</td>
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<td>• Managing / Avoiding Scope Creep</td>
<td>4.4.5.1 Scope creep</td>
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<td>4.5 Strategic and Financial Planning for Clinical Information Systems</td>
<td>4.4.5.2 Managing expectations</td>
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<td>4E-1</td>
<td>STRATEGIC PLANNING FOR CLINICAL INFORMATION SYSTEMS</td>
<td>• Strategy for information systems must align with organizational strategy</td>
<td>4.4.5.3 Balancing competing priorities</td>
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<td>• Strategic planning models can guide strategy formulation</td>
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<td>• Environmental scanning informs long range strategic planning</td>
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<td>• Components of sound strategic planning are common between strategic models</td>
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<td>• Measuring impact of strategic planning helps secure resources for future planning</td>
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**Note:** The table above outlines the topics covered in the AMIA Clinical Informatics Board Review Course.
Abstract

The Core Content for Clinical Informatics defines the boundaries of the discipline and informs the Program Requirements for Fellowship Education in Clinical Informatics. The Core Content includes four major categories: fundamentals, clinical decision making and care process improvement, health information systems, and leadership and management of change. The AMIA Board of Directors approved the Core Content for Clinical Informatics in November 2008.

Background

The Core Content for a medical subspecialty defines the boundaries of the discipline and informs the Program Requirements for Fellowship Education. Program Requirements identify the knowledge and skills that must be mastered through the course of fellowship training and specify accreditation requirements for training programs. The American Board of Medical Specialties considers these two documents along with other requirements and factors when deciding whether to establish a new medical subspecialty. The Core Content for Clinical Informatics is the result of a two-year national development process initiated by the American Medical Informatics Association and supported by the Robert Wood Johnson Foundation. In November 2008, the AMIA Board of Directors approved both the Core Content and Program Requirements for clinical informatics.

Definition and Description of the Subspecialty

Clinical informaticians transform health care by analyzing, designing, implementing, and evaluating information and communication systems that enhance individual and population health outcomes, improve patient care, and strengthen the clinician-patient relationship.

Clinical informaticians use their knowledge of patient care combined with their understanding of informatics concepts, methods, and tools to:

- assess information and knowledge needs of health care professionals and patients,
- characterize, evaluate, and refine clinical processes,
- develop, implement, and refine clinical decision support systems, and
- lead or participate in the procurement, customization, development, implementation, management, evaluation, and continuous improvement of clinical information systems.

Physicians who are board-certified in clinical informatics collaborate with other health care and information technology professionals to promote patient care that is safe, efficient, effective, timely, patient-centered, and equitable.

Affiliations of the authors: Department of Medical Informatics, University of Utah (RMG), Salt Lake City, UT; Regenstrief Institute and Indiana Health Information Exchange (JMO), Indianapolis, IN; American Medical Informatics Association (EBS, JJW, DED), Bethesda, MD; Arizona Emergency Medicine, Phoenix, AZ; Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine (JHH), Philadelphia, PA; University of Virginia School of Medicine (DED), Charlottesville, VA.

Clinical informaticians work at the intersection of these three domains, and must demonstrate mastery of:

- medical knowledge,
- the field of informatics,
- the health care environment, including how business processes influence health care delivery and the flow of data among the major domains of the health system,
- how information systems and processes enhance or compromise the decision making and actions of health care team members,
- re-engineering health care processes,
- fundamental information system concepts, including the life cycle of information systems, the constantly evolving capabilities of information technology and health care, and the technical and nontechnical issues surrounding system implementation,
- how clinical information systems impact users and patients, how to support clinician users, and how to promote clinician adoption of systems,
- evaluation of information systems to provide feedback for system improvement,
- leadership in organizational change, fostering collaboration, communicating effectively, and managing large scale projects related to clinical information systems.

The core content for the subspecialty of clinical informatics comprises four major categories that must be mastered.

Fundamentals
The first core content category comprises basic knowledge that provides clinical informaticians with a common vocabulary and understanding of the environment in which they function.

Clinical informaticians draw from the broader field of biomedical and health informatics as they apply informatics methods, concepts, and tools to the practice of medicine. Thus, they must understand the culture, boundaries, and complexities of the field. Further, the stakeholders, structures, and processes that constitute the health system affect the information and knowledge needs of health care professionals and influence the selection and implementation of clinical information processes and systems. The flow of data, information, and knowledge among the various domains of the health system also creates important challenges for clinical informaticians as many of the data used in public health, personal health management, and clinical research originate in the clinical domain and reside in clinical information systems.

Clinical Decision Making and Care Process Improvement
The second core content category comprises knowledge and skills that enable a clinical informatician to implement effective clinical decision making systems and participate in the development of clinical processes that support effective, efficient, safe, timely, and equitable patient-centered care.

A primary goal of clinical informaticians is to strengthen clinical decision making by health care professionals and patients and to support and improve clinical care processes. This goal depends on implementing systems that support clinical objectives and, when necessary, identifying changes needed in clinical processes to take full advantage of clinical information system capabilities.

A range of theoretical and practical issues must be addressed in the development and implementation of clinical decision support tools. The cognitive and scientific underpinnings of medical decision making must be understood to capitalize on information system capabilities in improving clinical processes. Design of robust clinical information systems and processes relies upon knowledge management principles in acquiring, generating, representing, modeling, and maintaining information to support clinical decision making. Further, to achieve the full benefits of information systems and processes, clinical informaticians must be able to conceptualize improvements in clinical processes and decision making and collaborate with their clinical colleagues as well as information technology professionals to implement changes in the information systems and clinical processes.

Health Information Systems
The third core content category comprises knowledge and skills that enable a clinical informatician to participate in the development or selection of an information system for clinicians, prepare clinicians before implementation and support them during implementation and ongoing operation of a clinical information system, and evaluate the effectiveness of a system in meeting clinical needs.

Clinical informaticians need to assess the advantages and disadvantages of various technological approaches and determine the best fit for the clinical environment. They also need a common vocabulary and shared knowledge base to collaborate with information technology personnel. Since the quality of clinical data directly affects the effectiveness of information systems and clinical decision support tools as well as the reliability of clinical research that depends on those data, clinical informaticians work with interdisciplin-
nary teams to ensure that the data used to make clinical decisions meet state-of-the-art standards.

Information systems are not limited to hardware and software; they include people, processes, and policies that support the use of the technology. Thus, clinical informaticians must address these components as part of system analysis (planning) and implementation. System evaluation is required to determine whether a clinical information system is meeting its goals. Clinical informaticians need to understand the full range of issues related to evaluation so that they can determine the appropriate evaluative methods and provide feedback for successful information system implementation and use.

There are myriad health information systems and these systems are constantly evolving. Thus, the Core Content identifies the common elements of health information systems used in different clinical settings and does not include an exhaustive list of clinical information systems.

Leadership and Management of Change
The fourth core content category comprises knowledge and skills that enable clinical informaticians to lead and manage changes associated with the introduction and adoption of clinical information systems.

Successful implementation of information systems requires behavioral, cultural, and social change within an organization. Thus, clinical informaticians require knowledge and skills in understanding and analyzing organizational culture, planning organizational change, building and working in effective multidisciplinary teams, and leading information system development and implementation. Clinical informaticians must be able to listen, understand needs, articulate plans, explain rationales, inform constituents, report results, and foster collaboration. They must relate clinical information system needs and plans to larger organizational strategic goals and be proficient in project management to oversee the implementation of new systems and processes.

Core Content

1. Fundamentals: The basic knowledge that provides clinical informaticians with a common vocabulary and understanding of the environment in which they function.

1.1. Clinical Informatics
1.1.1. The discipline of informatics
1.1.1.1. Definitions of informatics
1.1.1.2. History of informatics (e.g., evolution of health records)
1.1.1.3. Domains/subspecialties of informatics
1.1.1.4. Careers in informatics
1.1.1.5. Professional organizations
1.1.1.6. Current and future challenges for informatics
1.1.2. Key informatics concepts, models, and theories
1.1.3. Clinical informatics literature
1.1.3.1. Core literature
1.1.3.2. Critical analysis of informatics literature
1.1.4. International clinical informatics practices
1.1.5. Ethics and professionalism
1.1.6. Legal and regulatory issues

1.2. The Health System
1.2.1. Determinants of individual and population health
1.2.2. Primary domains, organizational structures, cultures, and processes
1.2.2.1. Health care delivery
1.2.2.2. Public health
1.2.2.3. Clinical research
1.2.2.4. Education of health professionals
1.2.2.5. Personal health
1.2.3. The flow of data, information, and knowledge within the health system
1.2.4. Policy & regulatory framework
1.2.5. Health economics and financing
1.2.6. Forces shaping health care delivery
1.2.7. Institute of Medicine quality components
1.2.7.1. Safety
1.2.7.2. Effectiveness
1.2.7.3. Efficiency
1.2.7.4. Patient-centeredness
1.2.7.5. Timeliness
1.2.7.6. Equity

2. Clinical Decision Making and Care Process Improvement: The knowledge and skills that enable a clinical informatician to implement effective clinical decision making systems and participate in the development of clinical processes that support effective, efficient, safe, timely, equitable, and patient-centered care.

2.1. Clinical Decision Support
2.1.1. The nature and cognitive aspects of human decision making
2.1.1.1. General
2.1.1.2. Medical
2.1.2. Decision science
2.1.2.1. Decision analysis
2.1.2.2. Probability theory
2.1.2.3. Utility and preference assessment
2.1.2.4. Cost effectiveness analysis
2.1.2.5. Test characteristics (e.g., sensitivity, specificity, predictive value)
2.1.3. Application of clinical decision support
2.1.3.1. Types of decision support (e.g., alerts, reminders, prompts)
2.1.3.2. Users of decision support (including clinicians and patients)
2.1.3.3. Implementing, evaluating, and maintaining decision support tools
2.1.4. Transformation of knowledge into clinical decision support tools
2.1.4.1. Knowledge generation
2.1.4.2. Knowledge acquisition
2.1.4.3. Knowledge modeling
2.1.4.4. Knowledge representation
2.1.4.5. Knowledge management and maintenance
2.1.5. Legal, ethical, and regulatory issues
2.1.6. Quality and safety issues
2.1.7. Supporting decisions for populations of patients

2.2. Evidence-based Patient Care
2.2.1. Evidence sources
2.2.2. Evidence grading
2.2.3. Clinical guidelines
2.2.4. Implementation of guidelines as clinical algorithms
2.2.5. Information retrieval and analysis
  2.2.5.1. Search skills
  2.2.5.2. Critical analysis of biomedical literature

2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
  2.3.1. Methods of workflow analysis
  2.3.2. Principles of workflow re-engineering
  2.3.3. Quality improvement principles and practices

3. Health Information Systems: The knowledge and skills that enable a clinical informatician to participate in the development or selection of an information system for clinicians; prepare clinicians prior to implementation and support them during implementation and ongoing operation of a clinical information system; and evaluate the effectiveness of a system in meeting clinical needs.

3.1. Information Technology Systems
  3.1.1. Computer Systems
    3.1.1.1. Programming
    3.1.1.2. Data and control structures
    3.1.1.3. Software development methods (e.g., agile, waterfall, spiral, rapid prototyping)
    3.1.1.4. System integration
    3.1.1.5. Quality
    3.1.1.6. Information systems design and analysis (e.g., logical schema, normalization/denormalization, process modeling)
  3.1.2. Architecture
    3.1.2.1. Systems (e.g., distributed, centralized, relational, object-oriented, warehouses/data marts)
    3.1.2.2. Networks
    3.1.2.3. Data/database
  3.1.3. Networks
    3.1.3.1. Topologies
    3.1.3.2. Telecommunications
  3.1.4. Security
    3.1.4.1. The HIPAA Security Rule and other government regulations
    3.1.4.2. Firewalls
    3.1.4.3. Virtual private networks
    3.1.4.4. Encryption
  3.1.5. Data
    3.1.5.1. Integrity
    3.1.5.2. Mapping
    3.1.5.3. Manipulation (e.g., querying, SQL, reporting)
    3.1.5.4. Representation and types
    3.1.5.5. Warehousing
    3.1.5.6. Data mining and knowledge discovery
  3.1.6. Technical approaches that enable sharing data
    3.1.6.1. Integration versus interfacing
    3.1.6.2. Dealing with multiple identifiers
    3.1.6.3. Anonymization of data

3.2. Human Factors Engineering
  3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
  3.2.2. HCI Evaluation, usability testing, study design and methods
  3.2.3. Interface design standards and design principles
  3.2.4. Usability engineering

3.3. Health Information Systems and Applications
  3.3.1. Types of functions offered by systems
  3.3.2. Types of settings where systems are used
  3.3.3. Electronic health/medical records systems as the foundational tool
  3.3.4. Telemedicine

3.4. Clinical Data Standards
  3.4.1. Standards development history and current process
  3.4.2. Data standards and data sharing
  3.4.3. Transaction standards
  3.4.4. Messaging standards
  3.4.5. Nomenclatures, vocabularies, and terminologies
  3.4.6. Ontologies and taxonomies
  3.4.7. Interoperability standards

3.5. Information System Lifecycle
  3.5.1. Institutional governance of clinical information systems
  3.5.2. Clinical information needs analysis and system selection
    3.5.2.1. Methods for identifying clinician information system needs
    3.5.2.2. Assessment of clinical process changes that will be required
    3.5.2.3. Elements of a system requirements specification document (e.g., technical specifications, intellectual property, patents, copyright, licensing, contracting, confidentiality, specific organizational needs such as user training and support)
    3.5.2.4. Risk analysis and mitigation
    3.5.2.5. The costs of health information and communications technologies
  3.5.3. Clinical information system implementation
    3.5.3.1. Elements of a system implementation plan
    3.5.3.2. Models of user training and support processes that can meet clinician needs
    3.5.3.3. Processes and mechanisms that obtain and respond to clinician feedback
  3.5.4. Clinical information system testing, before, during and after implementation
  3.5.5. Clinical information system maintenance
    3.5.5.1. Disaster recovery and downtime
    3.5.5.2. Clinical information system transitions and decommissioning of systems
  3.5.6 Clinical information system evaluation
    3.5.6.1. Outcomes relevant to the clinical goals and quality measures
3.5.6.2. Qualitative and quantitative methods for evaluating clinical information systems

3.5.6.3. Evaluation plan design

4. Leading and Managing Change: The knowledge and skills that enable clinical informaticians to lead and manage changes associated with implementing clinical information systems and promoting adoption by health professionals.

4.1. Leadership Models, Processes, and Practices
   4.1.1. Dimensions of effective leadership
   4.1.2. Governance (e.g., processes; responsibility versus authority)
   4.1.3. Negotiation
   4.1.4. Conflict management
   4.1.5. Collaboration
   4.1.6. Motivation
   4.1.7. Decision making

4.2. Effective Interdisciplinary Teams
   4.2.1. Human resources management (e.g., hiring, performance reviews and feedback, professional development, termination)
   4.2.2. Team productivity and effectiveness (e.g., articulating team goals, defining rules of operation, clarifying individual roles)
   4.2.3. Group management processes (e.g., nominal group, consensus mapping, Delphi method)
   4.2.4. Managing meetings
   4.2.5. Managing group deliberations

4.3. Effective Communications
   4.3.1. Effective presentations to groups
   4.3.2. Effective one-on-one communication
   4.3.3. Writing effectively for various audiences and goals
   4.3.4. Developing effective communications program to support system implementation

4.4. Project Management
   4.4.1. Basic principles
   4.4.2. Identifying resources
   4.4.3. Resource allocation
   4.4.4. Project management tools (non-software specific)
   4.4.5. Informatics project challenges
      4.4.5.1. Scope creep
      4.4.5.2. Managing expectations
      4.4.5.3. Balancing competing priorities

4.5. Strategic and Financial Planning for Clinical Information Systems
   4.5.1. Establishing mission and objectives
   4.5.2. Environmental scanning
   4.5.3. Strategy formulation
   4.5.4. Action planning and strategy implementation
   4.5.5. Capital and operating budgeting
   4.5.6. Principles of managerial accounting
   4.5.7. Evaluation of planning process

4.6. Change Management
   4.6.1. Assessment of organizational culture and behavior
   4.6.2. Change theories (e.g., precede-proceed, social influence theories, complex adaptive systems)
   4.6.3. Change management strategies
   4.6.4. Strategies for promoting adoption and effective use of clinical information systems

References

Core Content for the Subspecialty of Clinical Informatics

Reed M Gardner, J Marc Overhage, Elaine B Steen, et al.

*J Am Med Inform Assoc* 2009 16: 153-157
doi: 10.1197/jamia.M3045

Updated information and services can be found at:
http://jamia.bmj.com/content/16/2/153.full.html

**References**

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Suggested Advance Reading for Clinical Informatics Board Review Course (CIBRC)

P1 - Pathology Informatics


1A: History and Current State of Informatics

AMIA Board white paper: definition of biomedical informatics and specification of core competencies for graduate education in the discipline http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3534470/

1B and 4E-2: Ethics, Regulation and Finance Topics


The Operating Budget - AAUPwiki: http://aaupwiki.princeton.edu/index.php/The_Operating_Budget


570-Does HIPAA permit health care providers to use e-mail to discuss with their patients | HHS.gov http://www.hhs.gov/hipaa/for-professionals/faq/570/does-hipaa-permit-health-care-providers-to-use-email-to-discuss-health-issues-with-patients/index.html

1C: The Health System


2A-1 – Clinical Decision-Making

Online Course: PennState STAT 507 “Epidemiological Research Methods”, Lesson 10.3: Sensitivity, specificity, positive predictive value, negative predictive value

Online statistics lectures by Rahul Patwari, MD

Tradeoff between sensitivity and specificity

Predictive values

Screening tests

ROC Curves

2A-2 – Applied Decision Support


2A-3: Knowledge Acquisition and Use for Clinical Decision Support

Decision Support, Knowledge Representation and Management in Medicine http://www.schattauer.de/en/magazine/subject-areas/journals-a-z/imia-yearbook/archive/issue/2254/manuscript/6445.html

2B: Evidence-Based Practice and Information Retrieval

Introduction to Evidence-Based Practice http://guides.mclibrary.duke.edu/c.php?g=158201&p=1036002

Suggested Advance Reading for Clinical Informatics Board Review Course 2016
PubMed Tutorial

2C-1 Workflow Analysis and Process Redesign


2C-2 – Healthcare Quality Improvement


3A-1 – Computer Programming & Methods of Software Development

Javascript tutorial at http://www.w3schools.com/js/default.asp

Sections of interest:
- Syntax, Statements, Variables, Operators, Arithmetic, Assignment, Data Types, Functions, Objects, Scope, Strings, Numbers, Arrays, Booleans, Comparisons, Conditions, Switch, Loop For / While

YouTube pseudocode tutorial
https://www.youtube.com/watch?v=Rg-fO7rDsd
TraceTable example on YouTube

https://www.youtube.com/watch?v=UhziRgmVKuQ

3A-2 – Systems, Databases, Networks

Review and complete the first 10 exercises on this website: http://sqlzoo.net/

3A-3 - Security

The HIPAA Security Rule.
See the following sections in http://www.hhs.gov/hipaa/for-professionals/security/
  1. Summary of the Security Rule
  2. Breach Notification (Breach Reporting, Guidance)
  3. Covered Entities & Business Associates
  4. FAQ for Professionals

For The Record: Protecting Electronic Health Information
See the following sections in http://www.nap.edu/read/5595/chapter/1

  Table of Contents is found on Page xv
  1. Executive Summary
  2. Technical Approaches to Protecting Electronic Health Information

US-cert.gov regarding security
Multiple publications available under “publications”.
See:

And other subjects that you believe you need to cover in greater background

“Wall of Shame” (Breaches):

Suggested Advance Reading for Clinical Informatics Board Review Course 2016
Phishing
What is Phishing | Phishing Scams | Report Phishing Scams

3A-4: Healthcare Data Reuse: Challenges and Strategies
Health Care Data Analytics (chapter from Hoyt, authored by Hersh)
http://skynet.ohsu.edu/~hersh/hoyt-14-analytics.pdf

3B – Human Computer Interaction
Review the 11 Safety Enhanced Design Briefs on this website:
https://sbmi.uth.edu/nccd/SED/Briefs/

http://www.useit.com/papers/heuristic/heuristic_list.html


Jakob Nielsen on Paper Prototyping
https://www.nngroup.com/articles/paper-prototyping/
https://www.nngroup.com/reports/paper-prototyping-training-video/

3C - Health Information Systems & Applications

Difference in Hub, Switch, Bridge, & Router » Nutt.net

Switch vs Router vs Hub vs Bridge Vs Repeater Vs Access point
3D1-3: Clinical Data Standards

Data Standards, Data Quality, and Interoperability

http://library.ahima.org/PB/DataStandards#.V5S4fVmVqm5w

3E1-2 - Implementation & Operations of Clinical Information Systems

If you want to learn more about VistA (Veterans Integrated Systems Technical Architecture:
http://www.ehealth.va.gov/docs/VistA_Monograph.pdf

Medicare Guidelines for Teaching Physicians, Interns and Residents:
Defines macro, E/M regulations:

3E-3: Evaluation of Clinical Information Systems

Evaluation of Information Systems in Health Care


4A - Leadership

Al-Sawai A. Leadership of healthcare professionals: where do we stand?

4B - Building Effective Healthcare IT Teams

4C – Communication Strategies


4D – Project Management

Primer on Project Management. April 2012. 

4E-1 Strategic Planning


4F - Change Management


[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4909978/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4909978/)
Welcome and Overview

William Hersh, MD, FACP, FACMI
Course Director
Welcome and overview

- The clinical informatics subspecialty and its history
- What to expect on the Board Exam
- What to expect from this course
Clinical informatics subspecialty

• Subspecialty open to physicians of all primary specialties
  – But not those without a specialty or whose specialty certification has lapsed

• Following usual path of five years of “grandfathering” training requirements to take certification exam before formal fellowships required
  – Two paths to eligibility for exam in first five years
    • Practice pathway – practicing 25% time for at least three years within last five years (education counts at half time of practice)
    • Non-traditional fellowships – qualifying educational or training experience, e.g., NLM fellowship, or educational program (master’s degree, certificate?)

• ABPM rules, course specification, and registration
  – http://www.theabpm.org/
History of clinical informatics subspecialty

- 2009 – American Medical Informatics Association (AMIA) develops and publishes plans for
  - Curriculum (Gardner, JAMIA, 2009)
  - Training requirements (Safran, JAMIA, 2009)
- 2011 – American Board of Medical Specialties (ABMS) approves; American Board of Preventive Medicine (ABPM) becomes administrative home
  - Subspecialty open to physicians of all primary specialties but not those without a specialty or whose specialty certification has lapsed
- 2013 – First certification exam offered by ABPM via “grandfathering” pathways
  - Clinical Informatics Board Review Course (CIBRC) launched
  - 455 physicians pass exam (92% pass rate)
History (cont.)

• 2014 – ACGME fellowship accreditation rules released
  – First programs accredited and one launched
  – Another 332 pass certification exam (90% pass rate; 787 total)

• 2015
  – More fellowship programs accredited (15 total) and launched (4) (Longhurst, JAMIA, 2016)
  – Another 320 pass certification exam (80% pass rate; 1107 total)

• 2016
  – More programs accredited (20 total) and launched
Future of clinical informatics subspecialty

• 2017
  – Last year of “grandfathering”
• 2018
  – Must complete ACGME-accredited fellowship to become board-certified
Clinical informatics subspecialty (cont.)

- Following usual path of five years of “grandfathering” training requirements to take certification exam before formal fellowships required
  - Two paths to eligibility for exam in first five years
    - Practice pathway – practicing 25% time for at least three years within last five years (education counts at half time of practice)
    - Non-traditional fellowships – qualifying educational or training experience, e.g., NLM fellowship, or educational program (master’s degree)
    - All experiences are additive

- ABPM rules, course specification, and registration
  - [http://www.theabpm.org/](http://www.theabpm.org/)
What to expect on the Board Exam

• What we know
  – Curriculum outlined based on paper from Gardner (2009)
    – reproduced in ABPM course study guide
      • Not updated since 2009 (!)
  – Percentage of distribution of test items
    • Fundamentals - 10%
    • Clinical Decision Making and Care Process Improvement - 30%
      • Health Information Systems - 40%
      • Leading and Managing Change - 20%
  – Examination being produced by 15-member group under ABPM auspices
    • Protected from us by firewall
What to expect from this course

• Adhering to core content distributed proportionally based on ABPM study guide
  – Organized into lectures
  – Aiming for broad overview and coverage of major themes
  – Provide more references for further study

• Additional sessions
  – Approaching exam
  – “Homework” exercises and review of sample questions
  – General discussion
  – Social hour
Challenges for the faculty

• Experienced educators but not experienced “teaching to the test”
• Minimal details from ABPM on exam content
• Core content is typically covered in master’s degree program – how to cover essentials in this three-day course
• Varied knowledge of many current informatics practitioners – from none to degrees and fellowships
## Core Content Outline

### 1. Fundamentals

1.1. Clinical Informatics
   - 1.1.1. The discipline of informatics
   - 1.1.2. Key informatics concepts, models, and theories
   - 1.1.3. Clinical informatics literature
   - 1.1.4. International clinical informatics practices
   - 1.1.5. Ethics and professionalism
   - 1.1.6. Legal and regulatory issues

1.2. The Health System
   - 1.2.1. Determinants of individual and population health
   - 1.2.2. Primary domains, organizational structures, cultures, and processes
   - 1.2.3. The flow of data, information, and knowledge within the health system
   - 1.2.4. Policy & regulatory framework
   - 1.2.5. Health economics and financing
   - 1.2.6. Forces shaping health care delivery
   - 1.2.7. Institute of Medicine quality components

### 2. Clinical Decision Making and Care Process Improvement

2.1. Clinical Decision Support
   - 2.1.1. The nature and cognitive aspects of human decision making
   - 2.1.2. Decision science
   - 2.1.3. Application of clinical decision support
   - 2.1.4. Transformation of knowledge into clinical decision support tools
   - 2.1.5. Legal, ethical, and regulatory issues
   - 2.1.6. Quality and safety issues
   - 2.1.7. Supporting decisions for populations of patients

2.2. Evidence-based Patient Care
   - 2.2.1. Evidence sources
   - 2.2.2. Evidence grading
   - 2.2.3. Clinical guidelines
   - 2.2.4. Implementation of guidelines as clinical algorithms
   - 2.2.5. Information retrieval and analysis

2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
   - 2.3.1. Methods of workflow analysis
   - 2.3.2. Principles of workflow re-engineering
   - 2.3.3. Quality improvement principles and practices

### 3. Health Information Systems

3.1. Information Technology Systems
   - 3.1.1. Computer Systems
   - 3.1.2. Architecture
   - 3.1.3. Networks
   - 3.1.4. Security
   - 3.1.5. Data
   - 3.1.6. Technical approaches that enable sharing data

3.2. Human Factors Engineering
   - 3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
   - 3.2.2. HCI Evaluation, usability testing, study design and methods
   - 3.2.3. Interface design standards and design principles
   - 3.2.4. Usability engineering
   - 3.2.5. Health Information Systems and Applications
   - 3.3.1. Types of functions offered by systems
   - 3.3.2. Types of settings where systems are used
   - 3.3.3. Electronic health/medical records systems as the foundational tool
   - 3.3.4. Telemedicine
   - 3.4. Clinical Data Standards
   - 3.4.1. Standards development history and current process
   - 3.4.2. Data standards and data sharing
   - 3.4.3. Transaction standards
   - 3.4.4. Messaging standards
   - 3.4.5. Nomenclatures, vocabularies, and terminologies
   - 3.4.6. Ontologies and taxonomies
   - 3.4.7. Interoperability standards

3.5. Information System Lifecycle
   - 3.5.1. Institutional governance of clinical information systems
   - 3.5.2. Clinical information needs analysis and system selection
   - 3.5.3. Clinical information system implementation
   - 3.5.4. Clinical information system testing, before, during and after implementation
   - 3.5.5. Clinical information system maintenance
   - 3.5.6. Clinical information system evaluation

### 4. Leading and Managing Change

4.1. Leadership Models, Processes, and Practices
   - 4.1.1. Dimensions of effective leadership
   - 4.1.2. Governance
   - 4.1.3. Negotiation
   - 4.1.4. Conflict management
   - 4.1.5. Collaboration
   - 4.1.6. Motivation
   - 4.1.7. Decision making

4.2. Effective Interdisciplinary Teams
   - 4.2.1. Human resources management
   - 4.2.2. Team productivity and effectiveness
   - 4.2.3. Group management processes
   - 4.2.4. Managing meetings
   - 4.2.5. Managing group deliberations

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   - 4.4.1. Basic principles
   - 4.4.2. Identifying resources
   - 4.4.3. Resource allocation
   - 4.4.4. Project management tools (non-software specific)
   - 4.4.5. Informatics project challenges

4.5. Strategic and Financial Planning for Clinical Information Systems
   - 4.5.1. Establishing mission and objectives
   - 4.5.2. Environmental scanning
   - 4.5.3. Strategy formulation
   - 4.5.4. Action planning and strategy implementation
   - 4.5.5. Capital and operating budgeting
   - 4.5.6. Principles of managerial accounting
   - 4.5.7. Evaluation of planning process

4.6. Change Management
   - 4.6.1. Assessment of organizational culture and behavior
   - 4.6.2. Change theories
   - 4.6.3. Change management strategies
   - 4.6.4. Strategies for promoting adoption and effective use of clinical information systems
1A: History and Current State of Informatics

William Hersh, MD, FACP, FACMI
Oregon Health & Science University
Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
   1.1.1. The discipline of informatics
   1.1.2. Key informatics concepts, models, theories
   1.1.3. Clinical informatics literature
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   1.2.7. Institute of Medicine quality components

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   4.1.1. Dimensions of effective leadership
   4.1.2. Governance
   4.1.3. Negotiation
   4.1.4. Conflict management
   4.1.5. Collaboration
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   4.2. Effective Interdisciplinary Teams
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   4.4.1. Basic principles
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   4.5.6. Principles of managerial accounting
   4.5.7. Evaluation of planning process
   4.6. Change Management
   4.6.1. Assessment of organizational culture and behavior
   4.6.2. Change theories
   4.6.3. Change management strategies
   4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core content covered

1.1. Clinical Informatics
   1.1.1 The discipline of informatics
      1.1.1.1 Definitions of informatics
      1.1.1.2 History of informatics (e.g., evolution of health records)
      1.1.1.3 Domains/subspecialties of informatics
      1.1.1.4 Careers in informatics
      1.1.1.5 Professional organizations
      1.1.1.6 Current and future challenges for informatics
   1.1.2 Key informatics concepts, models, and theories
   1.1.3 Clinical informatics literature
      1.1.3.1 Core literature
      1.1.3.2 Critical analysis of informatics literature
   1.1.4 International clinical informatics practices
Key topics

• Terminology surrounding informatics and related disciplines and professions
• Major milestones in history of informatics
• Evolution of the medical record (e.g., SOAP, EHR, PHR)
• Major people and organizations in informatics
1A – History and Current State of Informatics

- Definitions of informatics
- History of informatics (e.g., evolution of health records)
- Domains/subspecialties of informatics
- Careers in informatics
- Professional organizations
- Current and future challenges for informatics
- Key informatics concepts, models, and theories
Definitions of informatics

• AMIA (Kulikowski, 2012)
• (Hersh, 2009)
• (Bernstam, 2010)
• European view (Hasman, 2012)
AMIA view (Kulikowski, 2012)

• Biomedical informatics (BMI) is “the interdisciplinary field that studies and pursues the effective uses of biomedical data, information, and knowledge for scientific inquiry, problem solving, decision making, motivated by efforts to improve human health.”

• “BMI investigates and supports reasoning, modeling, simulation, experimentation, and translation across the spectrum from molecules to individuals and to populations, from biological to social systems, bridging basic and clinical research and practice and the healthcare enterprise.”
AMIA view (Kulikowski, 2012)

Biomedical informatics (BMI) education and research

Methods, techniques, theories

Bioinformatics and structural (Imaging) informatics

Health informatics (HI): clinical informatics and public health informatics

Informatics in translational science: translational bioinformatics (TBI) and clinical research informatics (CRI)

Basic research

Applied research and practice

Molecules, cells, tissues, organs

Patients, individuals, populations, societies
Another definition (Hersh, 2009)

• *Biomedical and health informatics* (BMHI) is the field concerned with the optimal use of information, often aided by technology, to improve individual health, healthcare, public health, and biomedical research
  – Informatics applied in a more focused domain is {X} informatics, e.g., nursing, dental, pathology, primary care, etc.
  – Can be classified by “level” of domain but also has some overarching areas, e.g., imaging and research

• Practitioners of BMHI are usually called *informaticians* (sometimes *informaticists*)
More definitions

- “The science of information applied to biomedicine ... data plus meaning.” (Bernstam, 2010)
- European and global perspectives (Haux, 2010; Hasman, 2011; Geissbuhler, 2011)
- Early definition: “storage, acquisition, and use of information” (Greenes, 1990)
- “Fundamental theorem” (Friedman, 2009)
What informatics “is and isn’t” (Friedman, 2012)

• **Is**
  
  – Cross-training where basic informational science meets a biomedical application domain
  
  – Relentless pursuit of assisting people
  
  – Tower of achievement
    
    • Model formulation
    
    • System development
    
    • System implementation
    
    • Study of effects

• **Isn’t**
  
  – Scientists or clinicians tinkering with computers
  
  – Analysis of large data sets per se
  
  – Circumscribed roles related to deployment of electronic health records (*point of disagreement)
  
  – Profession of health information management
  
  – Anything done using a computer
History of informatics
(Collen, 1994)

• Origin of term attributed to Dreyfus in 1962 (Fourman, 2002)

• Achieved widespread use in France (informatique), Russia, and later rest of Europe in 1960s to denote computing issues related to information use

• “Medical informatics” first used in 1974 (Collen, 1994)

• At present, most significant use is in biomedical arena, but it is used by other domains, such as law, chemistry, social sciences, etc.
Some early systems in informatics

- **EHR**
  - COSTAR – Massachusetts General Hospital (Barnett, 1979)
  - HELP – Utah (Kuperman, 1991)
  - TMR – Duke (Stead, 1988)
  - Regenstrief – Indiana (McDonald, 1988)
  - El Camino – California (Carter, 1987)
  - VistA – Veteran’s Administration (Brown, 2003)

- **Other**
  - MYCIN (Shortliffe, 1975; Clancy, 1984)
  - Internist-1/QMR (Miller, 1982)
  - ELHILL (Lindberg, 1986)
  - Problem-knowledge coupler (Weed, 1969)
Careers in informatics (Hersh, 2010)

- Traditional groupings of information professionals in health care
  - Information technology (IT) – usually with computer science or information systems background
  - Health information management (HIM) – historical focus on medical records
  - Clinical informatics (CI) – often from healthcare backgrounds, performing analysis, training, etc.
  - Others – librarians, managers, etc.
# Careers in informatics

<table>
<thead>
<tr>
<th>Category</th>
<th>Jobs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic</td>
<td>Informatics researcher or teacher</td>
</tr>
<tr>
<td>Professional</td>
<td>Chief Information Officer, Chief Medical/Nursing Informatics Officer, Developer, Trainer</td>
</tr>
<tr>
<td>Liaison</td>
<td>Represent clinical or research community in IT initiatives, e.g., clinical champion</td>
</tr>
</tbody>
</table>

(Hersh, 2006) adapted from (Covvey, 2001)
Careers of informatics leaders

• Who are the leaders in IT and informatics?
  – Chief Information Officer (CIO)
  – Chief Medical Informatics Officer (CMIO)
  – Chief Nursing Informatics Officer (CNIO)
  – Chief Technology Officer (CTO)
  – Many other titles, no standards

• Hospitals and healthcare organizations increasingly creating operational “clinical informatics” departments
  – Often separate from IT (and CIO)
  – Usually with clinical leadership, often CMIO
  – Increasingly incorporate HIM
Chief Medical Informatics Officer (CMIO)

- Position now an important part of healthcare organizations, serving as (Kilbridge, 2012)
  - Liaison between clinicians and IT
  - Executive informatician
  - Director of clinical IT systems – leading the path forward

- Analysis of five CMIOs (Leviss, 2006)
  - Leadership, communication, and consensus-building among most important skills
  - Desired to be part of senior physician executive team
  - Did not want to be see as just “techie” doctors
Gartner-AMDIS CMIO annual survey *(Shaffer, 2015)*

- 95 respondents, most from integrated delivery systems, with remainder from hospitals and group practices
- Priorities now include EHR optimization, data analytics, and population health
- Key challenges are competing priorities, organizational culture, clinician disconnect as systems expand, and shortages of resources and talent
- 87% have additional master’s degree, PhD, and/or training such as AMIA 10x10
- Many pursued/pursuing clinical informatics subspecialty
  - 48% have received
  - 20% pursuing
Gartner-AMDIS CMIO survey (cont.)

- 68% still practice medicine – slowly declining over years
- Reporting relationships
  - 33% to Chief Medical Officer (CMO)
  - 32% to CIO
  - 17% to Chief Executive Officer (CEO) or Chief Operating Officer (COO)
  - 9% dual to CMO and CIO
  - Most would prefer to report to CMO or dual CMO/CIO
- 64% have people reporting to them, with most of rest having small staffs
  - Responsibility without authority?
- Average salary $343K
Professional organizations

- AMIA (formerly American Medical Informatics Association)
  - www.amia.org

- Mission
  - AMIA advances the informatics professions relating to health and disease. To this end it advances the use of health information and communications technology in clinical care and clinical research, personal health management, public health/population, and translational science with the ultimate objective of improving health.
Other professional organizations

- American Health Information Management Association (AHIMA) – [www.ahima.org](http://www.ahima.org)
- Alliance for Nursing Informatics (ANI) – [www.allianceni.org](http://www.allianceni.org)
- Association of Medical Directors of Information Systems (AMDIS) – [www.amdis.org](http://www.amdis.org)
- Public Health Informatics Institute (PHII) – [www.phii.org](http://www.phii.org)
- International Society for Computational Biology (ISCB) – [www.iscb.org](http://www.iscb.org)
- Society for Imaging Informatics in Medicine (SIIM) – [www.siim.org](http://www.siim.org)
- Association for Computing Machinery (ACM) – [www.acm.org](http://www.acm.org)
- Medical Library Association (MLA) – [www.mlanet.org](http://www.mlanet.org)
Medical and nursing specialty societies (non-exhaustive)

- American Medical Association (AMA) – www.ama-assn.org
- American Nurses Association (ANA) – www.nursingworld.org
- Association of American Medical Colleges (AAMC) – www.aamc.org
- American College of Physicians (ACP) – www.acponline.org
- American Academy of Family Physicians (AAFP) – www.aafp.org
Current and future challenges –
start of a list

• Healthcare spending continues to rise; most see need to stabilize or reduce
• Implementation is difficult
• Return on investment is difficult to measure (and conceptualize)
• How much is too much? Is it all hype?
• Complexity creates risk; simplicity seems unsatisfying
Key informatics concepts, models, and theories – start of a list

- Bayes’ Theorem
- Moore’s Law
- Metcalfe’s Law – but not really: $n(n-1)/2$
- Greek Oracle problem (Miller, 1990)
- “Curly braces” problem (Samwald, 2012)
- Homer Warner’s summarization of informatics: “10% medicine, 10% technology, 80% sociology” and its implications for the field
- Metrics used in diagnostic decision-making and information retrieval – recall/sensitivity, precision, and specificity calculated in 2x2 tables
Clinical informatics literature

• Journals
  – *Journal of the American Medical Informatics Association* (JAMIA)
  – *Journal of Medical Internet Research* (JMIR)
  – *International Journal of Medical Informatics* (IJMI)
  – *Methods of Information in Medicine* (MIM)
  – *Journal of Biomedical Informatics* (JBI)
  – *Applied Clinical Informatics* (ACI)
  – BMC family (*Medical Informatics & Decision-Making*)
  – Clinical specialty-specific
  – Information/computer science and others

• Conference proceedings
  – AMIA – annual
  – MEDINFO – formerly triennial, now biennial
Critical analysis of informatics literature

• General approaches covered in 2B-2 and 3E-3

• Some unique challenges in “evidence-based informatics” (Friedman, 2006)
  – Appropriate outcomes measures may be indirect from system intervention
  – Unit of analysis – may be beyond person and include clinic, hospital unit, etc.
International clinical informatics practices

• Until recently, US was a laggard behind other developed countries, e.g.,
  – Widespread adoption in European countries although even they have much less use of advanced systems (Osborn, 2015)
  – National exemplars: Denmark (Protti, 2010), UK (Payne, 2011)
  – Even efforts in developing countries (e.g., Quiros, 2009; Tierney, 2010)
  – But US now has mostly caught up due to HITECH Act (DesRoches, 2015)
Class interaction

• Which area of informatics is most pertinent to the following individuals?
  – Public health officer
  – Chief Medical Informatics Officer
  – Fitness app developer
  – Chief Research Informatics Officer
Additional suggested readings

• Key

• Supplemental
1A: History and Current State of Informatics


Ethics, Privacy, Legal, Regulatory and Financial Issues in Informatics

Lecture 1B

Thomas H Payne, MD, FACMI
University of Washington
Clinical Informatics Board Review Course

Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
   1.1.1. The discipline of informatics
   1.1.2. Key informatics concepts, models, theories
   1.1.3. Clinical informatics literature
   1.1.4. International clinical informatics practices
   1.1.5. Ethics and professionalism
   1.1.6. Legal and regulatory issues
   1.2. The Health System
   1.2.1. Determinants of individual and population health
   1.2.2. Primary domains, organizational structures, cultures, and processes
   1.2.3. The flow of data, information, and knowledge within the health system
   1.2.4. Policy & regulatory framework
   1.2.5. Health economics and financing
   1.2.6. Forces shaping health care delivery
   1.2.7. Institute of Medicine quality components

2. Clinical Decision Making and Care Process Improvement
   2.1. Clinical Decision Support
      2.1.1. The nature and cognitive aspects of human decision making
      2.1.2. Decision science
      2.1.3. Application of clinical decision support
      2.1.4. Transformation of knowledge into clinical decision support tools
      2.1.5. Legal, ethical, and regulatory issues
      2.1.6. Quality and safety issues
      2.1.7. Supporting decisions for populations of patients
      2.2. Evidence-based Patient Care
         2.2.1. Evidence sources
         2.2.2. Evidence grading
         2.2.3. Clinical guidelines
         2.2.4. Implementation of guidelines as clinical algorithms
         2.2.5. Information retrieval and analysis
      2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
         2.3.1. Methods of workflow analysis
         2.3.2. Principles of workflow re-engineering
         2.3.3. Quality improvement principles and practices

3. Health Information Systems
   3.1. Information Technology Systems
      3.1.1. Computer Systems
      3.1.2. Architecture
      3.1.3. Networks
      3.1.4. Security
      3.1.5. Data
      3.1.6. Technical approaches that enable sharing data
      3.2. Human Factors Engineering
         3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
         3.2.2. HCI Evaluation, usability testing, study design and methods
         3.2.3. Interface design standards and design principles
         3.2.4. Usability engineering
         3.3. Health Information Systems and Applications
            3.3.1. Types of functions offered by systems
            3.3.2. Types of settings where systems are used
            3.3.3. Electronic health/medical records systems as the foundational tool
            3.3.4. Telemedicine
            3.4. Clinical Data Standards
               3.4.1. Standards development history and current process
               3.4.2. Data standards and data sharing
               3.4.3. Transaction standards
               3.4.4. Messaging standards
               3.4.5. Nomenclatures, vocabularies, and terminologies
               3.4.6. Ontologies and taxonomies
               3.4.7. Interoperability standards
            3.5. Information System Lifecycle
               3.5.1. Institutional governance of clinical information systems
               3.5.2. Clinical information needs analysis and system selection
               3.5.3. Clinical information system implementation
               3.5.4. Clinical information system testing, before, during and after implementation
               3.5.5. Clinical information system maintenance
               3.5.6. Clinical information system evaluation

4. Leading and Managing Change
   4.1. Leadership Models, Processes, and Practices
      4.1.1. Dimensions of effective leadership
      4.1.2. Governance
      4.1.3. Negotiation
      4.1.4. Conflict management
      4.1.5. Collaboration
      4.1.6. Motivation
      4.1.7. Decision making
      4.2. Effective Interdisciplinary Teams
         4.2.1. Human resources management
         4.2.2. Team productivity and effectiveness
         4.2.3. Group management processes
         4.2.4. Managing meetings
         4.2.5. Managing group deliberations
      4.3. Effective Communications
         4.3.1. Effective presentations to groups
         4.3.2. Effective one-on-one communication
         4.3.3. Writing effectively for various audiences and goals
         4.3.4. Developing effective communications program to support system implementation
      4.4. Project Management
         4.4.1. Basic principles
         4.4.2. Identifying resources
         4.4.3. Resource allocation
         4.4.4. Project management tools (non-software specific)
         4.4.5. Informatics project challenges
      4.5. Strategic and Financial Planning for Clinical Information Systems
         4.5.1. Establishing mission and objectives
         4.5.2. Environmental scanning
         4.5.3. Strategy formulation
         4.5.4. Action planning and strategy implementation
         4.5.5. Capital and operating budgeting
         4.5.6. Principles of managerial accounting
      4.6. Change Management
         4.6.1. Assessment of organizational culture and behavior
         4.6.2. Change theories
         4.6.3. Change management strategies
         4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core Content Covered

1.1 Clinical Informatics
   1.1.5 Ethics and professionalism
   1.1.6 Legal and regulatory issues

3.5 Strategic and Financial Planning for Clinical Information Systems
   4.5.5 Capital and operating budgeting
   4.5.6 Principles of managerial accounting
Key topics

• International codes of practice and ethical codes relevant to clinical informatics.
• US legal and regulatory rulings most relevant to clinical informatics.
• Oversight of clinical computing activities by local bylaws and compliance groups.
• General principles of capital and operating budgeting as they pertain to clinical information systems
• General principles of managerial accounting
• Key financial concepts used in financial planning for clinical information systems
Definitions

Confidentiality. A condition in which information is shared or released in a controlled manner.

The HIPAA Security Rule defines “confidentiality” to mean that e-PHI is not available or disclosed to unauthorized persons.

Security. A number of measures that organizations implement to protect information and systems. It includes efforts not only to maintain the confidentiality of information but also to ensure the integrity and availability of that information and the information systems used to access it.

Privacy. An individual’s desire to limit the disclosure of personal information.
Ethical and Legal Considerations

• International Codes and Principles
• US Ethical Codes
• US Law
Codes and Principles

International
- Article 12 Universal Declaration of Human Rights
- Hippocratic Oath
- European Convention on Human Rights

US
- Code of Fair Information Practice
- Belmont Report and the Common Rule
- Conflict of Interest
Universal Declaration of Human Rights

Article 12
No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks.

Hippocratic Oath

Whatever I see or hear in the lives of my patients, whether in connection with my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private.

Translated by Michael North, National Library of Medicine, 2002.

Code of Fair Information Practice

1. There must be no personal data record-keeping systems whose very existence is secret.

2. There must be a way for a person to find out what information about the person is in a record and how it is used.

3. There must be a way for a person to prevent information about the person that was obtained for one purpose from being used or made available for other purposes without the person's consent.

4. There must be a way for a person to correct or amend a record of identifiable information about the person.

5. Any organization creating, maintaining, using, or disseminating records of identifiable personal data must assure the reliability of the data for their intended use and must take precautions to prevent misuses of the data.


Belmont Report and Common Rule

- The Belmont Report on Ethical Principles and Guidelines for the Protection of Human Subjects of Research. April 18, 1979
  1. Respect for Persons.
  2. Beneficence. (1) do not harm and (2) maximize possible benefits and minimize possible harms.
- For all participating departments and agencies the Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance.
AMIA Conflict of Interest policy

- A real or apparent conflict of interest may arise when a leader has some other interest that might suggest divided loyalty on the part of the leader between obligations to AMIA, on one hand, and to some other organization or cause, on the other. The “other interest” may arise from a transaction between AMIA and a third party, or a leader’s volunteer or paid relationship with a third party, which may compromise their ability to provide unbiased and undivided loyalty to AMIA. There is no monetary threshold for a COI. The AMIA COI policies extend to relationship that a spouse, domestic partner, parent or child of an affected individual.
US Law

- Bill of Rights
- HIPAA
- State and local laws
- Flows of patient information permitted by law
United States Bill of Rights

**Fourth Amendment** – Protection from unreasonable search and seizure.

The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.
DIVISION A—APPROPRIATIONS PROVISIONS

TITLE I—AGRICULTURE, RURAL DISTRICT, AND RELATED
TITLE II—COMMERCIAL, JUSTICE, AND
TITLE III—DEPARTMENT OF DEFENSE
TITLE IV—ENERGY AND WATER DEVELOPMENT
TITLE V—FINANCIAL SERVICES AND INSURANCE
TITLE VI—DEPARTMENT OF HOUSING AND RURAL DEVELOPMENT
TITLE VII—INTERIOR, ENVIRONMENT, ANDRelated Programs
TITLE VIII—DEPARTMENTS OF LABOR AND EDUCATION, AND
TITLE IX—LEGISLATIVE BRANCH
TITLE X—MILITARY CONSTRUCTION AND RELATED AGENCIES
TITLE XI—STATE, FOREIGN OPERATIONS, AND RELATED PROGRAMS
TITLE XII—TRANSPORTATION, HOUSING AND URBAN DEVELOPMENT, AND RELATED AGENCIES

TITLE XIII—HEALTH INFORMATION TECHNOLOGY

TITLE XIV—STATE FISCAL STABILIZATION FUND

TITLE XV—ACCOUNTABILITY AND TRANSPARENCY

TITLE XVI—GENERAL PROVISIONS—THIS ACT

DIVISION B—TAX, UNEMPLOYMENT, HEALTH, STATE FISCAL RELIEF, AND RELATED PROVISIONS

TITLE I—TAX PROVISIONS
TITLE II—ASSISTANCE FOR UNEMPLOYED WORKERS AND STRUGGLING FAMILIES
TITLE III—PREMIUM ASSISTANCE FOR COPRA BENEFITS

TITLE IV—MEDICARE AND MEDICAID HEALTH INFORMATION TECHNOLOGY; MISCELLANEOUS MEDICARE PROVISIONS

TITLE V—STATE FISCAL RELIEF
TITLE VI—BROADBAND TECHNOLOGY OPPORTUNITIES PROGRAM
TITLE VII—LIMITS ON EXECUTIVE COMPENSATION

“HITECH” Act

American Recovery and Reinvestment Act
Flows of Alice’s health information

Source: For The Record, Institute of Medicine, 1997
Model and context for security and privacy

- Threat assessment
- Asset list
- Policy
- Education
- Technical measures
Privacy protections within EMRs

• It is very difficult to predict which clinician will need to view which record.
• Most US hospitals use policy and audits to protect against access to records for which physicians have no professional relationship.
• Sanctions occur for inappropriate access
Clinical computing systems and the law

• The importance of authentication and authorization
• Concept of non-repudiation
• Patient billing is based on codes, and codes have to be based on Medical Record documentation.
• Audit trails, document version history
• Close cooperation with compliance and general counsel
True or False

The HITECH Act refers to sections of the Accountable Care Act that provide financial incentives for meaningful use of certified electronic health records.
CMS guidelines for use of macros

Reimbursement is closely tied to documentation, whether on paper, through dication or using an EMR.

A macro is a command in a computer or dictation application in an electronic medical record that automatically generates predetermined text that is not edited by the user. The teaching physician may use a macro as the required personal documentation if he or she personally adds it in a secured or password-protected system. In addition to the teaching physician’s macro, either the resident or the teaching physician must provide customized information that is sufficient to support a medical necessity determination. The note in the electronic medical record must sufficiently describe the specific services furnished to the specific patient on the specific date. If both the resident and the teaching physician use macros only, this is considered insufficient documentation.
September 24, 2012

American Hospital Association
Richard A. Thompson
President and Chief Executive Officer
325 Seventh Street, N.W.
Washington, DC 20004

Association of Academic Health Centers
Steve Warran
President and Chief Executive Officer
1400 Sixteenth Street, NW, Suite 720
Washington, DC 20036

National Association of Public Hospitals and Health Systems
Bruce Siegel, MD, MPH
President and Chief Executive Officer
1301 Pennsylvania Avenue, NW
Suite 950
Washington DC 20004

Dear Chief Executive Officers,

As leaders in the health care system, our nation’s hospitals have been at the forefront of adopting electronic health records for use in coordinating care, improving quality, reducing paperwork, and eliminating duplicative tests. Over 55 percent of hospitals have already qualified for incentive payments authorized by Congress to encourage health care providers to adopt and meaningfully use this technology. Used appropriately, electronic health records have the potential to save money and save lives.

However, there are troubling indications that some providers are using this technology to game the system, possibly to obtain payments to which they are not entitled. False documentation of medical records in order to inflate what providers get paid. There are also reports that some hospitals may be using electronic health records to facilitate “spreading” of the intensity of care.

This letter underscores our resolve to ensure payment accuracy and to prevent and prosecute health care fraud. A patient’s care information must be verified individually to ensure accuracy; it cannot be cut and pasted from a different record of the patient, which risks medical errors as well as overpayments. The Centers for Medicare and Medicaid Services (CMS) is specifically reviewing billing through audits of facility and provider payments. Additionally, CMS is initiating more extensive medical reviews to ensure that providers are coding evaluation and management services accurately. This includes comparative billing reports that identify outlier facilities. CMS has the authority to address inappropriate increases in coding intensity in its payment rules, and CMS will consider future payment reductions as warranted.

We will not tolerate health care fraud. The President initiated in 2009 an unprecedented Cabinet-level effort to combat health care fraud and protect the Medicare trust fund, and we take those responsibilities very seriously.

Law enforcement will take appropriate steps to pursue health care providers who misuse electronic health records to bill for services never provided. The Department of Justice, Department of Health and Human Services, the FBI, and other law enforcement agencies are monitoring these trends, and will take action where warranted. New tools provided by the health care law authorize CMS to stop Medicare payments upon suspicion of fraud and to mine data to detect it in the first place. These efforts have contributed to record-high collections and prosecutions. Prosecutions in 2011 were 75 percent higher than in 2008. That said, we will continue to escalate our efforts to prevent fraud and pursue it aggressively when it has occurred.

The nation’s hospitals share our goal of a health system that offers high quality, affordable care. We thank you for your relentless work toward this goal which can be better achieved only if all Americans have privacy-protected electronic health records. The health information technology incentive program promotes electronic health records that go beyond documentation and billing and towards meaningful use as a foundation for new payment and delivery models. The Affordable Care Act has accelerated the spread of such models like Accountable Care Organizations, patient-centered homes, and value-based purchasing which shift the incentives away from volume and towards value. As we phase-in electronic health records, though, we ask for your help in ensuring that these tools are not misused or abused.

Sincerely,

Kathleen Sebelius
Secretary
U.S. Department of Health & Human Services

Eric H. Holder, Jr.
Attorney General
U.S. Department of Justice
The HIPAA Security Rule

A. Requires awareness and compliance of security professionals but does not extend to the general workforce.
B. Requires protection against published and known security threats only
C. Defines confidentiality, integrity and availability
D. Does not cover availability of electronic PHI
E. Pertains to transmission and storage but not impermissible use of e-PHI
JCAHO IM Standards

• Patient-Specific information
• 6.1 The hospital has a complete and accurate medical record for every individual assessed, cared for, treated or served.
• 6.2 Records contain patient-specific information, as appropriate, to the care, treatment, and services provided.
• 6.3 The medical record thoroughly documents operative or other high risk procedures and the use of moderate or deep sedation or anesthesia.
JCAHO IM Standards

• Information Management Planning
  – 1.1 The hospital plans and designs information management processes to meet internal and external information needs.
• Confidentiality and Security
  – 2.1 Information privacy and confidentiality are maintained.
  – 2.2 Information security, including data integrity, is maintained.
  – 2.3 The hospital has a process for maintaining continuity of information.
JCAHO IM Standards

• 6.4 For patients receiving continuing ambulatory care services, the medical record contains a summary list of all significant diagnoses, procedures, drug allergies, and medications.

• 6.5 Designated qualified personnel accept and transcribe verbal orders from authorized individuals.

• 6.6 The hospital can provide access to all relevant information from a patient’s record when needed for use in patient care, treatment and services.
Medical Records Committee

- Oversight to meet goals of information management.
- Oversight for implementation of regulations.
- Oversight for meeting accreditation standards.
- Policy and Procedure approval.
- Understanding of record and systems functionality and impact on information flow.
- Advisory and direction in areas of
  - System functionality and work flow
  - Appropriate Entries into the record
  - Chart Completion
  - Forms management
- Audits and Quality review with action steps.
Health Information Management

• The hospital leaders have overall responsibility for managing information.
• Hospital Bylaws, Rules & Regulations establishes the Medical Records Committee, and professional staff record responsibilities.
• Hospital Policy & Procedures guide hospital operations.
• Regulatory Bodies – State & Federal
  – State: Division of Health,
  – Federal: CMS; Medicare, HIPAA
  – Accreditation – Joint Commission on Accreditation for Healthcare Operations (JCAHO)
Key Operations

- **Coding** and the analysis of coded data are key operations
  - Clinical Classification Systems
  - There are many other recognized classification systems
  - ICD-10 and CPT (HIPAA standard)
    - Billing and Payment for healthcare services
    - research
    - Turns data into useful information for process improvement, quality and patient safety
HIM Key Operations

• Release of Information (ROI)
  – Disclosures to outside organizations must meet all HIPAA, state and federal disclosure regulations.
  – Dept. handles all incoming requests for records.
  – Determine and prepare records to be disclosed according to regulations.

• Master Patient Index and Encounters
  – Every patient has one medical record number.
  – Every patient visit has an encounter.
HIM Credentials & Certifications

- Coding Certifications
- Privacy Certifications
- Health Information Credentials
  - RHIA (Registered Health Information Administrator)
  - RHIT (Registered Health Information Technician)
Key topics

• General principles of capital and operating budgeting as they pertain to clinical information systems

• General principles of managerial accounting

• Key financial concepts used in financial planning for clinical information systems
Definitions, 1

**Capital budgeting:** Planning process for expenditure of relatively large sums on long-term assets such as replacing worn out assets with new ones and developing new business opportunities. [Tiffen 2007]

**Operating budgeting:** A detailed projection of all estimated income and expenses based on forecasted revenue during a given period (usually one year). A complete operating budget consists of not only a projected profit and loss statement but also a supporting cash flow statement, as well as a balance sheet. [Rollins, Yale]
Definitions, 2

**Depreciation:** To lower the price or estimated value of [Webster], particularly of a long-term asset that has diminishing value over time.

**Net present value:** The difference between the present value of all cash inflows and the present value of all cash outflows; used to determine whether or not a project is an acceptable investment. [Garrison, 1994].
Principles of managerial accounting

[Garrison, 1994]

- Managerial accounting is concerned with providing information to managers, in contrast to financial accounting, which is concerned with providing information to stockholders and others outside an organization.
- Includes accounting information (budgets, performance reports for controlling), tools for organizing and directing and decision making.
- There are many differences between financial and managerial accounting.
Managerial accounting, in contrast to financial accounting: [Garrison, 1994]

- Focuses on providing data for managers
- Places more emphasis on the future
- Places more emphasis on non-monetary data
- Emphasizes segments of an organization rather than just the organization as a whole.
- Is not governed by generally accepted accounting principles
Principles of managerial accounting

Tools

• Fixed and variable costs
• Profit and loss (P&L) statement
• Operating leverage
• Cost-volume-profit analysis
Budget types

- **Statistics.** Calculates the budget needed for various "what-if" scenarios.
- **Revenue.** Revenue receipts of government and the expenditure met from these revenues.
- **Cash.** A prediction of future cash receipts and expenditures for a particular time period.
- **Expense.** Includes spending data items.
- **Operating**
- **Capital**
Time Value Analysis

Future value of lump sum

Present value of lump sum

Net present value is the value of the sum of future cash flows presented in today’s dollars.

Net Present Value formula: 

\[ NPV(i, N) = \sum_{t=0}^{N} \frac{R_t}{(1+i)^t} \]
The time value of money is accounted for by the concept of compounding interest. Because a sum invested today will accrue interest in the future, a fixed sum paid in the future is worth less than the same amount today.

<table>
<thead>
<tr>
<th>Year</th>
<th>Compounded Amount</th>
<th>Discounted Amount</th>
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<tbody>
<tr>
<td>0</td>
<td>1.000</td>
<td>1.000</td>
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<tr>
<td>1</td>
<td>1.050</td>
<td>0.952</td>
</tr>
<tr>
<td>2</td>
<td>1.103</td>
<td>0.907</td>
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<td>3</td>
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<tr>
<td>4</td>
<td>1.216</td>
<td>0.823</td>
</tr>
<tr>
<td>5</td>
<td>1.276</td>
<td>0.784</td>
</tr>
</tbody>
</table>
Balance sheet

Assets = Liabilities + Equity

- **Current** (short-term debt)
- **Fixed** (e.g., buildings, equipment)
- **Long-term debt**

**Current** (e.g., cash, others convertible to cash in year)
Income Statement

Operating earnings = Gross Profit – (Operating Expenses + Depreciation)

Cash flow
Cash flow is the amount of cash that changed hands during an accounting period.

True or false:
Cash flow is basically the same thing as profit.

ANSWER:
False. A sale may contribute to profit for the year, but may not result in cash till the next year.
# Sample IT budget
## FY 15

<table>
<thead>
<tr>
<th>Project</th>
<th>Capital*</th>
<th>Operating*</th>
<th>Capital &amp; Operating Total*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Center</td>
<td>$50.0</td>
<td>$35.0</td>
<td>$85.0</td>
</tr>
<tr>
<td>Outpatient EMR</td>
<td>$50.0</td>
<td>$20.0</td>
<td>$70.0</td>
</tr>
<tr>
<td>Help Desk</td>
<td>$0.0</td>
<td>$2.0</td>
<td>$2.0</td>
</tr>
<tr>
<td>End User Devices</td>
<td>$0.5</td>
<td>$3.0</td>
<td>$3.5</td>
</tr>
<tr>
<td>Network</td>
<td>$1.0</td>
<td>$4.0</td>
<td>$5.0</td>
</tr>
<tr>
<td><strong>TOTAL PROJECT AND PRODUCTION SUPPORT</strong></td>
<td><strong>$101.5</strong></td>
<td><strong>$64.0</strong></td>
<td><strong>$165.5</strong></td>
</tr>
</tbody>
</table>

* in millions

Fiscal year: July 1, 2014 – June 30, 2015
The costs of HICT

Implementation
• Support
• Training program
• Build processes
• Administration

RDTE (research, development, training, evaluation)

Maintenance
• Support/maintenance contracts
• Application support
• User support
• Technical support
• Upgrades—hardware and software
• Complying with legal and regulatory requirements
The largest category of hospital expenses for most organizations is:

A. Pharmaceuticals
B. Depreciation
C. Salaries and benefits
D. Provision for uncollectable accounts
Hospital expenses
(fictitious example)

- Salaries, Wages, Benefits: 50%
- Pharmaceuticals, Supplies: 31%
- All other Supplies: 8%
- Depreciation & Interest: 3%
- Prov for Uncollectible Accts: 8%
ROI from clinical systems

[Glaser, NIH, 2002]
Total Cost of Ownership (TCO)

- **Hardware and software**
  - Computer, network
  - Purchasing research
  - Migration
  - Risks

- **Operations**
  - Infrastructure
  - Electricity
  - Diminished performance
  - Security

- **Long term expenses**
  - Replacement
  - Future upgrade
  - Decommissioning

Consider life cycle of system or project, not just initial purchase or licensing cost

Additional suggested readings


• HIPAA Security Rule at http://hhs.gov
1C: The Health System

William Hersh, MD, FACP, FACMI

Oregon Health & Science University
**Core Content Covered in this Lecture**

### 1. Fundamentals
1.1. Clinical Informatics
1.1.1. The discipline of informatics
1.1.2. Key informatics concepts, models, theories
1.1.3. Clinical informatics literature
1.1.4. International clinical informatics practices
1.1.5. Ethics and professionalism
1.1.6. Legal and regulatory issues

### 1.2. The Health System
1.2.1. Determinants of individual and population health
1.2.2. Primary domains, organizational structures, cultures, and processes
1.2.3. The flow of data, information, and knowledge within the health system
1.2.4. Policy & regulatory framework
1.2.5. Health economics and financing
1.2.6. Forces shaping health care delivery
1.2.7. Institute of Medicine quality components

### 2. Clinical Decision Making and Care Process Improvement
2.1. Clinical Decision Support
2.1.1. The nature and cognitive aspects of human decision making
2.1.2. Decision science
2.1.3. Application of clinical decision support
2.1.4. Transformation of knowledge into clinical decision support tools
2.1.5. Legal, ethical, and regulatory issues
2.1.6. Quality and safety issues
2.1.7. Supporting decisions for populations of patients

### 2.2. Evidence-based Patient Care
2.2.1. Evidence sources
2.2.2. Evidence grading
2.2.3. Clinical guidelines
2.2.4. Implementation of guidelines as clinical algorithms
2.2.5. Information retrieval and analysis

### 2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
2.3.1. Methods of workflow analysis
2.3.2. Principles of workflow re-engineering
2.3.3. Quality improvement principles and practices

### 3. Health Information Systems
3.1. Information Technology Systems
3.1.1. Computer Systems
3.1.2. Architecture
3.1.3. Networks
3.1.4. Security
3.1.5. Data
3.1.6. Technical approaches that enable sharing data
3.2. Human Factors Engineering
3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
3.2.2. HCI Evaluation, usability testing, study design and methods
3.2.3. Interface design standards and design principles
3.2.4. Usability engineering
3.3. Health Information Systems and Applications
3.3.1. Types of functions offered by systems
3.3.2. Types of settings where systems are used
3.3.3. Electronic health/medical records systems as the foundational tool
3.3.4. Telemedicine
3.4. Clinical Data Standards
3.4.1. Standards development history and current process
3.4.2. Data standards and data sharing
3.4.3. Transaction standards
3.4.4. Messaging standards
3.4.5. Nomenclatures, vocabularies, and terminologies
3.4.6. Ontologies and taxonomies
3.4.7. Interoperability standards
3.5. Information System Lifecycle
3.5.1. Institutional governance of clinical information systems
3.5.2. Clinical information needs analysis and system selection
3.5.3. Clinical information system implementation
3.5.4. Clinical information system testing, before, during and after implementation
3.5.5. Clinical information system maintenance
3.5.6. Clinical information system evaluation

### 4. Leading and Managing Change
4.1. Leadership Models, Processes, and Practices
4.1.1. Dimensions of effective leadership
4.1.2. Governance
4.1.3. Negotiation
4.1.4. Conflict management
4.1.5. Collaboration
4.1.6. Motivation
4.1.7. Decision making
4.2. Effective Interdisciplinary Teams
4.2.1. Human resources management
4.2.2. Team productivity and effectiveness
4.2.3. Group management processes
4.2.4. Managing meetings
4.2.5. Managing group deliberations
4.3. Effective Communications
4.3.1. Effective presentations to groups
4.3.2. Effective one-on-one communication
4.3.3. Writing effectively for various audiences and goals
4.3.4. Developing effective communications program to support system implementation
4.4. Project Management
4.4.1. Basic principles
4.4.2. Identifying resources
4.4.3. Resource allocation
4.4.4. Project management tools (non-software specific)
4.4.5. Informatics project challenges
4.5. Strategic and Financial Planning for Clinical Information Systems
4.5.1. Establishing mission and objectives
4.5.2. Environmental scanning
4.5.3. Strategy formulation
4.5.4. Action planning and strategy implementation
4.5.5. Capital and operating budgeting
4.5.6. Principles of managerial accounting
4.5.7. Evaluation of planning process
4.6. Change Management
4.6.1. Assessment of organizational culture and behavior
4.6.2. Change theories
4.6.3. Change management strategies
4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core content covered

1.2. The Health System
   1.2.1 Determinants of individual and population health
   1.2.2 Primary domains, organizational structures, cultures, and processes
      1.2.2.1 Health care delivery
      1.2.2.2 Public health
      1.2.2.3 Clinical research
      1.2.2.4 Education of health professionals
      1.2.2.5 Personal health
   1.2.3 The flow of data, information, and knowledge within the health system
   1.2.4 Policy & regulatory framework
   1.2.5 Health economics and financing
   1.2.6 Forces shaping health care delivery
   1.2.7 Institute of Medicine quality components
      1.2.7.1 Safety
      1.2.7.2 Effectiveness
      1.2.7.3 Efficiency
      1.2.7.4 Patient-centeredness
      1.2.7.5 Timeliness
      1.2.7.6 Equity
Key topics

• Structure and function of the US healthcare system
• Current problems and proposed solutions for the US health care system
• Key Institute of Medicine reports over the last two decades and the context they set for informatics
• Incentivizing the adoption of health information technology
1C – The Health System

- Determinants of individual and population health
- Primary domains, organizational structures, cultures, and processes
- The flow of data, information, and knowledge within the health system
- Policy and regulatory framework
- Health economics and financing
- Forces shaping health care delivery
- Health care quality and improvement
- The Health Information Technology for Economic and Clinical Health (HITECH) Act and “meaningful use” of the electronic health record
Determinants of individual and population health

- Policymaking – local, state, and national
- Social factors – economics, environment, education, etc.
- Health services – health care, public health
- Individual behavior – diet, activity, lifestyle
- Biology and genetics
Primary domains, organizational structures, cultures, and processes

- Health care delivery
- Public health
- Clinical research
- Education of health professionals
- Personal health
Health care delivery – levels of care

- Primary care – initial and ongoing care, typically provided in an office or clinic
- Secondary care – specialty care provided in the community
- Tertiary care – highly specialized care usually provided by referral in a large, typically academic, medical center
- Quaternary care – sometimes used as an extension of tertiary care in reference to advanced levels of medicine that are highly specialized and not widely accessed
Stakeholders – the “p’s”

- Patient – the one who gets healthcare, often called a consumer or citizen when they are well
- Provider – those who “provide” healthcare, e.g., physicians, nurses, allied health
- Purchaser – those who buy healthcare, usually employers or the government
- Payor – those who “pay” the healthcare system, i.e., the insurance companies and government
- Public health – protectors of the public’s health
And there are major problems

- US pays more for all aspects of care (OECD, 2011; Squires, 2012)
  - Silver lining is leveling of costs last few years (Martin, 2016)
- US has a “health disadvantage”: life expectancy and infant mortality among lowest of advanced countries (Woolf, 2013)
- System has as much as 20% waste (Berwick, 2012)
  - Overtreatment
  - Failures of care coordination
  - Failures of care delivery – best practices
  - Administrative complexity
  - Pricing failures – above market
  - Fraud and abuse
Public health

• The “science of protecting and improving the health of communities through education, promotion of healthy lifestyles, and research for disease and injury prevention”
  – http://www.cdcfoundation.org/content/what-public-health

• “Health care is vital to all of us some of the time, but public health is vital to all of us all of the time”
  – C. Everett Koop, Former US Surgeon General
Public health functions and activities

• Public health performs its missions through its core functions
  – Assessment
  – Policy Development
  – Assurance

• Public health activities include
  – Prevent epidemics and the spread of disease
  – Protect against environmental hazards
  – Prevent injuries
  – Promote and encourage healthy behaviors
  – Respond to disasters and assists communities in recovery
  – Assure the quality and accessibility of health services
Public health perspective

• Public health tends to take perspective of health of populations
  – One of its basic sciences is epidemiology – study of disease in populations
  – However, public health is increasingly involved in other forms of health promotion and prevention, e.g., obesity, nutrition, etc.

• May result in different perspective than individual care
  – Population-based view focuses on preventing disease as well as societal impacts on health
  – Usually a government (regional or federal) activity
Clinical research (US National Institutes of Health; www.nih.gov)

- Clinical research comprises studies and trials in human subjects that fall into the three sub-categories
  - Patient-oriented research – research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects, including
    - Mechanisms of human disease
    - Therapeutic interventions
    - Clinical trials
    - Development of new technologies
  - Epidemiologic and behavioral studies
  - Outcomes research and health services research
Translational research
(Zerhouni, 2007)

• Accelerating research results from laboratory to clinical environment to community along T1/T2/T3 axis (Dougherty, 2008)

• Benefits require collaboration and partnerships, facilitated by informatics (Richesson, 2012)
Education of health professionals

- Mostly in professional schools – medicine, nursing, dentistry, pharmacy, allied health
- Usually culminating in
  - Certification – national, through 24 private, non-profit boards
  - Licensure – through state government
- Continuing education – historically focused on courses and credits, now shifting to “maintenance of certification” (Rhodes, 2007)
Personal health

• Decision-making (Mass. BCBS, 2007)
  – Half of adults make healthcare decisions for others in their family (children, elders, etc.)
  – Three-quarters are interested in information to help inform decisions (quality ratings, physician experience, etc.)
    • Much of the kinds of information they seek are not available
    • As such, they often make decisions rapidly with little information

• Most want access to their data and information, including 60% by electronic means (Deloitte, 2008)
Flow of data, information, and knowledge (NCVHS, 2009)

<table>
<thead>
<tr>
<th>Data Sources</th>
<th>Data Users</th>
<th>Data Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>Hospital</td>
<td>Discharge Summary</td>
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<td>Quality Reporting</td>
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<td>Operational Assessment</td>
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<tr>
<td>Labs</td>
<td>Physicians</td>
<td>Office Visits</td>
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<td>Quality Reporting</td>
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<tr>
<td>Prescriptions</td>
<td>Person/Patient</td>
<td>Personal Health Record</td>
</tr>
<tr>
<td>Ambulatory Centers</td>
<td>Labs</td>
<td>Test Results</td>
</tr>
<tr>
<td>Public Health</td>
<td>Public Health</td>
<td>Communicable Disease Reporting</td>
</tr>
<tr>
<td>Person/Patient</td>
<td>Payer</td>
<td>Benefit Checking Claims</td>
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<tr>
<td></td>
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<td>Quality Audits</td>
</tr>
<tr>
<td></td>
<td>Researchers</td>
<td>Research Studies</td>
</tr>
</tbody>
</table>
From data and information to knowledge (Mulrow, 1998)

EVIDENCE
- Patient data
- Basic, clinical, and epidemiological research
- Randomized controlled trials
- Systematic reviews

PATIENT/CLINICIAN PREFERENCES
- Cultural beliefs
- Personal values
- Education
- Experience

CONSTRAINTS
- Formal policies and laws
- Community standards
- Time
- Financial

GUIDELINES

KNOWLEDGE

CLINICAL DECISION

ETHICS

Clinical Informatics Board Review Course
Policy and regulatory framework

• Federal: Department of Health and Human Services (HHS)
  – Centers for Medicare and Medicaid Services (CMS)
  – Centers for Disease Control and Prevention (CDC)
  – Food and Drug Administration (FDA)
  – National Institutes of Health (NIH)
• State and local – various
Health economics and financing

• No matter who pays the cost (patient, employer, or government), most healthcare is financed on the notion of insurance
  – Everyone pays some, those who need it use it

• Payment methods
  – Private fee-for-service
  – Private managed care, a.k.a., HMOs, PPOs
  – Government-financed, a.k.a., single-payer
  – Government-provided
How is healthcare financed in the US?

• Annual publication of California Health Care Foundation gives good overview: Health Care Costs 101 (Wilson, 2016)

• Major findings
  – Total spending has been projected to reach 18% of GDP by 2016
  – Per-person spending on healthcare more than doubled from 1996 to $9523 in 2014
  – About half of spending growth is due to medical price inflation – the rising cost of providing existing services to patients, with much of rest due to aging population
Major healthcare payors in US

- Private health insurance – for most employed citizens and their dependents, except those in lower-paying jobs
- Medicare – government insurance for elderly and disabled
- Medicaid – government insurance for indigent
- State Children's Health Insurance Program (SCHIP) – government insurance for uninsured low-income children
- Other expenses due to out-of-pocket, public health, and other expenditures
- Payer mix is percentage of revenue from private insurance vs. government insurance vs. self-paying individuals
  - Mix important because Medicare and Medicaid pay hospitals less than what it costs to treat patients
How is the money spent and paid? (Wilson, 2016)
Forces shaping health care delivery

• The Affordable Care Act (ACA, or “Obamacare”) is likely to remain the law of the land (KFF, 2011; Ogundimu, 2011; Selker, 2013, etc.)
  – www.healthcare.gov
  – Flow chart (KFF, JAMA, 2012)
• Massive legislation has three broad goals
  – Regulation and coverage – e.g., eliminating coverage restrictions, creating temporary high-risk pools
  – Major expansion of coverage – e.g., individual mandates, health insurance exchanges, employer penalties, Medicaid expansion
  – Bending the cost curve – e.g., provide incentives for higher-quality, lower-cost care
Obamacare

- Small business tax credits
- Close Medicare “donut hole”
- Requirement for larger (>50) employers to offer health insurance coverage
- Expand Medicaid for low-income Americans (<133% of poverty level)
- Creation of health insurance exchanges
- Prohibit denial of insurance for pre-existing illnesses
- Increase payroll tax of upper-income Americans and some other taxes
- Individual mandate for health insurance
- And much more (KFF, 2011)
Politics of Obamacare

• Has something for everyone to dislike
  – Left-wingers – no single-payer system (Medicare for all) or government option
  – Right-wingers – too much taxes and regulation as well as desire to see all things Obama fail
  – Healthcare delivery policy wonks – too much emphasis on insurance, not enough on delivery reform
• Politics are toxic – rational debate difficult
  – Polls consistently find more support each and every provision except individual mandate than law itself (KFF, 2011)
  – End-of-life consultations become “death panels,” which are not even part of law (Holan, 2009; Nyhan, 2013)
  – Some conservative politicians claim goal is to replace Medicare (single-payer socialized medicine) with ACA (regulated private insurance) (Kessler, 2011)
  – More people dislike “Obamacare” than “ACA” (Coy, 2013)
Has the ACA been successful?

- So far, mostly in reducing rate of uninsurance
  - Over 20 million Americans who previously were uninsured now have health insurance due to insurance exchanges, Medicaid expansion, and children on plans to age 26 (Uberoi, 2016)
  - Rate of uninsurance lowered from >20% to 11.5-13.1% (Uberoi, 2016)
  - Larger drop in uninsured seen in states with Medicaid expansion, e.g., reduced in Oregon from 14% to 5% (despite major problems with health insurance exchange Web site) (OHSU, 2014)
Despite focus on insurance, ACA also addresses cost and quality

- "Bundled payments" and "accountable care"
  - Patient-Centered Medical Home (PCMH) aims to provide a "home" for patients to get coordinated care (Nielsen, 2016)
  - Accountable Care Organizations (ACOs) provide flexible financial support in exchange for accepting accountability for overall quality and cost, aka "shared savings" (Pham, 2015)
    - Modest evidence of benefit (Nielsen, 2016), including Oregon Medicaid "Coordinated Care Organizations" (CCOs) (McConnell, 2016)
- Focus on care "that works"
  - Independent Payment Advisory Board (IPAB) – federal agency tasked with changing Medicare coverage and reimbursement when cost targets not met (aka, "death panels")
Health care quality and the IOM reports

• In recent times, driven by “triple aim” (Berwick, 2008)
  – Better health
  – Better healthcare
  – Lower cost
• Quality measured in three categories at individual and organizational levels (Donabedian, 2002)
  – Structural – factors that make it easier or harder to deliver high-quality care, e.g., hospital location, volume, physician licensure, nurse staffing levels
  – Process – factors describing healthcare content and activities, e.g., adherence to guidelines for screening, treatment, etc.
  – Outcomes – changes attributable to care, e.g., mortality, morbidity, functional status
• (More in Lecture 2C-2)
Early IOM reports that identified the problems and set the agenda

- *The Computer-Based Patient Record (Dick, 1997)* – paper records are illegible, inefficient, and error-prone; computer-based record vital to modern healthcare
- *For the Record: Protecting Electronic Health Information (1997)* – benefits of electronic health information compromised by inadequate protection; informed HIPAA legislation
- *Networking Health (2000)* – value of networks important but do not need separate health Internet; availability more important than bandwidth
- *To Err is Human (Kohn, 2000)* – medical errors are common and a systems problem
- *Crossing the Quality Chasm (2001)* – Developed set of aims and rules for high-quality 21st century healthcare
Quality aims for 21st century healthcare (IOM, 2001)

• Healthcare should be
  – Safe – avoid injuries from care intended to help
  – Effective – provide service based on scientific knowledge and avoid care unlikely to benefit
  – Patient-centered – care respectful of patients’ preferences, needs, and values
  – Timely – reduce waits and delays in care
  – Efficient – avoid waste of equipment, supplies, and energy
  – Equitable – provide care that does not vary based on personal characteristics
Rules for 21\textsuperscript{st} century healthcare

- Patient needs and values should drive variation in care
- Care based on continuous healing relationships, i.e., 24/7 and by all modalities
- Patient as source of control
- Shared knowledge, free flow of information, and transparency of information
- Anticipation of needs rather than reacting to them
- Evidence-based decision making
More recent IOM reports

• *Knowing What Works in Health Care* (Eden, 2008) – introduced the learning health system and comparative effectiveness research

• *Digital Infrastructure for the Learning Healthcare System* (Grossman, 2011) – data and information systems needed

• *Health IT and Patient Safety* (2012) – health IT can cause harm as well as benefit

• *Best Care, Lower Cost* (Smith, 2012) – implementing comprehensive vision of the learning health system
Spurring adoption of health information technology

“To improve the quality of our health care while lowering its cost, we will make the immediate investments necessary to ensure that within five years, all of America’s medical records are computerized … It just won’t save billions of dollars and thousands of jobs – it will save lives by reducing the deadly but preventable medical errors that pervade our health care system.”

January 5, 2009

Health Information Technology for Economic and Clinical Health (HITECH) Act of the American Recovery and Reinvestment Act (ARRA) (Blumenthal, 2010)

- Incentives for electronic health record (EHR) adoption by physicians and hospitals (up to $27B)
- Direct grants administered by federal agencies ($2B, including $118M for workforce development)
Centerpiece of HITECH is incentives for “meaningful use”

- Conceptually originated in legislation by Stark (2010)
  - Must use certified EHR connected for health information exchange and able to submit data on clinical quality measures
- All MU criteria must “map” to one or more of five goals for the healthcare system
  - Improving quality, safety, and efficiency
  - Engaging patients in their care
  - Increasing coordination of care
  - Improving the health status of the population
  - Ensuring privacy and security
- Examples
  - Implement drug-drug interaction checks → Improving quality, safety, and efficiency
  - Provide summary of care to patients → Engaging patients in their care
Implementation

• Implemented through increased Medicare or Medicaid reimbursement to
  – Eligible professionals (EPs)
    • Medicare: MD, DO, DDS/DMD, DPM, OD, DC
    • Medicaid: MD, DO, DDS/DMD, Certified Nurse Midwives, Nurse Practitioners, Physicians Assistants operating at an FQHC/RHC
    • Hospital-based EPs not eligible (>90% service in hospital, e.g., pathologist, emergency physician)
  – Eligible hospitals (EHs)
    • Medicare: Acute Care Hospitals, Critical Access Hospitals (CAHs)
    • Medicaid: Acute Care Hospitals, CAHs, Children’s Hospitals
Implemented in three stages –

www.healthit.gov

Stage 1
Meaningful Use Criteria
(Capture/share data)

Stage 2 Meaningful Use Criteria
(Advanced care processes with decision support)

Stage 3 Meaningful Use Criteria (Improved Outcomes)
Incentive amounts

• Eligible for incentives paid through Medicare and Medicaid reimbursement
• $44-63K for EPs
• $2-9M to EHs
• Vary by
  – Medicare vs. Medicaid qualification
  – Amount of Medicare or Medicaid patients seen
  – For hospitals, number of discharges per year
MU operationalized

• Stage 1
  – Objectives announced in 2010
  – Program began payments on
    • January 1, 2011 for EPs
    • October 1, 2010 for EHs

• Stage 2
  – Objectives announced in 2012
  – Start pushed back one year to 2014
  – Raised the bar, with additional emphasis on patient engagement and health information exchange
  – “Modified” in 2015 to consolidate Stages 1-2
Criteria for Stages 1-2 MU
(Blumenthal, 2010; Metzger, 2012)

• Core objectives – all must be met
• Menu objectives – selected from set
• Stage 1
  – EPs must meet 15 core and 5 of 10 menu objectives
  – EHs must meet 14 core and 5 of 10 menu objectives
  – For EPs and EHs, one menu objective must be a public health measure
• Stage 2
  – EPs must meet 17 core and 3 of 6 menu objectives
  – EHs must meet 16 core and 3 of 6 menu objectives
New timeline after introduction of Stage 2

<table>
<thead>
<tr>
<th>1st Year</th>
<th>Stage of Meaningful Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>1</td>
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<tr>
<td>2012</td>
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<tr>
<td>2013</td>
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<td>2014</td>
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<td>2015</td>
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<tr>
<td>2016</td>
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</tr>
<tr>
<td>2017</td>
<td></td>
</tr>
</tbody>
</table>
## Stage 1 MU – core objectives  
(Blumenthal, 2010)

<table>
<thead>
<tr>
<th>Objective Description</th>
<th>Percentage of Patients Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Record patient demographics (sex, race, ethnicity, date of birth, preferred language, and in the event of mortality)</td>
<td>More than 50% of patients' demographic data recorded as structured data</td>
</tr>
<tr>
<td>Record vital signs and chart changes (height, weight, blood pressure, body-mass index, growth charts for children)</td>
<td>More than 50% of patients 2 years of age or older have height, weight, and blood pressure recorded as structured data</td>
</tr>
<tr>
<td>Maintain up-to-date problem list of current and active diagnoses</td>
<td>More than 80% of patients have at least one entry recorded as structured data</td>
</tr>
<tr>
<td>Maintain active medication list</td>
<td>More than 80% of patients have at least one entry recorded as structured data</td>
</tr>
<tr>
<td>Maintain active medication allergy list</td>
<td>More than 80% of patients have at least one entry recorded as structured data</td>
</tr>
<tr>
<td>Record smoking status for patients 13 years of age or older</td>
<td>More than 50% of patients 13 years of age or older have smoking status recorded as structured data</td>
</tr>
<tr>
<td>For individual professionals, provide patients with clinical summaries for each office visit; for hospitals, provide an electronic copy of hospital discharge instructions on request</td>
<td>Clinical summaries provided to patients for more than 50% of all office visits within 3 business days; more than 50% of all patients who are discharged from the inpatient department or emergency department of an eligible hospital or critical access hospital and who request an electronic copy of their discharge instructions are provided with it</td>
</tr>
<tr>
<td>On request, provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies, and for hospitals, discharge summary and procedures)</td>
<td>More than 50% of requesting patients receive electronic copy within 3 business days</td>
</tr>
<tr>
<td>Generate and transmit permissible prescriptions electronically (does not apply to hospitals)</td>
<td>More than 40% are transmitted electronically using certified EHR technology</td>
</tr>
<tr>
<td>Computer provider order entry (CPOE) for medication orders</td>
<td>More than 30% of patients with at least one medication in their medication list have at least one medication ordered through CPOE</td>
</tr>
<tr>
<td>Implement drug–drug and drug–allergy interaction checks</td>
<td>Functionality is enabled for these checks for the entire reporting period</td>
</tr>
<tr>
<td>Implement capability to electronically exchange key clinical information among providers and patient-authorized entities</td>
<td>Perform at least one test of EHR’s capacity to electronically exchange information</td>
</tr>
<tr>
<td>Implement one clinical decision support rule and ability to track compliance with the rule</td>
<td>One clinical decision support rule implemented</td>
</tr>
<tr>
<td>Implement systems to protect privacy and security of patient data in the EHR</td>
<td>Conduct or review a security risk analysis, implement security updates as necessary, and correct identified security deficiencies</td>
</tr>
<tr>
<td>Report clinical quality measures to CMS or states</td>
<td>For 2011, provide aggregate numerator and denominator through attestation; for 2012, electronically submit measures</td>
</tr>
</tbody>
</table>
# Stage 1 MU – menu objectives (Blumenthal, 2010)

<table>
<thead>
<tr>
<th>Implement drug formulary checks</th>
<th>Drug formulary check system is implemented and has access to at least one internal or external drug formulary for the entire reporting period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorporate clinical laboratory test results into EHRs as structured data</td>
<td>More than 40% of clinical laboratory test results whose results are in positive/negative or numerical format are incorporated into EHR as structured data</td>
</tr>
<tr>
<td>Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach</td>
<td>Generate at least one listing of patients with a specific condition</td>
</tr>
<tr>
<td>Use EHR technology to identify patient-specific education resources and provide those to the patient as appropriate</td>
<td>More than 10% of patients are provided patient-specific education resources</td>
</tr>
<tr>
<td>Perform medication reconciliation between care settings</td>
<td>Medication reconciliation is performed for more than 50% of transitions of care</td>
</tr>
<tr>
<td>Provide summary of care record for patients referred or transitioned to another provider or setting</td>
<td>Summary of care record is provided for more than 50% of patient transition or referrals.</td>
</tr>
<tr>
<td>Submit electronic immunization data to immunization registries or immunization information systems</td>
<td>Perform at least one test of data submission and follow-up submission (where registries can accept electronic submissions)</td>
</tr>
<tr>
<td>Submit electronic syndromic surveillance data to public health agencies</td>
<td>Perform at least one test of data submission and follow-up submission (where public health agencies can accept electronic data)</td>
</tr>
<tr>
<td>Additional choices for hospitals and critical access hospitals</td>
<td>More than 50% of patients 65 years of age or older have an indication of an advance directive status recorded</td>
</tr>
<tr>
<td>Record advance directives for patients 65 years of age or older</td>
<td>Perform at least one test of data submission and follow-up submission (where public health agencies can accept electronic data)</td>
</tr>
<tr>
<td>Submit of electronic data on reportable laboratory results to public health agencies</td>
<td>More than 20% or patients 65 years of age or older or 5 years of age or younger are sent appropriate reminders</td>
</tr>
<tr>
<td>Additional choices for eligible professionals</td>
<td>More than 10% of patients are provided electronic access to information within 4 days of its being updated in the EHR</td>
</tr>
<tr>
<td>Send reminders to patients (per patient preference) for preventive and follow-up care</td>
<td>Perform at least one test of data submission and follow-up submission (where public health agencies can accept electronic data)</td>
</tr>
<tr>
<td>Provide patients with timely electronic access to their health information (including laboratory results, problem list, medication lists, medication allergies)</td>
<td></td>
</tr>
</tbody>
</table>
## Stage 2 EP Core Objectives

<table>
<thead>
<tr>
<th>Core Objective</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. CPOE</td>
<td>Use CPOE for more than 60% of medication, 30% of laboratory, and 30% of radiology</td>
</tr>
<tr>
<td>2. E-Rx</td>
<td>E-Rx for more than 50%</td>
</tr>
<tr>
<td>3. Demographics</td>
<td>Record demographics for more than 80%</td>
</tr>
<tr>
<td>4. Vital Signs</td>
<td>Record vital signs for more than 80%</td>
</tr>
<tr>
<td>5. Smoking Status</td>
<td>Record smoking status for more than 80%</td>
</tr>
<tr>
<td>6. Interventions</td>
<td>Implement 5 clinical decision support interventions + drug/drug and drug/allergy</td>
</tr>
<tr>
<td>7. Labs</td>
<td>Incorporate lab results for more than 55%</td>
</tr>
<tr>
<td>8. Patient List</td>
<td>Generate patient list by specific condition</td>
</tr>
<tr>
<td>9. Preventive Reminders</td>
<td>Use EHR to identify and provide reminders for preventive/follow-up care for more than 10% of patients with two or more office visits in the last 2 years</td>
</tr>
</tbody>
</table>
## Stage 2 EP Core Objectives

<table>
<thead>
<tr>
<th>Core Objective</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Patient Access</td>
<td>Provide online access to health information for more than 50% with more than 5% actually accessing</td>
</tr>
<tr>
<td>11. Visit Summaries</td>
<td>Provide office visit summaries for more than 50% of office visits</td>
</tr>
<tr>
<td>12. Education Resources</td>
<td>Use EHR to identify and provide education resources more than 10%</td>
</tr>
<tr>
<td>13. Secure Messages</td>
<td>More than 5% of patients send secure messages to their EP</td>
</tr>
<tr>
<td>14. Rx Reconciliation</td>
<td>Medication reconciliation at more than 50% of transitions of care</td>
</tr>
<tr>
<td>15. Summary of Care</td>
<td>Provide summary of care document for more than 50% of transitions of care and referrals with 10% sent electronically and at least one sent to a recipient with a different EHR vendor or successfully testing with CMS test EHR</td>
</tr>
<tr>
<td>16. Immunizations</td>
<td>Successful ongoing transmission of immunization data</td>
</tr>
<tr>
<td>17. Security Analysis</td>
<td>Conduct or review security analysis and incorporate in risk management process</td>
</tr>
</tbody>
</table>
## Stage 2 EP Menu Objectives

<table>
<thead>
<tr>
<th>Menu Objective</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Imaging Results</td>
<td>More than 10% of imaging results are accessible through Certified EHR Technology</td>
</tr>
<tr>
<td>2. Family History</td>
<td>Record family health history for more than 20%</td>
</tr>
<tr>
<td>3. Syndromic Surveillance</td>
<td>Successful ongoing transmission of syndromic surveillance data</td>
</tr>
<tr>
<td>4. Cancer</td>
<td>Successful ongoing transmission of cancer case information</td>
</tr>
<tr>
<td>5. Specialized Registry</td>
<td>Successful ongoing transmission of data to a specialized registry</td>
</tr>
<tr>
<td>6. Progress Notes</td>
<td>Enter an electronic progress note for more than 30% of unique patients</td>
</tr>
</tbody>
</table>
# Stage 2 Hospital Core Objectives

<table>
<thead>
<tr>
<th>Core Objective</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. CPOE</td>
<td>Use CPOE for <strong>more than 60%</strong> of medication, <strong>30%</strong> of laboratory, and <strong>30%</strong> of radiology</td>
</tr>
<tr>
<td>2. Demographics</td>
<td>Record demographics for <strong>more than 80%</strong></td>
</tr>
<tr>
<td>3. Vital Signs</td>
<td>Record vital signs for <strong>more than 80%</strong></td>
</tr>
<tr>
<td>4. Smoking Status</td>
<td>Record smoking status for <strong>more than 80%</strong></td>
</tr>
<tr>
<td>5. Interventions</td>
<td>Implement <strong>5</strong> clinical decision support interventions + drug/drug and drug/allergy</td>
</tr>
<tr>
<td>6. Labs</td>
<td>Incorporate lab results for <strong>more than 55%</strong></td>
</tr>
<tr>
<td>7. Patient List</td>
<td>Generate patient list by specific condition</td>
</tr>
<tr>
<td>8. eMAR</td>
<td>eMAR is implemented and used for more than <strong>10%</strong> of medication orders</td>
</tr>
</tbody>
</table>
## Stage 2 Hospital Core Objectives

<table>
<thead>
<tr>
<th>Core Objective</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Patient Access</td>
<td>Provide online access to health information for more than 50% with more than 5% actually accessing</td>
</tr>
<tr>
<td>10. Education Resources</td>
<td>Use EHR to identify and provide education resources more than 10%</td>
</tr>
<tr>
<td>11. Rx Reconciliation</td>
<td>Medication reconciliation at more than 50% of transitions of care</td>
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<tr>
<td>12. Summary of Care</td>
<td>Provide summary of care document for more than 50% of transitions of care and referrals with 10% sent electronically and at least one sent to a recipient with a different EHR vendor or successfully testing with CMS test EHR</td>
</tr>
<tr>
<td>13. Immunizations</td>
<td>Successful ongoing transmission of immunization data</td>
</tr>
<tr>
<td>14. Labs</td>
<td>Successful ongoing submission of reportable laboratory results</td>
</tr>
<tr>
<td>15. Syndromic Surveillance</td>
<td>Successful ongoing submission of electronic syndromic surveillance data</td>
</tr>
<tr>
<td>16. Security Analysis</td>
<td>Conduct or review security analysis and incorporate in risk management process</td>
</tr>
</tbody>
</table>
## Stage 2 Hospital Menu Objectives

<table>
<thead>
<tr>
<th>Menu Objective</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Progress Notes</td>
<td>Enter an electronic progress note for <strong>more than 30%</strong> of unique patients</td>
</tr>
<tr>
<td>2. E-Rx</td>
<td><strong>More than 10%</strong> electronic prescribing (eRx) of discharge medication orders</td>
</tr>
<tr>
<td>3. Imaging Results</td>
<td><strong>More than 10%</strong> of imaging results are accessible through Certified EHR Technology</td>
</tr>
<tr>
<td>4. Family History</td>
<td>Record family health history for <strong>more than 20%</strong></td>
</tr>
<tr>
<td>5. Advanced Directives</td>
<td>Record advanced directives for <strong>more than 50%</strong> of patients 65 years or older</td>
</tr>
<tr>
<td>6. Labs</td>
<td>Provide structured electronic lab results to EPs for <strong>more than 20%</strong></td>
</tr>
</tbody>
</table>
With rules for Stage 3 came also Modified Stage 2

• Objectives finalized in 2015 (O’Neill, 2015)
• Stages 1-2 combined into Modified Stage 2, required from 2015-2017
• EPs and EHs can attest to Stage 3 starting in 2017
• Uncertainty over future of program due to Medicare Access & CHIP Reauthorization Act (MACRA) of 2015 that will combine all CMS quality programs, including MU, into a single program
# Timeline for Stages 2-3

<table>
<thead>
<tr>
<th>First MU Year</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019+</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>Modified Stage 2</td>
<td>Modified Stage 2</td>
<td>Modified Stage 2 or Stage 3</td>
<td>Stage 3</td>
<td>Stage 3</td>
</tr>
<tr>
<td>2012</td>
<td>Modified Stage 2</td>
<td>Modified Stage 2</td>
<td>Modified Stage 2 or Stage 3</td>
<td>Stage 3</td>
<td>Stage 3</td>
</tr>
<tr>
<td>2013</td>
<td>Modified Stage 2</td>
<td>Modified Stage 2</td>
<td>Modified Stage 2 or Stage 3</td>
<td>Stage 3</td>
<td>Stage 3</td>
</tr>
<tr>
<td>2014</td>
<td>Modified Stage 2</td>
<td>Modified Stage 2</td>
<td>Modified Stage 2 or Stage 3</td>
<td>Stage 3</td>
<td>Stage 3</td>
</tr>
<tr>
<td>2015</td>
<td>Modified Stage 2</td>
<td>Modified Stage 2</td>
<td>Modified Stage 2 or Stage 3</td>
<td>Stage 3</td>
<td>Stage 3</td>
</tr>
<tr>
<td>2016</td>
<td>N/A</td>
<td>Modified Stage 2</td>
<td>Modified Stage 2 or Stage 3</td>
<td>Stage 3</td>
<td>Stage 3</td>
</tr>
<tr>
<td>2017</td>
<td>N/A</td>
<td>N/A</td>
<td>Modified Stage 2 or Stage 3</td>
<td>Stage 3</td>
<td>Stage 3</td>
</tr>
<tr>
<td>2018</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Stage 3</td>
<td>Stage 3</td>
</tr>
<tr>
<td>2019+</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Stage 3</td>
</tr>
</tbody>
</table>
# Modified Stage 2 (O’Neil, 2015)

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><strong>Protect Patient Health Information</strong></td>
<td>a. Conduct or review a security risk analysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Establish a risk management process and correct any problems or deficiencies identified</td>
</tr>
<tr>
<td>2.</td>
<td><strong>Use Clinical Decision Support to Improve Performance on High-Priority Health Conditions</strong></td>
<td>a. Implement 5 clinical decision support interventions related to 4 or more clinical quality measures at a relevant point in patient care</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Enable functionality for drug-drug and drug-allergy interaction checks</td>
</tr>
<tr>
<td>3.</td>
<td><strong>Use Computerized Provider Order Entry (CPOE) for Medication, Laboratory, and Radiology Orders</strong></td>
<td>a. More than 60 percent of medication orders</td>
</tr>
<tr>
<td></td>
<td>CPOE must be used for:</td>
<td>b. More than 30 percent of the laboratory orders</td>
</tr>
<tr>
<td></td>
<td></td>
<td>c. More than 30 percent of radiology orders</td>
</tr>
<tr>
<td>4.</td>
<td><strong>Generate and Transmit Permissible Prescriptions Electronically (eRx)</strong></td>
<td>a. For Providers: more than 50 percent of prescriptions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. For Hospitals/CAHs: More than 10 percent of hospital discharge medication orders</td>
</tr>
<tr>
<td>5.</td>
<td><strong>Provide Patients with a Summary of Care Record for Each Transition of Care or Referral and Electronically Transmit Such Summary</strong></td>
<td>a. The referring provider must provide and electronically transmit such summaries for more than 10 percent of transitions and referrals</td>
</tr>
</tbody>
</table>
### Modified Stage 2 (cont.)

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Details</th>
</tr>
</thead>
</table>
| 6.     | Use Clinically Relevant Information from Certified Electronic Health Record Technology (CEHRT) to Identify Patient-specific Education Resources and Provide those Resources to the Patient | a. For providers: patient specific education resources must be provided to more than 10 percent of all unique patients  
b. For hospitals/CAHs: patient specific education resources must be provided to more than 10 percent of all unique patients admitted to the hospital’s inpatient or emergency department |
| 7.     | Perform Medication Reconciliation for any Patient Received from Another Setting of Care          | a. Medication reconciliation must be performed for more than 50 percent of patients transitioned into the care of the provider or hospital’s inpatient or emergency department |
| 8.     | Provide Patients the Ability to View Online, Download, and Transmit their Health Information within 4 Business Days of the Information Being Available to the Provider | a. More than 50 percent of all unique patients must be provided timely access to view online, download, and transmit to a third party their health information  
i. In 2015 and 2016, at least one patient must use such functionality  
ii. In 2017, more than 5 percent of patients must use such functionality |
| 9.     | Use Secure Electronic Messaging to Communicate with Patients on Relevant Health Information       | a. In 2015, patients must have the capability to send and receive a secure electronic message with their provider  
b. In 2016, at least one patient must send or receive a message  
c. In 2017, more than 5 percent of patients must send or receive a message |
| 10.    | Provider or Hospital Actively Engages with a Public Health Agency to Submit Electronic Public Health Data from CEHRT Provider must submit the following data to public health agencies: | a. Immunization data  
b. Syndromic surveillance data  
c. Specialized registry reporting  
d. Electronic reportable laboratory results |
## Stage 3 (O’Neil, 2015)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Protect Electronic Patient Health Information (ePHI) Created or Maintained by the CEHRT through the Implementation of Appropriate Technical, Administrative, and Physical Safeguards</td>
</tr>
</tbody>
</table>
|   | a. A security risk analysis must be conducted, including addressing the security (including encryption) of data created or maintained by the CEHRT  
b. Security updates must be implemented as necessary  
c. Identified security deficiencies must be corrected as part of the provider’s risk management process |
| 2. | Electronic Prescribing: Generate and Transmit Permissible Prescriptions Electronically (eRx) |
|   | a. For Providers: more than 60 percent of prescriptions must be transmitted electronically using CEHRT  
b. For Hospitals/CAHs: More than 25 percent of hospital discharge medication orders must be transmitted electronically |
| 3. | Implement Clinical Decision Support (CDS) Interventions Focused on Improving Performance on High-Priority Health Conditions |
|   | a. 5 CDS interventions related to 4 or more CQMs must be used at a relevant point in care  
b. Drug-drug and drug-allergy interaction checks must be enabled and implemented |
| 4. | Use Computerized Provider Order Entry (CPOE) for Medication, Laboratory, and Diagnostic Imaging Orders  
CPOE must be used for: |
|   | a. More than 60 percent of medication orders  
b. More than 60 percent of laboratory orders  
c. More than 60 percent of diagnostic imaging orders |
| 5. | Provide Patient with Timely Electronic Access to Health Information and Patient Specific Education Materials |
|   | a. More than 80 percent of all unique patients seen or discharged:  
i. Must be provided timely access to view online, download, and transmit his or her health information; and  
ii. The provider must ensure the patient’s health information is available for the patient to access using any application of their choice that is configured to interact with the provider’s CEHRT  
b. Provider must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients |
Stage 3 (cont.)

| 6. Patient Engagement and Coordination of Care: Use CEHRT to Engage with Patients or their Authorized Representatives for Improved Coordination of Care | a. More than 10 percent of all unique patients (or their authorized representative) must actively engage with the EHR and either:
   i. View, download, or transmit to a third party their health information; or
   ii. Access their health information through the use of an application in the provider’s CEHRT; or
   iii. A combination of (i) and (ii)

| 7. Health Information Exchange (HIE): A Summary of Care Record is Provided when Transitioning or Referring a Patient to Another Setting of Care and Incorporates Summary of Care Information from Other Providers into their EHR Using the Functions of CEHRT | b. More than 25 percent of all unique patients must receive an electronic message using the CEHRT

| Patient generated health data or data from a nonclinical setting must be incorporated into the CEHRT for more than 5 percent of all unique patients |

| 8. Public Health and Clinical Data Registry Reporting: The Provider Actively Engages with a Public Health Agency or Clinical Data Registry to Submit Electronic Public Health Data in a Meaningful Way Using CEHRT | a. Immunization data

| Providers must report the following information to the appropriate setting: |

| b. Syndromic surveillance data |
| c. Electronic case reporting |
| d. Public health registry reports |
| e. Clinical data registry reports |
| f. Electronic reportable laboratory result reports |
Clinical Quality Measures (CQMs)

<table>
<thead>
<tr>
<th>Provider Type</th>
<th>Prior to 2014</th>
<th>2014 and Beyond Stage 2</th>
</tr>
</thead>
</table>
| EPs           | Complete 6 of 44  
3 core (or alternate)  
3 menu       | Complete 9 of 64  
At least one measure in each of three National Quality Strategy (NQS) domains |
| EHs and CAHs  | Report all 15 measures | Complete 16 of 29  
At least one measure in each of three NQS domains |

EP CQMs – prior to 2014

• Core
  – Hypertension: Blood Pressure Measurement
  – Preventive Care and Screening Measure Pair
    • Tobacco Use Assessment
    • Tobacco Cessation Intervention
  – Adult Weight Screening and Follow-up
• Alternatives – if denominator of any core measures = 0
  – Weight Assessment and Counseling for Children and Adolescents
  – Preventive Care and Screening: Influenza Immunization for Patients 50 Years Old or Older
  – Childhood Immunization Status
• Must report on 3 of 38 additional measures
EH CQMs – prior to 2014

- Anticoagulation overlap therapy
- Emergency department throughput – admission decision time to ED departure time for admitted patients
- Emergency department throughput – median time from ED arrival to ED departure for admitted patients
- Incidence of potentially preventable venous thromboembolism
- Intensive Care Unit venous thromboembolism prophylaxis
- Ischemic or hemorrhagic stroke – antithrombotic therapy by day 2
- Ischemic or hemorrhagic stroke – rehabilitation assessment
- Ischemic or hemorrhagic stroke – stroke education
- Ischemic stroke – anticoagulation for atrial fibrillation/flutter
- Ischemic stroke – discharge on anti-thrombotics
- Ischemic stroke – discharge on statins
- Ischemic stroke – thrombolytic therapy for patients arriving within 2 hours of symptom onset
- Platelet monitoring on unfractionated heparin
- Venous thromboembolism discharge instructions
- Venous thromboembolism prophylaxis within 24 hours of arrival
2014 CQMs


• Each CQM has electronic specification (eCQM) that uses HQMF (XML-based) and NLM value set

• Beginning in 2014, Medicare EPs and EHs must electronically report CQM data to CMS (Medicaid EPs and EHs to state)
NQS domains

- Patient and Family Engagement
- Patient Safety
- Care Coordination
- Population and Public Health
- Efficient Use of Healthcare Resources
- Clinical Processes/Effectiveness
HITECH money paid through end of 2015

<table>
<thead>
<tr>
<th>Category</th>
<th>Registered</th>
<th>Paid</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP Medicare</td>
<td>362,586</td>
<td>306,083</td>
<td>$8.3B</td>
</tr>
<tr>
<td>EP Medicaid</td>
<td>191,613</td>
<td>156,955</td>
<td>$4.3B</td>
</tr>
<tr>
<td>Hospitals</td>
<td>4,859</td>
<td>4,880</td>
<td>$18.9B</td>
</tr>
<tr>
<td>EP Medicare Advantage</td>
<td>14,845</td>
<td>14,845</td>
<td>$451M</td>
</tr>
<tr>
<td>Total</td>
<td>559,058</td>
<td>482,763</td>
<td>$31.9B</td>
</tr>
</tbody>
</table>

http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html
EHR adoption resulting from MU

Office-based physicians
(DesRoches, 2015)

Emergency departments
(Jamoom, 2015)

Outpatient departments
(Jamoom, 2015)

Non-federal hospitals
(Henry, 2016)
Additional suggested readings

• Key

• Supplemental


2A-1: Clinical Decision-Making

Bimal R. Desai, MD, MBI, FAAP
The Children’s Hospital of Philadelphia
### Core Content Covered in this Lecture

#### 1. Fundamentals
1.1. Clinical Informatics
   - 1.1.1. The discipline of informatics
   - 1.1.2. Key informatics concepts, models, and theories
   - 1.1.3. Clinical informatics literature
   - 1.1.4. International clinical informatics practices
   - 1.1.5. Ethics and professionalism
   - 1.1.6. Legal and regulatory issues

1.2. The Health System
   - 1.2.1. Determinants of individual and population health
   - 1.2.2. Primary domains, organizational structures, cultures, and processes
   - 1.2.3. The flow of data, information, and knowledge within the health system
   - 1.2.4. Policy & regulatory framework
   - 1.2.5. Health economics and financing
   - 1.2.6. Forces shaping health care delivery
   - 1.2.7. Institute of Medicine quality components

#### 2. Clinical Decision Making and Care Process Improvement
2.1. Clinical Decision Support
   - 2.1.1. The nature and cognitive aspects of human decision making
   - 2.1.2. Decision science
   - 2.1.3. Application of clinical decision support
   - 2.1.4. Transformation of knowledge into clinical decision support tools
   - 2.1.5. Legal, ethical, and regulatory issues
   - 2.1.6. Quality and safety issues
   - 2.1.7. Supporting decisions for populations of patients

2.2. Evidence-based Patient Care
   - 2.2.1. Evidence sources
   - 2.2.2. Evidence grading
   - 2.2.3. Clinical guidelines
   - 2.2.4. Implementation of guidelines as clinical algorithms
   - 2.2.5. Information retrieval and analysis

2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
   - 2.3.1. Methods of workflow analysis
   - 2.3.2. Principles of workflow re-engineering
   - 2.3.3. Quality improvement principles and practices

#### 3. Health Information Systems
3.1. Information Technology Systems
   - 3.1.1. Computer Systems
   - 3.1.2. Architecture
   - 3.1.3. Networks
   - 3.1.4. Security
   - 3.1.5. Data
   - 3.1.6. Technical approaches that enable sharing data

3.2. Human Factors Engineering
   - 3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
   - 3.2.2. HCI Evaluation, usability testing, study design and methods
   - 3.2.3. Interface design standards and design principles
   - 3.2.4. Usability engineering
   - 3.2.5. Health Information Systems and Applications
     - 3.3.1. Types of functions offered by systems
     - 3.3.2. Types of settings where systems are used
     - 3.3.3. Electronic health/medical records systems as the foundational tool

3.3.1. Telemedicine
3.4. Clinical Data Standards
   - 3.4.1. Standards development history and current process
   - 3.4.2. Data standards and data sharing
   - 3.4.3. Transaction standards
   - 3.4.4. Messaging standards
   - 3.4.5. Nomenclatures, vocabularies, and terminologies
   - 3.4.6. Ontologies and taxonomies
   - 3.4.7. Interoperability standards

3.5. Information System Lifecycle
   - 3.5.1. Institutional governance of clinical information systems
   - 3.5.2. Clinical information needs analysis and system selection
   - 3.5.3. Clinical information system implementation
   - 3.5.4. Clinical information system testing, before, during and after implementation
   - 3.5.5. Clinical information system maintenance
   - 3.5.6. Clinical information system evaluation

#### 4. Leading and Managing Change
4.1. Leadership Models, Processes, and Practices
   - 4.1.1. Dimensions of effective leadership
   - 4.1.2. Governance
   - 4.1.3. Negotiation
   - 4.1.4. Conflict management
   - 4.1.5. Collaboration
   - 4.1.6. Motivation
   - 4.1.7. Decision making

4.2. Effective Interdisciplinary Teams
   - 4.2.1. Human resources management
   - 4.2.2. Team productivity and effectiveness
   - 4.2.3. Group management processes
   - 4.2.4. Managing meetings
   - 4.2.5. Managing group deliberations

4.3. Effective Communications
   - 4.3.1. Effective presentations to groups
   - 4.3.2. Effective one-on-one communication
   - 4.3.3. Writing effectively for various audiences and goals
   - 4.3.4. Developing effective communications program to support system implementation

4.4. Project Management
   - 4.4.1. Basic principles
   - 4.4.2. Identifying resources
   - 4.4.3. Resource allocation
   - 4.4.4. Project management tools (non-software specific)
   - 4.4.5. Informatics project challenges

4.5. Strategic and Financial Planning for Clinical Information Systems
   - 4.5.1. Establishing mission and objectives
   - 4.5.2. Environmental scanning
   - 4.5.3. Strategy formulation
   - 4.5.4. Action planning and strategy implementation
   - 4.5.5. Capital and operating budgeting
   - 4.5.6. Principles of managerial accounting
   - 4.5.7. Evaluation of planning process

4.6. Change Management
   - 4.6.1. Assessment of organizational culture and behavior
   - 4.6.2. Change theories
   - 4.6.3. Change management strategies
   - 4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core Content Covered

2.1 Clinical Decision Support

2.1.1 The nature and cognitive aspects of human decision making

2.1.1.1 General
2.1.1.2 Medical

2.1.2 Decision science

2.1.2.1 Decision analysis
2.1.2.2 Probability theory
2.1.2.3 Utility and preference assessment
2.1.2.4 Cost effectiveness analysis
2.1.2.5 Test characteristics
Key Topics

- Everyday techniques of decision-making and potential biases.
- Relevance of “choice under uncertainty” to medical decisions.
- Using decision analysis to model complex decisions.
- Understanding how definitions of utility and patient preference impact the value of an outcome.
- Using cost effectiveness analysis to make decisions about allocation of constrained healthcare resources.
- Sensitivity, specificity, PPV, and NPV using the syntax “the probability of X given Y”.
- The applicability and limitations of sensitivity, specificity, PPV, and NPV to clinical decision-making, disease screening, and diagnostic testing.
2A-1 Clinical Decision-Making

- Healthcare context – uncertainty & risk
- Decision bias and heuristics
- Decision analysis: decision trees and Markov chains
- Incorporating patient preferences, utility, cost-effectiveness
- 2x2 contingency tables
- Sensitivity, specificity, NPV, PPV, ROC curves
- Relative risk, odds ratio, & Bayes theorem
Making Healthcare Decisions

• All medical decisions involve uncertainty, many involve risk
  – Diagnosis, testing, natural course of disease, effects of treatment are rarely “certain”
  – Choosing which variables to consider when making a decision is a challenge
• Some factors have characterizable / measurable risk → appeal of decision analysis
Expected Value vs. Expected Utility

• You have a 1:80 chance of winning $1000
  – If you gamble and win, you get $1000
  – If you gamble and lose, you get nothing.
  – If you don’t gamble, you are guaranteed $10

• Expected value of gambling:
  – $1000 \times \frac{1}{80} + 0 \times \frac{79}{80} = $12.50 (favors gambling)

• Expected utility is a function of value and also risk aversion, personal preferences / circumstances
  – If you desperately need $10, you might choose not to gamble
  – If you are a risk-taker or have lots of money, you might choose the gamble
Sources of Decision Bias

• Diagnostic inference is a problem of “revising opinion with imperfect information” (Hunink, p151)
• Blois’ Funnel: Breadth of diagnostic considerations are refined, restricted over course of interaction between patient and practitioner (Blois, 1984)
• Making decisions based on opinion is subject to predictable patterns of bias
Common Heuristics

• **Availability**
  – Overestimating probability of unusual events because of recent or memorable instances
  – “The last patient I saw with symptom X had disease Y, so we should test for Y”

• **Representativeness**
  – Overestimating rare diseases by matching patients to “typical picture” of that disease.
  – “representative heuristic is insensitive to pretest probabilities” (Hunink, p.151)
  – “He has features of the rare disease X, so we should test for it”
  – The medical adage “when you hear hoofbeats, think horses, not zebras” is a warning against errors due to this heuristic
Common Heuristics

• **Ascertainment bias**
  – Thinking is shaped by prior expectation
  – Examples include stereotyping or gender bias

• **Confirmation bias**
  – Tendency to look for confirming evidence rather than disconfirming evidence to refute it.
  – “Cherry picking” results from a large set of negative results

• **Diagnosis momentum**
  – Things that are initially diagnostic considerations, as they are passed from clinician to clinician, become “stickier” and more certain
Common Heuristics

• Anchoring
  – Failure to adjust probability of a disease or outcome based on new information
  – “I was told in sign-out that he had condition X, so I didn’t consider it might be condition Y, despite lab result Z”

• Premature Closure
  – Tendency to accept a diagnosis before it’s fully confirmed.
  – “When the diagnosis is made, the thinking stops”

• Value-induced bias
  – Overestimate probability of an outcome based on value associated with that outcome
  – Ex: “It would be horrible to miss a brain tumor in this patient with new onset headache, so we should get a head CT”
Defense Against Cognitive Bias

<table>
<thead>
<tr>
<th>Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop insight/awareness</td>
</tr>
<tr>
<td>Consider alternatives</td>
</tr>
<tr>
<td>Metacognition (&quot;thinking about how you think&quot;)</td>
</tr>
<tr>
<td>Decrease reliance on memory</td>
</tr>
<tr>
<td>Specific training</td>
</tr>
<tr>
<td>Simulation</td>
</tr>
<tr>
<td>Cognitive forcing strategies</td>
</tr>
<tr>
<td>Make task easier</td>
</tr>
<tr>
<td>Minimize time pressures</td>
</tr>
<tr>
<td>Establish accountability</td>
</tr>
<tr>
<td>Feedback about diagnostic errors</td>
</tr>
</tbody>
</table>

- Education about cognitive bias is an important defense
- Some of these can be aided through EHR design / CDS
  - Decrease reliance on memory (e.g. orderset for diagnosis of rheumatologic disorders)
  - Cognitive forcing strategies (e.g. CDS for clinical pathways)
  - Make task easier (e.g. display of complex information to highlight trends and outliers)

Adapted from Croskerry, 2003
Decision Analysis

- **Sum of probabilities** for options in a given scenario = 1
  - $P(\text{HIV}) + P(\text{not HIV}) = 1$

- **Conditional probabilities** ("probability of X given Y") notated with vertical pipe
  - $P(\text{HIV} \mid \text{IV drug use}) = \text{"probability of HIV given IV drug use"}$

- **Sequential events** can be described as a chance tree or graph

- This tree can be used to **model a decision** using the sum of the conditional probabilities
Decision Analysis – The Tree

- Decision node is a square
- Chance node is a circle
  - each branch assigned a probability
  - All branches at a node must add to $P = 1$
- Outcome node is a triangle
  - Assigned a “value” (cost, utility, QALY, relative value)
  - If life or death are the outcomes of interest: life = 1, death = 0
- “Rollback analysis” – multiplying the conditional probabilities and comparing the expected value of each branch of a decision node
Clinical Scenario

• Your patient has Acquired Information Overloadosis
  – The disease is fatal in 85% of untreated patients
  – The remaining 15% have spontaneous improvement and cure

• Treatment X confers fractional improvement in outcomes
  – When treated with X, survival improves from 15% to 20%
  – However, 10% of treated patients have a fatal reaction

Question: Is treatment better than non-treatment?
Choice: Give Med X

- **Yes**
  - Fatal reaction
    - \( P(Rxn) = 0.10 \)
    - \( 1-P(Rxn) = 0.90 \)
    - No reaction
  - Tx Success
    - \( P(Cure) = 0.20 \)
    - \( 1-P(Cure) = 0.80 \)
    - Tx Failure
    - Patient Dies
      - Value = 0
    - Patient Lives
      - Value = 1

- **No**
  - Spontaneous Cure
    - \( P(improvement) = 0.15 \)
    - \( 1-P(improvement) = 0.85 \)
    - Disease progresses
    - Patient Dies
      - Value = 0
    - Patient Lives
      - Value = 1
Example calculations

• **Expected Value of “Yes” branch = 0.18**
  - Fatal rxn = 0 x 0.1 = 0
  - No reaction = ((1 x 0.2) + (0 x 0.8)) x 0.9 = 0.18
  - Sum of both = 0 + 0.18 = **0.18**

• **Expected Value of “No” branch = 0.15**
  - Cure = 1 x 0.15 = 0.15
  - Progression = 0 x 0.85 = 0
  - Sum of probabilities of both = 0.15 + 0 = **0.15**

• Model very slightly favors giving X despite 10% chance of fatal reaction
Other Applications

• “What-if” or sensitivity analysis
  – Use a range of values to see how model changes
  – “What if the probability of treatment success due to med X is
    somewhere between 10% and 30%? At what threshold does the
    therapy become too risky?”

• Cost effectiveness analysis
  – The “value” of outcome nodes becomes units of cost instead of
    the values used in our example (Life = 1 / Death = 0)
Sensitivity Analysis

The diagram illustrates a sensitivity analysis for the estimated probability of improvement for a medical intervention, labeled 'Med X'. The x-axis represents the estimated probability of improvement ranging from 10% to 30%, while the y-axis represents the expected value ranging from 0 to 0.3.

- The red line indicates the expected value of the standard of care, which remains constant across the range of estimated probabilities.
- The green line shows the expected value of 'Med X', which increases as the estimated probability of improvement increases.

The model favors 'Med X' over the standard of care when the estimated probability of improvement is above a certain threshold. This threshold is indicated by the orange box labeled 'Model favors Med X'.

The diagram also highlights that the model favors 'Med X' when the estimated probability of improvement is greater than 18%. Therefore, for Med X to be favored, the estimated probability of improvement should be at least 18%.
Patient Preferences

- Often required to assign values to outcomes – two outcomes may not have same effectiveness or impact on quality of life (eg: surgical debulking vs. chemotherapy)
- The numerically favorable therapy is not the one the patient always prefers.
  - Therapy A: 50% chance of 10 year survival
    - Expected value = 5 years
  - Therapy B: 90% chance of 2 year survival
    - Expected value = 1.8 years
Utility

• Can be used in decision analysis to define the “value” of an outcome node. You adjust the value of the outcome based on the perceived utility of that outcome for that patient.

• Common approaches:
  – Standard gamble
    • Choose between $X$ time in state of illness vs. therapy with a known risk of cure or death
  – Time trade-off
    • Choose between $X$ time in state of illness vs. $Y$ time in state of perfect health
  – Visual analogue
    • Rate different health states on a scale where 0 = death, 100 = perfect health
Quality Adjusted Life Year

- Example using Time Trade-off
  - Ask the patient “Imagine living 10 years in your current state of health. Now imagine living for less than 10 years, but in a perfect state of health. How many years of perfect health do you believe are equal to 10 years of your current state of health?”
  - Suppose patient says 4 years of perfect health = 10 years of current illness. TTO = 0.4
  - Therefore, 3 years in current state = $3 \times 0.4 = 1.2$ QALY
  - Some believe that there are states of health that are worse than death, so QALY can have a negative value
Cost Effectiveness

- Operating with constrained resources
- UK – National Institute for Health and Clinical Excellence (NICE) uses QALY as part of cost-effectiveness analysis to choose pharmaceutical options
- Knowing cost and utility/value of an outcome allows you to calculate the Incremental Cost/Effectiveness Ratio (ICER)
  - Compare calculated ICER to the “willingness to pay” to determine if a therapy is cost effective
ICER / Cost Effectiveness Example

- ICER is a measure of the change in cost with change in a unit of effectiveness (usually QALY)
- ICER = (C1 - C2) / (E1 - E2)
  - Comparing hospital-based neonatal follow-up to web-based follow-up with screening tool
### ICER / Cost Effectiveness Example

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Cost</th>
<th>Incremental Cost</th>
<th>Effectiveness</th>
<th>Incremental Effectiveness</th>
<th>ICER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internet-based follow-up</td>
<td>86.1€</td>
<td>96.0€</td>
<td>0.944</td>
<td>-0.102</td>
<td>-941.2€</td>
</tr>
<tr>
<td>Hospital Visit</td>
<td>182.1€</td>
<td></td>
<td>0.842</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Hospital visits are 96€ more expensive and 0.102 units less effective than internet follow-up. In this study, one unit of effectiveness was defined as one avoided visit to the ED within the first month of life.
- Using the internet strategy, society would save 941€ for each avoided ED visit in the 1st month of life.
Markov Model

- Decision tree assumes a linear sequence – you only move in one direction on the tree.
- What if transitions between states are bidirectional or recursive?
- Markov Chain
  - Chain of events, each with a known, fixed probability of transition in a defined time period (aka “discrete time Markov Chain”)
  - “stochastic” (random)
  - 1st order chain is “memoryless” (next state doesn’t depend on prior state)

Two-state Markov chain, courtesy Wikipedia
Markov Model

• In this example, two discrete events E and A
• Shown as a directed graph, sum of transition probabilities = 1
• Imagine an animal that spends its life in 1 of 2 states: either Eating (E) or Asleep (A)
• Now imagine you have 100 of these creatures, all eating at one point in time \( t_0 \)
• How many would be eating (E) and asleep (A) after one period of time \( t_1 \)?
• It’s intuitive that at time “\( t_1 \)” there will be 30 eating, 70 asleep
• What about “\( t_2 \)” and beyond?
Enter the Matrix

• Represent the states transitions as a 2x2 Markov (aka stochastic) matrix

\[
\begin{bmatrix}
E(t_n) & A(t_{n+1}) \\
E(t_{n+1}) & A(t_n)
\end{bmatrix}
\begin{bmatrix}
0.3 \\
0.4
\end{bmatrix}
\begin{bmatrix}
0.7 \\
0.6
\end{bmatrix}
\]

• This matrix represents our 2-state graph
• Rows must add to 1 and values must be non-negative
• Rows represent state at time “n”
• Columns represent state at time “n+1”
• Values represent probability of transition from one state to another in the discrete time period
  – 1st row show probability that E→E (which is 0.3) and E→A (which is 0.7)
  – 2nd row shows probability that A→E (which is 0.4) and A→A (which is 0.6)
Enter the Matrix

- This 1x2 probability vector represents a starting state where 100% of animals are eating (E) and 0% are asleep (A)
  
  \[
  \begin{bmatrix}
  1 & 0
  \end{bmatrix}
  \] at time “t₀”

- Multiplying our stochastic matrix by the probability vector gives us a vector with the probability of the next state (t₁).

- Multiply each column value in stochastic matrix by the row value in the probability vector

\[
\begin{bmatrix}
0.3 & 0.7 \\
0.4 & 0.6
\end{bmatrix} \times \begin{bmatrix}
1 & 0
\end{bmatrix} =
\]

\[
\begin{bmatrix}
(1 \times 0.3) + (0 \times 0.4) & (1 \times 0.7) + (0 \times 0.6)
\end{bmatrix} = \begin{bmatrix}
0.3 & 0.7
\end{bmatrix}
\] at t₁

- So at t₁, 30% of animals are Eating and 70% are sleeping
Enter the Matrix

• Multiply probability vector at each time “t\textsubscript{n}” to get probability at “t\textsubscript{n+1}”

\[
\begin{bmatrix}
0.3 & 0.7 \\
0.4 & 0.6
\end{bmatrix}
\times
\begin{bmatrix}
0.3 & 0.7
\end{bmatrix}
= \\
\frac{(0.3 \times 0.3) + (0.7 \times 0.4)}{(0.3 \times 0.7) + (0.7 \times 0.6)}
= [0.37 \quad 0.63]
\text{ at } t\textsubscript{2}
\]

\[
\begin{bmatrix}
0.3 & 0.7 \\
0.4 & 0.6
\end{bmatrix}
\times
\begin{bmatrix}
0.37 & 0.63
\end{bmatrix}
= \\
\frac{(0.37 \times 0.3) + (0.63 \times 0.4)}{(0.37 \times 0.7) + (0.63 \times 0.6)}
= [0.36 \quad 0.64]
\text{ at } t\textsubscript{3}
\]

• So after 2 cycles (t\textsubscript{3}), P(E)=0.36, and P(A)=0.64

• What are the applications to healthcare and informatics?
Imagine a disease with 3 states, known probability of transition. Death is an “absorbing” state (you can’t move out of that state). Disability is a “tunnel” state (you only move in one direction through this state).
Modeling Disease Progression

We can simulate what happens to a cohort of patients. If you know the utility of each state, you can estimate the cumulative utility for things like QALY
Other Applications

Research Article

An Interface-driven Analysis of User Interactions with an Electronic Health Records System

KAI ZHENG, PHD, REMA PADMAN, PHD, MICHAEL P. JOHNSON, PHD, HERBERT S. DIAMOND, MD

Abstract
Objectives: This study sought to investigate user interactions with an electronic health records (EHR) system by uncovering hidden navigational patterns in the EHR usage data automatically recorded as clinicians navigated through the system’s software user interface (UI) to perform different clinical tasks.

Design: A homegrown EHR was adapted to allow real-time capture of comprehensive UI interaction events. These events, constituting time-stamped event sequences, were used to replay how the EHR was used in actual patient care settings. The study site is an ambulatory primary care clinic at an urban teaching hospital. Internal medicine residents were the primary EHR users.

Measurements: Computer-recorded event sequences reflecting the order in which different EHR features were sequentially accessed.

Methods: We apply sequential pattern analysis (SPA) and a first-order Markov chain model to uncover recurring UI navigational patterns.

Results: Of 17 main EHR features provided in the system, SPA identified 3 bundled features: “Assessment and Plan” and “Diagnosis,” “Order” and “Medication,” and “Order” and “Laboratory Test.” Clinicians often accessed these paired features in a bundle together in a continuous sequence. The Markov chain analysis revealed a global navigational pathway, suggesting an overall sequential order of EHR feature accesses. “History of Present Illness” followed by “Social History” and then “Assessment and Plan” was identified as an example of such global navigational pathways commonly traversed by the EHR users.

Conclusion: Users showed consistent UI navigational patterns, some of which were not anticipated by system designers or the clinic management. Awareness of such unanticipated patterns may help identify undesirable user behavior as well as reengineering opportunities for improving the system’s usability.

Other Applications

Figure 3. The feature transition probability matrix plotted as a network graph (the 17 features are horizontally positioned according to their sequential placement on the EHR’s UI. Size of a node is proportional to the feature’s overall frequency of use. Feature transitions with a probability lower than 0.15 are not shown. Bold arcs = transitions with a probability over 0.5; dashed arcs = nonadjacent feature transitions running counter to the default UI layout.
Class Exercise

• Here is a Markov model of patients treated for a specific cancer diagnosis.
• There are three possible outcomes after induction: remission (“Well”), relapse (“Cancer”), and death.
• The Markov model shows probability of transition between these states in a time period of one year.

(incidentally, the “U” refers to “utility” of each state, but we’re not using that in this example)

Question: In a cohort of patients, 90% are in remission (“Well”) and 10% have residual cancer (“Cancer”). After 2 years, what percent of patients are expected to have relapsed cancer?
### Class Exercise

#### Cycle State Probability

<table>
<thead>
<tr>
<th>Cycle</th>
<th>State</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>( t_0 )</td>
<td>Well</td>
<td>0.9</td>
</tr>
<tr>
<td></td>
<td>Cancer</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>Dead</td>
<td>0</td>
</tr>
<tr>
<td>( t_1 )</td>
<td>Well</td>
<td>((0.9*0.8) = 0.72)</td>
</tr>
<tr>
<td></td>
<td>Cancer</td>
<td>((0.9<em>0.2)+(0.1</em>0.8) = 0.26)</td>
</tr>
<tr>
<td></td>
<td>Dead</td>
<td>((0.1<em>0.2)+(0</em>1.0) = 0.02)</td>
</tr>
<tr>
<td>( t_2 )</td>
<td>Well</td>
<td>((0.72*0.8) = 0.576)</td>
</tr>
<tr>
<td></td>
<td>Cancer</td>
<td>((0.72<em>0.2)+(0.26</em>0.8) = 0.352)</td>
</tr>
<tr>
<td></td>
<td>Dead</td>
<td>((0.26<em>0.2)+(0.02</em>1.0) = 0.072)</td>
</tr>
</tbody>
</table>

After 2 years, 35% of the cohort is expected to have cancer.
Your well-earned moment of Zen...
Understanding Diagnostic Testing

• The author took a screening HIV test at his internist’s office. The test came back positive.

• His internist told him that there was a 99.9% probability that he had HIV, based on knowledge that in patients with no disease, the chance of a positive test was 1 in 1000.

• What common error did his internist make?

2x2 Contingency Tables

What questions do we care about related to diagnostic tests?

How to choose a diagnostic test
- (is the test any good?)
- What is likelihood of positive test if disease is present?
- What is likelihood of negative test if disease is absent?

How to interpret a diagnostic test
- (does the test have utility in clinical practice?)
- What is likelihood of disease if test is positive?
- What is likelihood of no disease if test is negative?
2x2 Contingency Tables

2x2 contingency table allows us to answer these questions

<table>
<thead>
<tr>
<th>Disease State</th>
<th>Disease +</th>
<th>Disease -</th>
<th>Everyone with disease</th>
<th>Everyone without disease</th>
<th>Everyone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test +</td>
<td>A True Positive</td>
<td>B False Positive</td>
<td>(A+B) Everyone with positive test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test -</td>
<td>C False Negative</td>
<td>D True Negative</td>
<td>(C+D) Everyone with negative test</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(A+C) Everyone with disease</td>
<td>(B+D) Everyone without disease</td>
<td>(A+B+C+D) Everyone</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
There’s a lot you can learn from this simple table…

- By convention, probability of an event $X$ is noted as “$P(X)$”

- Probability of $X$ given $Y$ is noted as “$P(X | Y)$” – this is known as a “conditional probability”.

\[
P(\text{Disease}) = \frac{\text{prevalence in sample population}}{\text{(Everyone with disease)}/ (\text{Everyone in sample population})} \]

\[
\frac{(A+C)}{(A+B+C+D)}
\]
There’s a lot you can learn from this simple table…

\[
P(\text{no disease}) = \frac{(B+D)}{(A+B+C+D)}
\]

\[
P(\text{test +}) = \frac{(A+B)}{(A+B+C+D)}
\]

\[
P(\text{test -}) = \frac{(C+D)}{(A+B+C+D)}
\]
There's a lot you can learn from this simple table...

What is the True Positive Rate?
• \( P(\text{test} + | \text{disease} +) = \)
• \( \text{TPR} = \frac{A}{A+C} \)

What is the False Negative Rate?
• \( P(\text{test} - | \text{disease} +) = \)
• \( \text{FNR} = \frac{C}{A+C} \) or \( 1-\text{TPR} \)

What is the True Negative Rate?
• \( P(\text{test} - | \text{disease} -) = \)
• \( \text{TNR} = \frac{D}{B+D} \)

What is the False Positive Rate?
• \( P(\text{test} + | \text{disease} -) = \)
• \( \text{FPR} = \frac{B}{B+D} \) or \( 1-\text{TNR} \)

<table>
<thead>
<tr>
<th></th>
<th>D +</th>
<th></th>
<th>D -</th>
</tr>
</thead>
<tbody>
<tr>
<td>T +</td>
<td>A</td>
<td>B</td>
<td>(A+B)</td>
</tr>
<tr>
<td></td>
<td>TP</td>
<td>FP</td>
<td></td>
</tr>
<tr>
<td>T -</td>
<td>C</td>
<td>D</td>
<td>(C+D)</td>
</tr>
<tr>
<td></td>
<td>FN</td>
<td>TN</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(A+C)</td>
<td>(B+D)</td>
<td>(A+B+C+D)</td>
</tr>
</tbody>
</table>
Sensitivity

**Sensitivity = True Positive Rate**

- \[ P(\text{test }+ \mid \text{disease }+) = \frac{A}{(A+C)} \]
- Conditional probability: “given the patient has disease, what is the likelihood the test will be positive?”

1-sensitivity = **False Negative Rate**

- Very sensitive tests have low FNR
- Sensitive tests are good for **ruling out disease** (you can trust a negative result)
- Sensitive tests are good **screening tests**

**SeNsitivity = rule OUT**

“SNOOUT”
Specificity

**Specificity = True Negative Rate**

- \( P(\text{test - | disease -} = D / (B+D) \)
- Conditional probability: “given the patient has no disease, what is the likelihood the test will be negative?”

**1-specificity = False Positive Rate**

- Very specific tests have low FNR
- Specific tests are good for ruling in disease (you can trust a positive result)
- Sensitive tests are good confirmatory tests

**Specificity = rule IN**

“SPIN”
Sensitivity & Specificity

- Both are conditional probabilities
- Both assume you know the disease state, not the test result.
- As such, they are measures of the test performance, not measures of test utility.
- Sensitivity and specificity are independent of rate of disease in the population.
- There is a tradeoff between sensitivity and specificity: you can increase sensitivity at the expense of specificity and vice versa.
What if We Know the Test Result?

• If you know the **test result** and are trying to determine disease state, Sensitivity and Specificity are not the correct measures.

• Instead, you need a different set of conditional probabilities:
  • What is likelihood of disease if test is positive?
  • What is likelihood of no disease if test is negative?
  • Fortunately, these are easy to derive, and they have their own names!

\[
\begin{array}{ccc}
 D^+ & D^- \\
 T^+ & A & B & (A+B) \\
 T^- & C & D & (C+D) \\
 & (A+C) & (B+D) & (A+B+C+D) \\
\end{array}
\]
Positive Predictive Value

- $P(\text{disease + | test +}) = \frac{A}{(A+B)}$
- “given a positive test, what is the likelihood of disease”

Note that PPV depends on likelihood of disease in population
Negative Predictive Value

\[ P(\text{disease - | test -}) = \frac{D}{C+D} \]

“given a negative test, what is the likelihood of no disease”

Note that NPV depends on likelihood of disease in population
Summary

Measures of Test Performance

**Sensitivity = TPR = Recall**
- Likelihood of positive test given disease
- Good for screening for disease
- Low false negative rate

**Specificity = TNR**
- Likelihood of negative test given no disease
- Good for confirming disease
- Low false positive rate

Measures of Clinical Utility of a Test

**Positive Predictive Value = Precision**
- Likelihood of disease given positive test

**Negative Predictive Value**
- Likelihood of no disease given negative test
Class Exercise:
Match the clinical scenario to the relevant statistic

- Testing for tuberculosis in patient with positive PPD: PPV
- Screening for ebola among travelers returning from W. Africa: Sensitivity
- Decision to omit urine culture in a febrile infant with negative urinalysis: Specificity
- Interpretation of positive rheumatoid factor in patient with no signs/symptoms of autoimmunity: NPV
Easy Mnemonic

1. **Sensitivity** = “Given presence of disease, what is the probability of a positive test”
2. **Specificity** = “Given absence of disease, what is the probability of a negative test”
3. **PPV** = “Given a positive test, what is the probability of disease”
4. **NPV** = “Given a negative test, what is the probability of no disease”

**IMPORTANT:** In Information Retrieval

“Recall” = Sensitivity
“Precision” = PPV
1. **Sensitivity** = \( P(+ \text{ test} | + \text{ disease}) \)
2. **Specificity** = \( P(- \text{ test} | - \text{ disease}) \)
3. **PPV** = \( P(+ \text{ disease} | + \text{ test}) \)
4. **NPV** = \( P(- \text{ disease} | - \text{ test}) \)

**IMPORTANT: In Information Retrieval**

“Recall” = Sensitivity

“Precision” = PPV
Class Exercise

- 1998 study looking at performance of various UTI screening strategies in infants
- A “positive dipstick” (defined as > trace Leukocyte Esterase OR + nitrites) had the following test characteristics:

<table>
<thead>
<tr>
<th>Test Characteristics</th>
<th>Total #</th>
<th>Positive Cx</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;LE or +Nit</td>
<td>3394</td>
<td>95</td>
<td>79</td>
<td>97</td>
<td>?</td>
</tr>
</tbody>
</table>

- In this population, what was the **baseline prevalence**?
- In this population, what was the **rate of UTI in those with a positive dipstick**?

Class Exercise

Class Exercise

What was the baseline prevalence?

- $\frac{95}{3394} = 2.7\%$

What was the rate of UTI among those with a positive dipstick?

- $\frac{75}{174} = 43\%$

So, in this population, a positive dipstick increases the probability of UTI from a pre-test (prior) probability of 2.7% to a post-test (posterior) probability of 43%
Back to Leonard...

- His internist told him that there was a 99.9% probability that he had HIV, based on knowledge that in patients with no disease, the chance of a positive test was only 1 in 1000 (or rather, a chance of negative test was 999 in 1000).

- Probability of [TEST] given [DISEASE] = sensitivity/specificity

- Probability of [DISEASE] given [TEST] = PPV/NPV

- His internist confused **specificity** with **positive predictive value**

- In other words, 1 in 1000 chance of false positive test is **very different** from a 999 in 1000 chance of disease given a positive test.
Impact of Prevalence on Test Interpretation

- Case of commercial HIV rapid screening test
- Published **sensitivity** (TPR) = 99.9%
- Published **specificity** (TNR) = 99.8%
- **False positive rate** is $1 - 0.998 = 2$ tests out of 1000

So, how does disease prevalence influence PPV and NPV?
Impact of Prevalence on Test Interpretation

- PPV of HIV Tests in Populations with Differing HIV Prevalence

  - If HIV Prevalence is 10%
    - PPV = 98%
  - If HIV Prevalence is 0.1%
    - PPV only 33%!

<table>
<thead>
<tr>
<th>HIV Prevalence</th>
<th>True Positive (Number)</th>
<th>False Positive (Number)</th>
<th>Positive Predictive Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>100</td>
<td>2</td>
<td>98%</td>
</tr>
<tr>
<td>5%</td>
<td>50</td>
<td>2</td>
<td>96%</td>
</tr>
<tr>
<td>2%</td>
<td>20</td>
<td>2</td>
<td>91%</td>
</tr>
<tr>
<td>1%</td>
<td>10</td>
<td>2</td>
<td>83%</td>
</tr>
<tr>
<td>0.5%</td>
<td>5</td>
<td>2</td>
<td>71%</td>
</tr>
<tr>
<td>0.2%</td>
<td>2</td>
<td>2</td>
<td>50%</td>
</tr>
<tr>
<td>0.1%</td>
<td>1</td>
<td>2</td>
<td>33%</td>
</tr>
</tbody>
</table>

Class Exercise

• You build an email filter to identify marketing spam, looking for key phrases like “opt-out” and “unsubscribe”

• After a day, you find the following:
  – 34 emails were trapped by the spam filter, of which 5 were not spam
  – 2 spam emails were not caught by the filter and made it to your inbox

• Two questions:
  – Assuming an email is spam, what is the likelihood of being trapped by your filter?
  – Assuming it is trapped by your filter, what is the likelihood of being spam?
Class Exercise

In our example, spam is the disease, and the email filter is a diagnostic test

- If spam, likelihood of being trapped = $P(+ \text{ test} \mid + \text{ disease}) = \text{sensitivity}$
- If trapped, likelihood of being spam = $P(+ \text{ disease} \mid + \text{ test}) = \text{precision/PPV}$

Next, draw your 2x2 table

<table>
<thead>
<tr>
<th>Spam Filter</th>
<th>Spam</th>
<th>Not Spam</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trapped</td>
<td>29</td>
<td>5</td>
<td>34</td>
</tr>
<tr>
<td>Not Trapped</td>
<td>2</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td></td>
<td>31</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>
If it is spam, what is the likelihood of being trapped?

- \( P(\text{test }+ \mid \text{disease }+) = TPR = \text{Sensitivity} = \text{Recall} \)
- **Recall = 29/31 = 94%**
- False negatives: 6 of every 100 spam emails are missed by Iron Dome

If it is trapped, what is the likelihood of being spam?

- \( P(\text{disease }+ \mid \text{test }+) = \text{PPV} = \text{Precision} \)
- **Precision = 29/34 = 85%**
- False positives: 15 of every 100 trapped emails are not spam
Consider a Lab Test

- Test performed on patients with and without the clinical condition of interest (assuming you have a gold standard)
- Will see a range of values about a mean, will likely see some overlap between those with and without the condition
- As test criterion is moved higher and lower, TPR and FPR will change
Receiver Operating Characteristic

• Visual representation of tradeoff between sensitivity and specificity – goal is to assist in detecting signal from noise

• **Graph of sensitivity vs. 1-specificity (TPR vs. FPR)**

• The “shoulder” or inflection point can help to determine optimal threshold for a test with a range of possible results

• The area under the curve allows you to compare different tests to determine which is better at distinguishing disease from normal (optimize TPR, minimize FPR) – higher AUC is better
ROC Curve

• Plot changes in TPR and FPR with changes in the test criterion
• Identify optimal criterion for a given test – look for inflection point
  – **Green** triangle: low TPR, low FPR
  – **Red** square: balance of TPR & FPR
  – **Orange** circle: modestly higher TPR, but at expense of high FPR
ROC Curve

- Previous example showed different cutoff values for the same test.
- What if you want to compare different tests?
  - Look for the one with highest area under the curve (AUC), which represents the test with the best ability to discriminate between true and false positives (you can achieve high TPR and still have low FPR).
  - A “bad” test will be flat, a diagonal line with no clear inflection point
  - In this example, the green test is better than the orange test. The red test cannot effectively discriminate between true and false positives
Relative Risk

- Ratio of probability of an event in exposed group to probability of event in unexposed group
- \( RR = \frac{P(\text{disease} | \text{exposure})}{P(\text{disease} | \text{no exposure})} \)
- RR must be positive; RR of 1 means no association; RR < 1 means decreased risk
  - Ex: Relative risk of lung cancer if you are a current smoker (>25 cig/day) = 10
  - Ex: Relative risk of prostate cancer if you are Asian = 0.4

<table>
<thead>
<tr>
<th>Strength</th>
<th>Decreased Risk (-)</th>
<th>Increased Risk (+)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weak</td>
<td>RR 0.7 - &lt;0.9</td>
<td>RR 1.1 - &lt;1.5</td>
</tr>
<tr>
<td>Moderate</td>
<td>RR 0.4 - &lt;0.7</td>
<td>RR 1.5 - &lt;3.0</td>
</tr>
<tr>
<td>Strong</td>
<td>RR 0.2 - &lt;0.4</td>
<td>RR 3.0 - &lt;7.0</td>
</tr>
<tr>
<td>Very Strong</td>
<td>RR &lt;0.2</td>
<td>RR &gt; 7.0</td>
</tr>
</tbody>
</table>
Class Exercise

• Surveillance cultures in an ICU identify patients with MRSA colonization.

• What is the relative risk of Skin/Soft tissue infection (SSTI) among patients with MRSA compared to those who do not have MRSA?

<table>
<thead>
<tr>
<th></th>
<th>MRSA?</th>
<th>SSTI</th>
<th>Healthy</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>12</td>
<td>77</td>
<td></td>
<td>89</td>
</tr>
<tr>
<td>No</td>
<td>4</td>
<td>279</td>
<td></td>
<td>283</td>
</tr>
</tbody>
</table>

RR = \frac{12/89}{4/283} = \frac{0.135}{0.014} = 9.6

In this population, the relative risk of developing an SSTI if patient is colonized with MRSA is 9.6
Bayes Theorem

• $P(A \mid B) = (P(B \mid A) \times P(A)) / P(B)$

• Probability of disease given a positive test =
  - Probability of positive test given disease (sensitivity)
  - Multiplied by the probability of disease (prior probability)
  - Divided by the probability of a positive test = Probability of true positive + probability of false positive
Likelihood Ratio

• Odds of X = P(X) / 1-P(X)
• Consider a coin toss:
  – Odds of heads are 1:1. Probability of heads are 1/2
• Event with 1:3 odds has probability of 0.25
• Conveniently, odds are related to the likelihood ratio
• Likelihood ratio has the unique property that it is a value that reflects both the sensitivity and specificity of a test in a single number.
• Post-test odds = pre-test odds x Likelihood Ratio
• Positive likelihood ratio (LR+) = sensitivity / 1-specificity = TPR/FPR
• Negative likelihood ratio (LR-) = 1-sensitivity / specificity = FNR/TNR
Worked Example

<table>
<thead>
<tr>
<th>Test Result</th>
<th>Jedi</th>
<th>Not a Jedi</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midichlorian +</td>
<td>19</td>
<td>7</td>
</tr>
<tr>
<td>Midichlorian -</td>
<td>2</td>
<td>439</td>
</tr>
</tbody>
</table>

- Sensitivity = $\frac{19}{(19+2)} = \sim 0.90$
- Specificity = $\frac{439}{(7 + 439)} = \sim 0.98$
- LR+ = sensitivity / 1-specificity = \sim 58
- Pre-test odds of being a Jedi are $\frac{(19+2)}{(7+439)} = 0.047$
- If test is positive, post-test odds are $0.047 \times 58 = 2.7$
- Since odds = $p(x)/1-p(x)$, you can determine that $p(x) = 73\%$
- *Note: you could also determine this by calculating PPV = $\frac{19}{(19+7)} = 73\%$
Fagan Nomogram

- Probability can be derived from odds, but takes an extra step
- For most people, odds are less intuitive
- Fagan nomogram allows you to determine post-test probability given the pre-test probability (prevalence) and LR+
  
- In our Jedi example, prevalence is \( \frac{21}{467} \approx 4.5\% \)
- If test is positive, probability of being a Jedi is over 70%
- If the test is negative, probability of being a Jedi is 0.5%

Source: Diagnostic Test Calculator, Alan Schwartz. Accessible at http://araw.mede.uic.edu/cgi-bin/testcalc.pl
Finding LR+ and LR-

• The Positive and Negative Likelihood Ratios (LR+ and LR-) are published and easily available for common signs, symptoms, and diagnostic tests

• Ex: **Rapid Test** for Strep Throat: **LR+ = 15.2**

• Ex: Any **ST-segment elevation** on ECG for diagnosing MI: **LR+ = 11.2**

• Ex: **Pain radiating to both arms** for diagnosing MI: **LR+ = 7.1**

Source: Centre for Evidence-Based Medicine, Toronto, “KTClearinghouse”, available at http://ktclearinghouse.ca/cebm/glossary/lr
Class Exercise

Clinical Scenario:

A 16 month female comes to your emergency department with high fever without an obvious source. You intend to order a urinalysis to determine if she may have a urinary tract infection.

• How would a positive test influence your decision?
• How would a negative test influence your decision?
Class Exercise

- Ex: Urinalysis for detection of UTI in children
- Published Positive Likelihood Ratio (LR+) = 5.6
- Published Negative Likelihood Ratio (LR-) = 0.03
  - Prevalence of UTI in febrile females 2 mo to 2 years presenting to an ED is 3.3% (i.e., prior probability in this population)
  - Can we use the Fagan Nomogram to help us determine probability of UTI when the test is positive vs. negative?
  - Do this using a printed Fagan nomogram or use the online calculator at http://araw.med.e.uic.edu/cgi-bin/testcalc.pl to answer this question

Source: Centre for Evidence-Based Medicine, Toronto, “KTClearinghouse”, available at http://ktclearinghouse.ca/cebm/glossary/lr
Class Exercise

• On left side of Fagan Nomogram, find your *prior probability* (aka pre-test probability). In our case, that’s 3.3%
• Draw a line across to the right that crosses the middle column at LR+ of 5.6
• Note that it intersects the right column at ~16% (blue line)
• Therefore, in this population, a positive test means there is a 16% probability the patient has a UTI
• Do the same for LR- (red line), post-test probability after a negative test is 0.1% - effectively ruling out disease

Source: Diagnostic Test Calculator, Alan Schwartz. Accessible at http://araw.med.uic.edu/cgi-bin/testcalc.pl
End of Lecture
Suggested Additional Reading


• Croskerry P. *The importance of cognitive errors in diagnosis and strategies to minimize them.* Acad Med. 2003; 78(8):775-780 [link]
Suggested Additional Resources

• **Online Course: PennState STAT 507 “Epidemiological Research Methods”, Lesson 10.3: Sensitivity, specificity, positive predictive value, negative predictive value**

• Online statistics lectures by Rahul Patwari, MD
  – Tradeoff between sensitivity and specificity
  – Predictive values
  – Screening tests
  – ROC Curves
2A-2: Applied Decision Support

Bimal R. Desai, MD, MBI, FAAP
The Children’s Hospital of Philadelphia
### Core Content Covered in this Lecture

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.2. Key informatics concepts, models, and theories</td>
<td>3.1.2. Architecture</td>
<td>4.1.2. Governance</td>
</tr>
<tr>
<td>1.1.3. Clinical informatics literature</td>
<td>3.1.3. Networks</td>
<td>4.1.3. Negotiation</td>
</tr>
<tr>
<td>1.1.5. Ethics and professionalism</td>
<td>3.1.5. Data</td>
<td>4.1.5. Collaboration</td>
</tr>
<tr>
<td>1.1.6. Legal and regulatory issues</td>
<td>3.1.6. Technical approaches that enable sharing data</td>
<td>4.1.6. Motivation</td>
</tr>
<tr>
<td>1.2. The Health System</td>
<td>3.2. Human Factors Engineering</td>
<td>4.1.7. Decision making</td>
</tr>
<tr>
<td>1.2.1. Determinants of individual and population health</td>
<td>3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)</td>
<td>4.2. Effective Interdisciplinary Teams</td>
</tr>
<tr>
<td>1.2.2. Primary domains, organizational structures, cultures, and processes</td>
<td>3.2.2. HCI Evaluation, usability testing, study design and methods</td>
<td>4.2.1. Human resources management</td>
</tr>
<tr>
<td>1.2.3. The flow of data, information, and knowledge within the health system</td>
<td>3.2.3. Interface design standards and design principles</td>
<td>4.2.2. Team productivity and effectiveness</td>
</tr>
<tr>
<td>1.2.4. Policy &amp; regulatory framework</td>
<td>3.2.4. Usability engineering</td>
<td>4.2.3. Group management processes</td>
</tr>
<tr>
<td>1.2.5. Health economics and financing</td>
<td>3.3. Health Information Systems and Applications</td>
<td>4.2.4. Managing meetings</td>
</tr>
<tr>
<td>1.2.6. Forces shaping health care delivery</td>
<td>3.3.1. Types of functions offered by systems</td>
<td>4.2.5. Managing group deliberations</td>
</tr>
<tr>
<td>1.2.7. Institute of Medicine quality components</td>
<td>3.3.2. Types of settings where systems are used</td>
<td>4.3. Effective Communications</td>
</tr>
<tr>
<td>2. Clinical Decision Making and Care Process Improvement</td>
<td>3.3.3. Electronic health/medical records systems as the foundational tool</td>
<td>4.3.1. Effective presentations to groups</td>
</tr>
<tr>
<td>2.1. Clinical Decision Support</td>
<td>3.3.4. Telemedicine</td>
<td>4.3.2. Effective one-on-one communication</td>
</tr>
<tr>
<td>2.1.1. The nature and cognitive aspects of human decision making</td>
<td>3.4. Clinical Data Standards</td>
<td>4.3.3. Writing effectively for various audiences and goals</td>
</tr>
<tr>
<td>2.1.2. Decision science</td>
<td>3.4.1. Standards development history and current process</td>
<td>4.3.4. Developing effective communications program to support system implementation</td>
</tr>
<tr>
<td><strong>2.1.3. Application of clinical decision support</strong></td>
<td>3.4.2. Data standards and data sharing</td>
<td>4.4. Project Management</td>
</tr>
<tr>
<td>2.1.4. Transformation of knowledge into clinical decision support tools</td>
<td>3.4.3. Transaction standards</td>
<td>4.4.1. Basic principles</td>
</tr>
<tr>
<td>2.1.5. Legal, ethical, and regulatory issues</td>
<td>3.4.4. Messaging standards</td>
<td>4.4.2. Identifying resources</td>
</tr>
<tr>
<td>2.1.6. Quality and safety issues</td>
<td>3.4.5. Nomenclatures, vocabularies, and terminologies</td>
<td>4.4.3. Resource allocation</td>
</tr>
<tr>
<td>2.1.7. Supporting decisions for populations of patients</td>
<td>3.4.6. Ontologies and taxonomies</td>
<td>4.4.4. Project management tools (non-software specific)</td>
</tr>
<tr>
<td>2.2. Evidence-based Patient Care</td>
<td>3.4.7. Interoperability standards</td>
<td>4.4.5. Informatics project challenges</td>
</tr>
<tr>
<td>2.2.1. Evidence sources</td>
<td>3.5. Information System Lifecycle</td>
<td>4.5. Strategic and Financial Planning for Clinical Information Systems</td>
</tr>
<tr>
<td>2.2.2. Evidence grading</td>
<td>3.5.1. Institutional governance of clinical information systems</td>
<td>4.5.1. Establishing mission and objectives</td>
</tr>
<tr>
<td>2.2.3. Clinical guidelines</td>
<td>3.5.2. Clinical information needs analysis and system selection</td>
<td>4.5.2. Environmental scanning</td>
</tr>
<tr>
<td>2.2.4. Implementation of guidelines as clinical algorithms</td>
<td>3.5.3. Clinical information system implementation</td>
<td>4.5.3. Strategy formulation</td>
</tr>
<tr>
<td>2.2.5. Information retrieval and analysis</td>
<td>3.5.4. Clinical information system testing, before, during and after implementation</td>
<td>4.5.4. Action planning and strategy implementation</td>
</tr>
<tr>
<td>2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement</td>
<td>3.5.5. Clinical information system maintenance</td>
<td>4.5.5. Capital and operating budgeting</td>
</tr>
<tr>
<td>2.3.1. Methods of workflow analysis</td>
<td>3.5.6. Clinical information system evaluation</td>
<td>4.5.6. Principles of managerial accounting</td>
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<td>2.3.2. Principles of workflow re-engineering</td>
<td></td>
<td>4.5.7. Evaluation of planning process</td>
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<td></td>
<td>4.6. Change Management</td>
</tr>
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<td></td>
<td></td>
<td>4.6.1. Assessment of organizational culture and behavior</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.6.2. Change theories</td>
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<tr>
<td></td>
<td></td>
<td>4.6.3. Change management strategies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.6.4. Strategies for promoting adoption and effective use of clinical information systems</td>
</tr>
</tbody>
</table>

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**AMIA**

INFORMATICS PROFESSIONALS. LEADING THE WAY.
Core Content Covered

2.1.3 Application of clinical decision support

2.1.3.1 Types of decision support (e.g., alerts, reminders, prompts)

2.1.3.2 Users of decision support (including clinicians and patients)

2.1.3.3 Implementing, evaluating, and maintaining CDS tools
Key Topics

- The difference between interruptive/modal and non-interruptive/modeless alerts
- CDS intervention classifications
  - by function (alerting, reminding, critiquing, etc)
  - by area of clinical care (prevention, diagnosis, treatment, follow-up, care planning).
  - by intended audience.
- The “five rights” and “10 commandments” of an effective CDS intervention.
- Review of current state of CDS effectiveness
- Common limitations of evaluations of CDS interventions and ways to overcome these limitations.
- Facilitating broader adoption of CDS tools through interoperability, clinical terminology, and guideline representation standards
- Common strategies for maintaining and updating decision support tools, and the risks of not having these strategies in place.
- Approaches for guideline representation and sharing of CDS content
2A-2 Applied Decision Support

- Key Components
- Opportunities for Decision Support
- Modes of delivery
- Interruptiveness
- Implementations & Example Categories
- Advanced Applications
- Designing CDS: The 5 Rights
- Evaluation
- Knowledge Representation & Sharing
Definition of Clinical Decision Support

- **Most restrictive:** an electronic system that provides structured guidance based on patient-specific inputs
  - Expert systems
  - Conditional alerts

- **Less restrictive:** any electronic tool that reduces the cognitive burden of patient care in an EHR
  - Order sets & corollary orders
  - Data visualization techniques, visual design standards

- **Least restrictive:** “Not all decision support is electronic decision support”
“Active knowledge systems which use two or more items of patient data to generate case-specific advice.” - Wyatt & Spiegenhalter, SCAMC 1991
# Functions of CDSS

<table>
<thead>
<tr>
<th>Function</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alerting</td>
<td>Highlighting out-of-range laboratory values</td>
</tr>
<tr>
<td>Reminding</td>
<td>Reminding the clinician to schedule a mammogram</td>
</tr>
<tr>
<td>Critiquing</td>
<td>Rejecting an electronic order</td>
</tr>
<tr>
<td>Interpreting</td>
<td>Interpreting the echocardiogram</td>
</tr>
<tr>
<td>Predicting</td>
<td>Predicting risk of mortality from a severity-of-illness score</td>
</tr>
<tr>
<td>Diagnosing</td>
<td>Listing a differential diagnosis for a patient with chest pain</td>
</tr>
<tr>
<td>Assisting</td>
<td>Tailoring the antibiotic choices for liver transplantation and renal failure</td>
</tr>
<tr>
<td>Suggesting</td>
<td>Generating suggestions for adjusting the mechanical ventilator</td>
</tr>
</tbody>
</table>

Randolph AG *et al.*. User’s guide to the medical literature XVIII. JAMA 1999. [Abstract]
Targets of CDS Determined by Clinical and Workflow Needs

• Desired Outcome / Clinical Target
  – Improve efficiency
  – Earlier detection / screening
  – Diagnosis / Treatment protocol
  – Prevent adverse outcome
  – Follow-up management
  – Cost reductions / convenience
Other Design Considerations

• Target Audience
  – which member of healthcare team?
  – Is intervention targeted to patients / families?

• Level of Control
  – Pre-emptive
  – Suppressible
  – Hard-stop
  – Interruptive
Modes of Delivery

- Templated data-collection (if you define CDS broadly)
- Suggestion (is this the correct diagnosis?)
- Summarization (eg: results review)
- Reminder
- Information
- Correct errors
- Recommend change in plan
Interruptiveness

- **On demand**
  - Link to formulary from within order

- **In-Line or Background** (modeless)
  - “Unread lab result” indicator on toolbar
  - Optional reminder for health maintenance

- **Popup or Interruptive** (modal)
  - Alerts
  - Reminders requiring acknowledgement
Specific Categories of CDS (Leapfrog)

- Therapeutic duplication
- Single & cumulative dose limits
- Allergies & cross allergies
- Contraindicated route of administration
- Drug-drug and drug-food interactions
- Corollary orders
- Cost of care
- Nuisance

- Contraindications / dose limits based on patient diagnosis
- Contraindications / dose limits based on patient age or weight
- Contraindications / dose limits based on laboratory studies
- Contraindications / dose limits based on radiology studies (e.g., recent or ordered IV contrast)
Ten Commandments For Effective CDS

(Bates, JAMIA 2003)

1. **Speed is everything** – expect sub-second latency

2. **Anticipate needs and deliver in real time** – e.g. showing relevant labs with med orders

3. **Fit into the user’s workflow** – external tools not as good as those at POC

4. **Little things can make a big difference** – “usability matters – a lot”, “make it easy to do the right thing”

5. **Physicians resist stopping** – don’t tell docs to not do something without offering an alternative
Ten Commandments For Effective CDS  
(Bates, JAMIA 2003)

6. Changing direction is easier than stopping
7. Simple interventions work best – try to fit guidelines onto a single screen
8. Ask for additional information only when you really need it – “likelihood of success is inversely proportional to the number of extra data elements needed”
9. Monitor impact, get feedback, and respond
10. Manage and maintain your knowledge-based systems
The 5 Rights of CDS
(Osheroff et al)

- **Right Information** – quality of knowledge base
- **Right Person** – target of CDS
- **Right Format** – implementation of CDS (speed, ease of use, comprehensibility)
- **Right Channel** – mode of CDS
- **Right Time** – workflow integration
Evaluation of CDS

• Limitations of Current Literature
  – Literature historically not-representative
    • Typically home-grown systems
    • Typically inpatient systems
  – Historically, there have been methodological limitations
    • Few RCTs (this has improved in past decade)
    • Process rather than outcome measures
    • Some literature focuses on performance of diagnostic / expert systems
    • Insufficient qualitative research
    • Insufficient HCI research
Evaluation of CDS

• Limitations of Current Implementations
  – For most organizations, implementing and maintaining an EHR is hard enough
  – Difficult to implement and evaluate CDS with constrained resources
Implementation Science Systematic Reviews

http://www.implementationscience.com/series/CCDSS

• Series of reviews of CDSS effectiveness in six areas:
  – Chronic disease management
  – Acute care management
  – Therapeutic drug monitoring and dosing
  – Drug prescribing and management
  – Diagnostic test ordering behavior
  – Primary preventative care

• Published as Open Access articles in August, 2011
Implementation Science: Chronic Disease Management

• 55 trials considered
  – 87% (n=48) measured impact on care process
    • 52% of these (n=25) showed significant improvement
  – 65% (n=35) measured impact on surrogate outcomes
    • 31% (n=11) showed benefits

“A small majority (just over half) of CCDSSs improved care processes in chronic disease management and some improved patient health. Policy makers, healthcare administrators, and practitioners should be aware that the evidence of CCDSS effectiveness is limited, especially with respect to the small number and size of studies measuring patient outcomes.”
Implementation Science: Acute Care Management

- 35 trials considered
  - 63% (n=22) showed improved process of care
    - 64% of med dosing assistants (9 of 14)
    - 82% management assistants with alerts/reminders (9 of 11)
    - 38% (3 of 8) guidelines / algorithms
    - 67% (2 of 3) diagnostic assistants
  - 20 studies looked at patient outcomes, but only 3 showed improvement

“The majority of CCDSSs demonstrated improvements in process of care, but patient outcomes were less likely to be evaluated and far less likely to show positive results.”
Implementation Science: Drug Monitoring & Dosing

• 33 randomized trials
  – Vitamin K antagonists (14)
  – Insulin (6)
  – Theophylline / aminophylline (4)
  – Aminoglycosides (3)
  – Digoxin (2)
  – Lidocaine (1)
• 76% were standalone systems, 85% were to be used by physicians
• 60% showed improved process, 21% showed improved outcome
• Insulin (in all studies) and Vitamin K (in meta-analysis) showed significant improvement

“Studies were small and generally of modest quality, and effects on patient outcomes were uncertain, with no convincing benefit in the largest studies. At present, no firm recommendation for specific systems can be given.”
Implementation Science: Drug Prescribing & Management

• 65 studies considered
  – Process of care improved in 37 of 59 (64%)
  – Outcomes improved in 6 of 29 (21%)

“CCDSSs inconsistently improved process of care measures and seldomly improved patient outcomes. Lack of clear patient benefit and lack of data on harms and costs preclude a recommendation to adopt CCDSSs for drug therapy management.”
Implementation Science: Diagnostic Test Ordering

• 35 studies identified – quality improved after 2000
  – 55% improved testing behavior (18 of 33)
  – 5 of 6 diagnostic testing
  – 5 of 8 treatment monitoring
  – 6 of 17 disease monitoring
  – 4 of 4 designed to reduce test ordering rates
  – Cost, user satisfaction, and workflow rarely measured or reported

“Some CCDSSs can modify practitioner test-ordering behavior…[S]tudies should describe in more detail potentially important factors such as system design, user interface, local context, implementation strategy, and evaluate impact on user satisfaction and workflow, costs, and unintended consequences.”
Implementation Science: Preventative Care

• 41 RCTs considered
  – Improved process of care in 63% (25 of 40)

“Evidence supports the effectiveness of CCDSSs for screening and treatment of dyslipidaemia in primary care with less consistent evidence for CCDSSs used in screening for cancer and mental health-related conditions, vaccinations, and other preventive care. CCDSS effects on patient outcomes, safety, costs of care, and provider satisfaction remain poorly supported.”
What Else Do We Know?

• Kawamoto et al, BMJ, 2005 – systematic review of CDS. Four predictors of improved practice:
  1. Provision of CDS as part of clinical workflow
  2. Provision of recommendations, not just assessments
  3. Provision of CDS at time/location of decision
  4. Computer based decision support
What Else Do We Know?

<table>
<thead>
<tr>
<th>Unintended Consequence</th>
<th>Frequency (%) n = 324</th>
</tr>
</thead>
<tbody>
<tr>
<td>More/new work for clinicians</td>
<td>19.8</td>
</tr>
<tr>
<td>Workflow issues</td>
<td>17.6</td>
</tr>
<tr>
<td>Never ending system demands</td>
<td>14.8</td>
</tr>
<tr>
<td>Paper persistence</td>
<td>10.8</td>
</tr>
<tr>
<td>Changes in communication patterns and practices</td>
<td>10.1</td>
</tr>
<tr>
<td>Emotions</td>
<td>7.7</td>
</tr>
<tr>
<td>New kinds of errors</td>
<td>7.1</td>
</tr>
<tr>
<td>Changes in the power structure</td>
<td>6.8</td>
</tr>
<tr>
<td>Overdependence on technology</td>
<td>5.2</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
</tr>
</tbody>
</table>

Medication Alerts & CPOE

- Clear benefit in reducing prescribing errors
  - Kaushal *et al*, JAMA, 2001
- Less clear that CPOE can prevent adverse drug events
  - van Rosse *et al*, Pediatrics, 2009
Process vs. Outcome Measures

- Systematic Review by Garg et al, JAMA, 2005
- Systems of interest:
  - Diagnostic Systems
  - Reminder Systems
  - Disease Management Systems
  - Drug Dosing / Prescribing
- Identified 97 trials looking at practitioner performance, 64% showed benefit
- Patient outcomes were not demonstrated to be impacted
  - 52 trials looked at patient outcomes
  - Insufficiently powered to see effect
  - Only 7 showed improvement in outcomes, none showed improvement in mortality
  - Surrogate outcomes (glycosylated Hgb, BP) were not improved
Knowledge Representation & Sharing

- “Curly Braces” problem
- Guideline representation & consumability
- Commercial CDS repositories
- Standards & definitions
- Opportunities for distributed CDS systems
Arden Syntax

Data:

```plaintext
systolic_blood_pressure := read last {get systolic blood pressure};

/* the value in braces is specific to your runtime environment */

systolic_pressure_threshold := 140;
stdout_dest := destination {stdout};
```

;;
Guideline Modeling

• Axis 1
  – Syntactic – “A or B and C” (missing parentheses?)
  – Semantic – “I will meet you at the bank” (which bank?)
  – Pragmatic (conflicting recommendations)
  – Underspecification – “children” (include infants? Teens?)
  – Strength qualifiers – “recommended as probably effective”
  – Passive voice – “should be performed”

• Axis 3
  – Condition – “if x-ray is not suggestive of pneumonia”
  – Action – “perform further evaluation”

Computer Interpretable Guidelines

- The guidelines must first lend themselves to computation
- The representation format must allow for clinical expressivity
  - Temporal dependencies
  - Complex rules
  - Strength of evidence
  - Imperative / optional actions
- Standard vocabularies and semantics
- Interoperable
- Portable
Example Guideline Modeling Frameworks

- GLIF
- Protegé
- Arden Syntax – 1990, HL7 & ANSI endorsed
- GEM – ASTM standard for representation in XML
- SEBASTIEN

http://www.openclinical.org/gmmsummaries.html
Figure 1. History of CIG approaches, positioned on a time axis (adapted from Elkin et al [10])
Knowledge Maintenance

- Reliance on EHR patient data
- Guideline authorship, review, update cycle
- Review patterns of use – process measures, override rates, sentinel events, and other measures of CDS effectiveness
- Role for service-oriented architecture for “plug-and-play” CDS systems

OpenCDS (www.opencds.org)
OpenCDS Features

• Uses the May 2011 HL7 standard specification for a Decision Support Service
• Built using open source software tools
• Robust authoring environment for rules
• Integration with standard terminologies (ICD9, SNOMED, LOINC, RxNORM)
• Can be integrated with other types of CDS tools, such as the HL7 Infobuttons standard
SMART on FHIR

• **2009:** NEJM article “No small change for the health information economy” by Mandl & Kohane suggested that EHRs should be an extensible platform, like an iPhone™
  
  – Liquidity of data – reduce impediment to data transfer
  – Substitutability of applications – modular and interoperable
  – Built to open standards for open- and closed-source developers
  – Development of an ecosystem of apps, free marketplace of ideas
SMART on FHIR

- **2010**: SMART = Substitutable Medical Applications and Reusable Technologies
  - 1st Gen: HTML, JavaScript, OAuth, Resource Description Framework (RDF) for metadata, and common terminologies like LOINC, RxNorm.
  - Lacked a standard for sharing granular clinical data
  - Poor initial uptake of “SMART Classic” by EHR vendors
- **2011**: HL7 community concerned that HL7 V3 was not gaining traction
  - Led to emergence of Resources for Health --> Fast Healthcare Interoperability Resources (FHIR)
- **2013**: SMART team adopts FHIR standard
SMART on FHIR

FHIR represents clinical data as “resources”


UML diagram for FHIR “Medication” Resource
SMART on FHIR

- **FHIR resources** can be represented as XML or JSON (“javascript object notation”), both very convenient ways for developers to access and manipulate data.
- **JSON** is one way to “serialize” a software object (instance of a class in object-oriented programming) to allow representation as a flat file, string, or message.
- FHIR allows developers to build “RESTful” applications
  - **REST** = Representational State Transfer
  - Acts on a Universal Resource Identifier (URI)
  - Uses HTTP methods (PUT, GET, POST, DELETE; which loosely represent the “create, read, update, delete” functions of a database)

```json
{
    "resourceType": "Medication",
    // from Resource: id, meta, implicitRules, and language
    // from DomainResource: text, contained, extension, and modifierExtension
    "code": [{ CodeableConcept }, // Codes that identify this medication
    "isBrand": <boolean>, // True if a brand
    "manufacturer": { Reference(Organization) }, // Manufacturer of the item
    "product": { // Administerable medication details
      "form": [{ CodeableConcept }, // powder | tablets | carton + "ingredient": [{ // Active or inactive ingredient
        "item": { Reference(SubstanceMedication) }, // RI The product contained
        "amount": { Ratio } // Quantity of ingredient present
      }],
      "batch": [{ // "lotNumber": <string>, // expirationDate": "<dateTimes>
        "expirationDate": "<dateTimes>
      }
    ],
    "package": [{ // Details about packaged medications
      "container": [{ CodeableConcept }, // E.g. box, vial, blister-pack
      "content": [{ // What is in the package
        "item": { Reference(Medication) }, // RI A product in the package
        "amount": { Quantity(SimpleQuantity) } // Quantity present in the package
      }]
    }
  }
}
```
SMART on FHIR

JSON representation of injectable Paclitaxel (compare to JSON template on previous slide)

```json
{
    "resourceType": "Medication",
    "id": "medexample016",
    "text": {
        "status": "generated",
        "div": "<div><p>Generated Narrative with Details</p></div><p><strong>Details</strong>: {
            "SNOMED CT code": "400352007", given as 'Paclitaxel 6mg/ml injection solution 5ml vial (product)'
        }
    },
    "code": [
        {
            "system": "http://snomed.info/sct",
            "code": "400352007",
            "display": "Paclitaxel 6mg/ml injection solution 5ml vial (product)"
        }
    ],
    "isBrand": false,
    "product": {
        "form": {
            "coding": [
                {
                    "system": "http://snomed.info/sct",
                    "code": "440132002",
                    "display": "Parenteral dosage form product"
                }
            ]
        }
    }
}
```

- **“code”** attribute refers to SNOMED concept **“400352007”** which unambiguously refers to “paclitaxel 6mg/ml injection solution, 5ml vial”
- **“form”** attribute refers to SNOMED concept **“440132002”** which unambiguously refers to “parenteral dosage form product”
- **FHIR Profiles** are used to constrain or extend FHIR Resources
- Developers can use FHIR Profiles to validate that payload meets application needs.
SMART on FHIR

- FHIR specifies
  - data model (resources)
  - format (XML, JSON)
  - method of access (RESTful API)

- SMART additionally provides
  - authorization (OAuth2),
  - authentication (OpenID Connect)
  - mechanism for EHR UI integration

Example SMART app “Duke PillBox”
http://medapptech.com/pillbox.html
Alert Fatigue

• Refers to state of user resistance to guidance provided by alerts, even those that might offer possible benefit or reduce harm, presumably because they are overwhelmed by unimportant alerts

• **Difficult to measure**
  – Literature typically uses alert override rates as proxy for “low utility”
  – EHR systems offer different alert designs for Drug-Drug interactions, custom CDS, and other alert types. Studies may be comparing apples to oranges.

• **Difficult to define**
  – What is an “appropriate” override rate?

• **Counterintuitive results**
  – Reducing alert burden dramatically does not dramatically reduce override rate
  – In fact, EHR override rates have remained flat or perhaps increased in the past decade
Alert Fatigue

- Exact, definite allergen matches least likely to be overridden
- Overall override rates increased between 2004 and 2013 from 83.3% to 87.6%

Topaz et al, JAMIA 2016
Alert Fatigue

Drug interaction alert override rates in the Meaningful Use era

No evidence of progress

A.D. Bryant¹; G.S. Fletcher¹,²; T.H. Payne¹,²

¹Department of Medicine, University of Washington; ²Information Technology Services, UW Medicine, University of Washington
Recommendations (for now)

1. Classify alerts into 3 levels – minor, moderate, severe
2. Develop a core set of critical drug drug interactions
3. Classify alerts into active and passive, only make critical alerts active (interruptive)
4. Conduct training on new improvements
5. Develop systems with automated feedback/learning to identify and move alerts from active/interruptive to passive/non-interruptive
End of Lecture
Supplemental Reading


Supplemental Reading

Supplemental Reading


References for More In-Depth Study

- Krall MA, Sittig DF. Clinician’s assessments of outpatient electronic medical record alert and reminder usability and usefulness requirements. Proc AMIA Annu Symp AMIA Symp. 2002;400–4. [Article]
References for More In-Depth Study

- Implementation Science Series


References for More In-Depth Study

• Guideline Modeling:
Preparing for the Certification Examination in Clinical Informatics

William Hersh, MD, FACP, FACMI
Course Director
What will the examination look like?

• Examination items
• Examination process

• (Kudos to Ben Munger, PhD for original content for this session)
Examination philosophy

• The best answer does not have to be the only indisputably correct response to the item as long as subject matter experts agree
• Always insert the word “best” in the stem
• There are no trick questions on the exam
• It would be “very unusual” for an item to reflect very recent events or issues
  – Though 2013 exam did have questions about “meaningful use”
• Give classic answers to classic questions
Examination items

• 177 items in 2013; probably about the same in 2016
  – 200 items total; some did not count
• All questions weighted equally
• Test score is sum of correct answers
  – No penalty for incorrect answers
• You don’t get points for trying to prove the examination committee wrong
  – Trying to outwit exam will only lower probability of being successful
Examination items (cont.)

• All items are multiple-choice, single best answer, with four possible choices
• Probability of being right is 25% if you know nothing about the content
• Pass rate in 2013 and 2014 was ~90%, dipping to ~80% on 2015
  • Different test or different test-takers?
# Exam distribution from 2013

<table>
<thead>
<tr>
<th>Content [Content of Board Exam %]</th>
<th>Core Content</th>
<th>Items Count</th>
<th>% of 177</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Fundamentals [10%]</strong></td>
<td></td>
<td></td>
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<tr>
<td>Clinical Informatics 1.1</td>
<td>13</td>
<td>7.34%</td>
<td></td>
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<tr>
<td>Health Systems 1.2</td>
<td>19</td>
<td>10.73%</td>
<td></td>
</tr>
<tr>
<td><strong>2. Clinical Decision Making and Care Process Improvement [30%]</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Decision Support 2.1</td>
<td>23</td>
<td>12.99%</td>
<td></td>
</tr>
<tr>
<td>Evidence-based Patient Care 2.2</td>
<td>8</td>
<td>4.52%</td>
<td></td>
</tr>
<tr>
<td>Clinical Workflow Analysis 2.3</td>
<td>4</td>
<td>2.26%</td>
<td></td>
</tr>
<tr>
<td><strong>3. Health Information Systems [40%]</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information Technology Systems 3.1</td>
<td>31</td>
<td>17.51%</td>
<td></td>
</tr>
<tr>
<td>Human Factors Engineering 3.2</td>
<td>5</td>
<td>2.82%</td>
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</tr>
<tr>
<td>HIS Applications 3.3</td>
<td>5</td>
<td>2.82%</td>
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</tr>
<tr>
<td>Clinical Data Standards 3.4</td>
<td>8</td>
<td>4.52%</td>
<td></td>
</tr>
<tr>
<td>Information Systems Lifecycle 3.5</td>
<td>20</td>
<td>11.30%</td>
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</tr>
<tr>
<td><strong>4. Leadership and Management Change [20%]</strong></td>
<td></td>
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<tr>
<td>Leadership Models 4.1</td>
<td>8</td>
<td>4.52%</td>
<td></td>
</tr>
<tr>
<td>Effective Interdisciplinary Teams 4.2</td>
<td>6</td>
<td>3.39%</td>
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<tr>
<td>Effective Communications 4.3</td>
<td>5</td>
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<td></td>
</tr>
<tr>
<td>Project Management 4.4</td>
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<tr>
<td>Strategic and Financial Planning 4.5</td>
<td>8</td>
<td>4.52%</td>
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<tr>
<td>Change Management 4.6</td>
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<td></td>
</tr>
<tr>
<td><strong>Grand TOTAL</strong></td>
<td>177</td>
<td><strong>100.00%</strong></td>
<td></td>
</tr>
</tbody>
</table>
References for best answers (from ABPM Study Guide)

<table>
<thead>
<tr>
<th>Author</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carter</td>
<td>Electronic Health Records</td>
</tr>
<tr>
<td>Degoulet</td>
<td>Introduction to Clinical Informatics</td>
</tr>
<tr>
<td>Elkin</td>
<td>Terminology and Terminological Systems</td>
</tr>
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<td>Friedman</td>
<td>Evaluation Methods</td>
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<td>Greenes</td>
<td>Clinical Decision Support</td>
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<tr>
<td>Kotter</td>
<td>Leading Change</td>
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<tr>
<td>O’Carroll</td>
<td>Public Health Informatics</td>
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<tr>
<td>Payne</td>
<td>Practical Guide to Clinical Computing</td>
</tr>
<tr>
<td>Pantanowitz</td>
<td>Pathology Informatics</td>
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<td>Shortliffe</td>
<td>Biomedical Informatics</td>
</tr>
<tr>
<td>Van Bemmel</td>
<td>Handbook of Medical Informatics</td>
</tr>
<tr>
<td>Wager</td>
<td>Health Care Information Systems</td>
</tr>
</tbody>
</table>

(Would add: Hoyt, Health Informatics; Finnell, Study Guide)
Three types of multiple-choice questions

<table>
<thead>
<tr>
<th>Type</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall</td>
<td>Recall learned knowledge</td>
</tr>
<tr>
<td>Interpretation skills</td>
<td>Ability to utilize knowledge to interpret or apply verbal, numeric or visual data</td>
</tr>
<tr>
<td>Problem-solving</td>
<td>Ability to integrate knowledge and presented data to resolve a problem or make an appropriate judgment</td>
</tr>
</tbody>
</table>
Multiple-choice question terminology

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Complete test question: question and all answers</td>
</tr>
<tr>
<td>Stem</td>
<td>Everything that precedes answers: question of stimulus</td>
</tr>
<tr>
<td>Possible answers</td>
<td>All answers from which a selection is made</td>
</tr>
</tbody>
</table>
Instructions to (AMIA) item writers

• Stem should be stated positively
• Avoid using “always” and “never” in stem
• Length of each answer should be approximately the same
• Each answer should be mutually exclusive, not overlapping
Instructions (cont.)

• Avoid using “all of the above” or “none of the above”
• Answers should be presented in alpha or numeric order
• Acronyms should be spelled out
Examination process

• ABPM examinations are administered through Pearson VUE computer testing centers
• Sign-up process is outlined on ABPM website at https://www.theabpm.org
• All individuals taking the exam should go to Pearson VUE Tutorial and Practice Exam at http://measurementresearch.com/testing/tutorial.shtml
• Download, install (Windows), and take (generic) practice exam
Taking Pearson VUE Examinations

• Items are presented one at a time
  – If there is extensive information or a stimulus related to the item it may be presented on a split screen

• You answer the items on the screen by selecting the appropriate answer itself or the circle next it

• You move from one item to another with NEXT button at the bottom right of the screen
Taking exams (cont.)

• Some items you need to scroll to see all the content
• You have option of viewing a clock that tells you time remaining in the exam
• There is a progress indicator in the upper right of screen
  • Indicates items you are on and remaining items on exam
Taking exams (cont.)

- You can move forward to an item or back to an item by selecting **PREVIOUS** and **NEXT** buttons on the bottom right of the screen.
- **NAVIGATOR** button on lower right of screen shows a list of the questions you have seen and their status.
Study approaches

• Exam distributions
• Understand acronyms
• Create a study matrix for the core content and this course
• Talk to faculty
Other learning resources

- Online version of this course
- AMIA simulated exam
- Educational programs
  - 10x10
  - Graduate programs
  - Other courses
- Standard textbooks
Application process (ABPM, about same for ABP)

• ABPM official rules

• My interpretation (no guarantees!)
  – http://informaticsprofessor.blogspot.com/2016/03/eligibility-for-clinical-informatics.html

• Must include
  – ABMS board certification
  – Current licensure
  – Fellowship training, or through 2017
    • Practice pathway
    • Non-accredited fellowship training
Application letters and verification process

- Talk to individuals writing letters
- Provide wording from requirements, e.g.,
  - “broad-based professional activity” and “significant Clinical Informatics responsibility”
Practice pathway

- Three years of clinical practice in clinical informatics (minimum 25%)
- Broad-based professional activity with significant responsibility
- Research and teaching count
- Verification is required by person or persons knowledgeable of you
Fellowship pathway

- Emergence of ACGME-accredited fellowships now
- For non-traditional fellowships, programs listed in ABPM proposal to ABMS
  - Includes most NLM and VA programs
- Those with master’s degrees seemed to be acceptable (or less training combined with pathway)
ABPM checklist

- Photocopy of all current medical licenses with expiration date
- Official transcript of any graduate level coursework or degrees
- Copy of fellowship training curriculum
- Verification form for each Clinical Informatics activity
- One letter of reference
2C-1: Clinical Workflow Analysis and Process Redesign

and

4F: Change Management

Alexis B. Carter, MD
Children’s Healthcare of Atlanta
Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
   1.1.1. The discipline of informatics
   1.1.2. Key informatics concepts, models, theories
   1.1.3. Clinical informatics literature
   1.1.4. International clinical informatics practices
   1.1.5. Ethics and professionalism
   1.1.6. Legal and regulatory issues
   1.2. The Health System
   1.2.1. Determinants of individual and population health
   1.2.2. Primary domains, organizational structures, cultures, and processes
   1.2.3. The flow of data, information, and knowledge within the health system
   1.2.4. Policy & regulatory framework
   1.2.5. Health economics and financing
   1.2.6. Forces shaping health care delivery
   1.2.7. Institute of Medicine quality components

2. Clinical Decision Making and Care Process Improvement
   2.1. Clinical Decision Support
   2.1.1. The nature and cognitive aspects of human decision making
   2.1.2. Decision science
   2.1.3. Application of clinical decision support
   2.1.4. Transformation of knowledge into clinical decision support tools
   2.1.5. Legal, ethical, and regulatory issues
   2.1.6. Quality and safety issues
   2.1.7. Supporting decisions for populations of patients
   2.2. Evidence-based Patient Care
   2.2.1. Evidence sources
   2.2.2. Evidence grading
   2.2.3. Clinical guidelines
   2.2.4. Implementation of guidelines as clinical algorithms
   2.2.5. Information retrieval and analysis

3. Health Information Systems
   3.1. Information Technology Systems
   3.1.1. Computer Systems
   3.1.2. Architecture
   3.1.3. Networks
   3.1.4. Security
   3.1.5. Data
   3.1.6. Technical approaches that enable sharing data
   3.2. Human Factors Engineering
   3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
   3.2.2. HCI Evaluation, usability testing, study design and methods
   3.2.3. Interface design standards and design principles
   3.2.4. Usability engineering
   3.3. Health Information Systems and Applications
   3.3.1. Types of functions offered by systems
   3.3.2. Types of settings where systems are used
   3.3.3. Electronic health/medical records systems as the foundational tool
   3.3.4. Telemedicine
   3.4. Clinical Data Standards
   3.4.1. Standards development history and current process
   3.4.2. Data standards and data sharing
   3.4.3. Transaction standards
   3.4.4. Messaging standards
   3.4.5. Nomenclatures, vocabularies, and terminologies
   3.4.6. Ontologies and taxonomies
   3.4.7. Interoperability standards

4. Leading and Managing Change
   4.1. Leadership Models, Processes, and Practices
   4.1.1. Dimensions of effective leadership
   4.1.2. Governance
   4.1.3. Negotiation
   4.1.4. Conflict management
   4.1.5. Collaboration
   4.1.6. Motivation
   4.1.7. Decision making
   4.2. Effective Interdisciplinary Teams
   4.2.1. Human resources management
   4.2.2. Team productivity and effectiveness
   4.2.3. Group management processes
   4.2.4. Managing meetings
   4.2.5. Managing group deliberations
   4.3. Effective Communications
   4.3.1. Effective presentations to groups
   4.3.2. Effective one-on-one communication
   4.3.3. Writing effectively for various audiences and goals
   4.3.4. Developing effective communications program to support system implementation
   4.4. Project Management
   4.4.1. Basic principles
   4.4.2. Identifying resources
   4.4.3. Resource allocation
   4.4.4. Project management tools (non-software specific)
   4.4.5. Informatics project challenges
   4.5. Strategic and Financial Planning for Clinical Information Systems
   4.5.1. Establishing mission and objectives
   4.5.2. Environmental scanning
   4.5.3. Strategy formulation
   4.5.4. Action planning and strategy implementation
   4.5.5. Capital and operating budgeting
   4.5.6. Principles of managerial accounting
   4.5.7. Evaluation of planning process
   4.6. Change Management
   4.6.1. Assessment of organizational culture and behavior
   4.6.2. Change theories
   4.6.3. Change management strategies
   4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core content covered

• 2.3. Clinical Workflow Analysis, Process Redesign
  2.3.1. Methods of workflow analysis
  2.3.2. Principles of workflow re-engineering
  
  NOTE: Quality Improvement will be covered elsewhere.

• 4.6. Change Management
  4.6.1. Assessment of organizational culture and behavior
  4.6.2. Change theories (e.g., precede-proceed, social influence theories, complex adaptive systems)
  4.6.3. Change management strategies
  4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Key topics - Workflow

• Design, Theory and Components of
  – Workflow
  – Workflow analysis
  – Process redesign

• Data Collection Methods

• Tools to visually represent workflow
Key topics - Workflow

• Process redesign: steps

• Relationship of process redesign and change management
## Definitions

<table>
<thead>
<tr>
<th>Concept</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workflow</td>
<td>A process during which documents, information or tasks are passed from one participant to another for action, according to a set of procedural rules (Ref #1)</td>
</tr>
<tr>
<td>Workflow analysis</td>
<td>Study of the way documents, information and people related to a process move through an organization, in order to improve efficiency (Ref #2)</td>
</tr>
<tr>
<td>Process Redesign</td>
<td>Examination and redesign of existing processes and workflows and putting them into action</td>
</tr>
<tr>
<td>(a.k.a. Workflow Re-engineering)</td>
<td></td>
</tr>
</tbody>
</table>
WORKFLOW
Workflow

• Includes mental and physical tasks
• Occurs at three levels
  – Inter-organizational
  – Intra-organizational, interpersonal
  – Individually (intra-personal)
• Steps may occur sequentially or simultaneously (Sheehan, 2012)
Workflow

• Includes the movement of
  – People and their actions
  – Information
  – Objects

• Through space and time (AHRQ)
WORKFLOW ANALYSIS: THEORIES AND STRATEGIES
Workflow Analysis

- Study of an **existing** workflow
- Need to capture all aspects of workflow
  - People and their actions
  - Information
  - Objects
Workflow Analysis

• Reduces complex process into individual components
• Creates visual representation of flow of people, information and objects
• Used to detect defects and waste
• May be high-level to very detailed
• CRITICAL to capture variations in addition to expected normal workflow
Workflow Analysis and Lean

• Lean technologies (Toyota Production System)
  – Primary focus is on workflow (value stream)
  – Waste (muda) vs. Value

• Important to observe at the place where the work is performed
  – LEAN gemba (Vorne, 2011-2016; Campbell, 2009; IHI, 2005)
Workflow Analysis

• Theories and Strategies
  – Computer science-based approaches
    • Petri-nets
    • Contextual Design
  – Computer-Supported Cooperative Work (CSCW)
    • Activity Theory
    • Coordination Theory
  – Cognitive Science
    • Cognitive Task Analysis
    • Distributed Cognition and UFuRT
  – Organizational Science
Workflow Analysis: Computer Science-Based Approaches

• **Petri-nets** *(Sheehan, 2012)*
  – Electronic capture of workflow where it touches the information system
  – Requires system use data and a workflow management system to understand workflow
  – Limited detection of interpersonal or non-system related elements of workflow
  – Example: **Process mining**
    • Uses system log file data to construct event-based depictions of processes using an information system
Workflow Analysis: Computer Science-Based Approaches

• **Contextual Design** *(Sheehan, 2012)*
  – Provides framework and techniques for *software designers* to understand primarily the human elements of workflow
  – Useful for organizational as well as individual workflow
Workflow Analysis: Computer Science-Based Approaches

• **Contextual Design** *(Sheehan, 2012)*

<table>
<thead>
<tr>
<th>Contextual inquiry</th>
<th>Work Modeling</th>
<th>Consolidation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interview worker in the field as they complete their tasks</td>
<td>Create models of results of contextual inquiry</td>
<td>Create a single statement of work practice</td>
</tr>
</tbody>
</table>

• **Goal of Contextual Inquiry: Uncover 4 aspects of work**
  1. Motive behind tasks
  2. Patterns used in carrying out tasks
  3. Structure that enables task completion
  4. Conceptual distinctions between aspects of work
Workflow Analysis: CSCW

• **Computer-Supported Cooperative Work (CSCW)** *(Sheehan, 2012)*
  – Goal: to understand the activities of *groups* engaged in collaborative work activities for the purposes of software design
  – **Activity Theory**
    • Humans engage in purposeful activities which are goal-directed and context-specific
    • Useful for individual as well as group workflow
  – **Coordination Theory**
    • Task-interdependencies among workers result in harmonious goal-achievement
    • Useful for group workflow analysis but *not* for individual workflow analysis
Workflow Analysis: CSCW
Activity Theory

• Activity Analysis and Development Framework (ActAD)
  – 4 Steps
    1. Describe activity network
    2. Assess development of work activities over time
       – Determine goals for the new software/tool
    3. Identify existing goal conflicts
    4. Develop future view of activity network
Workflow Analysis: CSCW
Activity Theory

• **Activity Checklist**
  – Focuses software developers on work aspects relevant to software design
  – Directs observations of work practices
  – More specific guidance than ActAD
Workflow Analysis: CSCW
Activity Theory

• Activity Checklist
  – Four categories in the checklist

<table>
<thead>
<tr>
<th>Means/ends</th>
<th>Focuses on hierarchical structure of activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environment</td>
<td>Context of activities</td>
</tr>
<tr>
<td>Learning, cognition, articulation</td>
<td>Internal cognitive components related to activities</td>
</tr>
<tr>
<td></td>
<td>External actions related to activities</td>
</tr>
<tr>
<td>Development</td>
<td>Anticipate changes to actions related to use of the new technology</td>
</tr>
</tbody>
</table>
Workflow Analysis: CSCW Collaboration Theory

• Task-interdependencies among workers result in harmonious goal-achievement

• Uncovering task interdependencies can result in identifying new ways to manage them

• Focus on
  – Pre-requisite tasks
  – Tasks which require shared resources
  – Tasks that require synchronization
Workflow Analysis: CSCW
Collaboration Theory

- Examines four processes underlying coordination and their components
  1. Coordination
  2. Group decision-making
  3. Communication
  4. Perception of common objects
- May involve tagging an object to map out process followed where it is used (tracer method)
Workflow Analysis
Cognitive Science

• **Cognitive science**
  – Multidisciplinary field
  – Concentrates on understanding human thought processes
  – Includes knowledge attainment, memory and problem solving
Workflow Analysis
Cognitive Science

• **Cognitive Task Analysis (CTA)**
  – Group of methods to examine *individual* human tasks
  – Cognitive walkthrough (CW)
    • Performed by a systems *analyst*
    • Simulates a user’s cognitive processes as they engage in tasks
  – Think-aloud protocol (TA)
    • Performed by a system *user*
    • Verbalizes thought processes as tasks are carried out
    • Analyst records the verbalization into a visual of the user’s mental model
Workflow Analysis
Cognitive Science

• Distributed cognition
  – Studies the collaborative nature of human cognition
  – People and objects constantly interact within a framework of social and cultural practices
Workflow Analysis
Cognitive Science

• Distributed Cognition
  – UFuRT (Zhang, 2009)
    • User, Functional, Representational and Task Analysis
    • Can be used for workflow analysis at all levels
    • Four phases
      1. Distributed user analysis
      2. Distributed functional analysis
      3. Distributed task analysis
      4. Distributed representational analysis
Workflow Analysis
Organizational Science

• **Organizational Science**
  – Aims to clarify internal organizational structures to influence change and direct process re-design
  – Two components of organizational routines
    • **Ostensive aspect**: general pattern of the routine
    • **Performative aspect**: specific actions performed by individual people within specific contexts
  – **Artifacts**: physical manifestations of the routine
Question: Petri-nets are distinct from other types of workflow analysis because they

A. Require the use of process mining
B. Require the use of software to capture data
C. Are better than other approaches at detecting interpersonal and non-system related elements of workflow
D. Are a computer science-based approach
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B. Computer-Supported Cooperative Work
C. Lean technology
D. Contextual design
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A. Petri-nets
B. Computer-Supported Cooperative Work
C. Lean technology
D. Contextual design
WORKFLOW ANALYSIS:
DATA COLLECTION METHODS
Workflow Analysis
Data Collection

• How people interact with existing technology and their roles
• Temporal dependencies
• Existing system triggers for activity
• Conditional workflows
• Creative workarounds incentivized by gaps in functionality
Workflow analysis
Data collection methods

Quantitative
- Collected via operational systems
- Collected via detached human observer (e.g., counting events)

Qualitative
- Capture details of everyday work practices
- Ethnographic Observation, including participant observation
  - Attends to meaning, goals, context
  - Attends to how people communicate
## Workflow analysis
### Data collection methods (Unertl, 2010)

<table>
<thead>
<tr>
<th>Methods</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethnographic observation</td>
<td>- Quantitative or qualitative or both</td>
</tr>
<tr>
<td>Interviews</td>
<td>- Open-ended ethnographic-based approaches on one end and highly structured approaches on the other</td>
</tr>
<tr>
<td>Structured observation</td>
<td>- Approaches appearing qualitative on the surface can be quantitative, depending on the design of data-collection instruments and data-analysis processes</td>
</tr>
<tr>
<td>Recording</td>
<td></td>
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<tr>
<td>Focus groups</td>
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<tr>
<td>Simulation</td>
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<tr>
<td>Modeling</td>
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<tr>
<td>Usability methods</td>
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<tr>
<td>Diary</td>
<td></td>
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<tr>
<td>Expert panel</td>
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<tr>
<td>Participant observation</td>
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<tr>
<td>Discourse Analysis</td>
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<tr>
<td>Artifact collection</td>
<td></td>
</tr>
<tr>
<td>Surveys</td>
<td></td>
</tr>
<tr>
<td>Software extraction</td>
<td></td>
</tr>
</tbody>
</table>
Workflow Analysis
Data collection methods (Sbaraini, 2011)

• **Grounded Theory**
  – Ethnographic method
  – Inductive analysis
    • Opposite of deductive analysis; studies detailed data first *before* arriving at a hypothesis/theory
  – Analysis occurs *in parallel* with data collection
  – Break data down into much smaller components and code them
    • **Codes** are combined/related to **categories** (or concepts)
Workflow Analysis
Data collection methods
(Patel et al, in Shortliffe, 2014)

• **Usability testing**
  – **Usability** incorporates five attributes that must be evaluated on the information system
  1. **Learnability** – how easy is it to learn?
  2. **Efficiency** – can it make an experienced user very efficient?
  3. **Memorability** – how easily can users remember how to use it?
  4. **Errors** – are these minimized? Are they easily detected?
  5. **Satisfaction** – are users happy with it?
WORKFLOW ANALYSIS: TOOLS
Workflow Analysis Tools

• Simple flowchart
  – Also known as a process map
  – Good at representing actions and decisions through time
  – Well suited to high-level workflow analyses
  – Less good at detailed workflow analysis where specific people (roles) and their actions/decisions need to be shown
Simple flowchart example
Workflow Analysis Tools

• **Swimlane Flowchart**
  – Uses swimlanes to represent the various functions of each person’s role in a workflow
  – Great tool for picking up redundancies and inefficiencies
Swimlane Flowchart Example

Review Queue (not using the Integrated Results Table)

MT/Resident

- Results go to IN-REVIEW status and post Review Queue/Clinical Validation
- Selects Verify
- If NO, selects Perform
- If YES, results go to Pathologist to Finish

Pathologist

- Requires correction and deletion of Integrated Results Table?
- Yes: select Modify Results
- No: select Article
- Selects Verify
- Make Corrections in Ascension Result Entry

RISK: Add next feature in Review queue
Pathologist will verify that next patient on list is the next patient in their patient workflow. MITIGATION: Create workflows that are labeled with "Pathologist last name" + "Next type" + "NEW RESULT" + "NEW ORDER" + "New thumps icon in same order as the rest..."
Swimlane Flowchart Example 2
Lean Workflow Tools

• Spaghetti diagrams
  – Physical map of movements of people in the workflow
  – Walking = waste
  – Poorly configured information systems create a lot of waste
Value Stream Analysis

• Document all steps required to complete a service from beginning to end
  – Include both steps with and without value
  – Document time between steps
  – Creates a value stream map (VSM)
Value Stream Map

Question: A swim lane flowchart differs from a simple flowchart in that it:

A. Focuses on the value stream
B. Is a physical map of movements of people in the workflow
C. Visually represents the actions taken by various roles
D. Maps out the steps in the process
Answer: A swim lane flowchart differs from a simple flowchart in that it:

A. Focuses on the value stream
B. Is a physical map of movements of people in the workflow
C. Visually represents the actions taken by various roles
D. Maps out the steps in the process
PROCESS REDESIGN
Process Redesign

• a.k.a. **Workflow re-engineering**
• Examination and redesign of existing processes and workflows and putting them into action
• Fundamental component of
  – Continuous Quality Improvement (CQI)
  – Total Quality Management (TQM)
  – Process Improvement
Process Redesign

• Models
  – Lean
  – Six Sigma
  – ISO
  – Baldrige
  – VA-TAMMCS
  – others
Process Redesign

• Steps common to all methods
  1. Workflow analysis
  2. Determine ideal workflow
  3. Gap analysis
  4. Mitigate obstacles to ideal state
  5. Finalize planned future state
  6. Testing
  7. Implement change
  8. Measure outcomes
  9. Determine/describe next future change

• REPEAT
Determine ideal workflow

- Should be based on evidence and best practice
- Ideal may not always be practical or feasible
Gap Analysis

• Includes determination of the gaps that exist between current state and your ideal future state

• Also includes:
  – Evaluation of how to close the gaps
    • Are there obstacles/barriers to the ideal future state?
  – Action plans to mitigate obstacles, where possible
    • Not all can be resolved

• Use of published tools is helpful (AHRQ)
Process Redesign: Next Steps

• Mitigate obstacles to future state where possible
• Develop the final details of the change to be made (the final future state plan)
  – based on your gap analysis and ability to mitigate obstacles
• Test against your finalized future state plan
• Implement the change
• Measure outcomes (pre vs. post data)
Process Redesign: Describing the next change (Milstein, 2016)

• **Logic model**
  – Picture of how the next change is supposed to work (before workflow analysis or other steps have occurred)
  – A.k.a. theory of change, road map
  – Components

<table>
<thead>
<tr>
<th>Purpose (mission)</th>
<th>Context</th>
<th>Inputs</th>
<th>Activities</th>
<th>Outputs</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td>Short term</td>
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<td>Mid-term</td>
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<td>Long term</td>
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</tbody>
</table>
Repeat the cycle

- Workflow analysis
- Determine ideal workflow
- Gap analysis
- Mitigate obstacles to ideal state where possible
- Finalize planned future state
- Testing
- Implement change
- Measure outcomes
- Determine next future change needed

Plan → Do → Check → Act / Adjust

Project Management → Maintenance

Change Management / Process Redesign
Reasons Why Process Redesign and Lean Can Fail (Hagg, 2008; Lorenzi, 2000)

- Failure to undergo all steps of process redesign
  - Failure to map current workflow
- Lack of sustained leadership support
- Misaligned incentives
- Lack of communication
- Inadequate people, time or money
- Poor usability of system
- Inadequate training
- Underestimation of complexity
- Lack of robust measurement and data feedback systems
- Cultural resistance to change or hostility toward information systems
- Inadequate or no use of Change Management strategies
CHANGE MANAGEMENT
Core content covered

• 4.6. Change Management
  4.6.1. Assessment of organizational culture and behavior
  4.6.2. Change theories (e.g., precede-proceed, social influence theories, complex adaptive systems)
  4.6.3. Change management strategies
  4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Key topics – Change Management

• Change is more rapid now than ever before which can increase resistance to further change
• Successful process redesign requires good change management skills
• Effecting change requires knowing your audience
• Theories provide a framework for change management activities
• Tailor your strategy to the affected culture and user group(s)
Change Management

• Approach to transitioning individuals, teams and organizations to a desired future state
• Successful process redesign requires the use of change management
Change Management: Assessing Existing Culture / Behavior

• Change is more rapid now than ever before
  – Can increase the level of resistance in systems which are already stressed
• Some organizational cultures embrace information technology more than others
• Assessment of environmental readiness for change must gauge:
  – the level of organizational stress
  – the amount of resources available (human, financial)
  – the degree to which organizational leadership embraces change
Change Management: Assessing Existing Culture / Behavior

• Change is possible in any organization
  – More resistant organizations require more upfront work with change management strategies more heavily employed

• Lack of engagement by affected end-users is likely to make change attempts fail

• Most change theories focus on people
Change Management: Assessing Existing Culture / Behavior

• Change managers should examine
  – Recent organizational change history
    • Leadership
    • Affected end-users
    • What decisions did people make when problems arose?
  – Existing resource constraints
  – Conflicting organizational priorities
CHANGE THEORIES
Change Management:
Change Theories

- **PRECEDE-PROCEED** *(Community ToolBox, 2016)*
  - PRECEDE: Predisposing, Reinforcing, and Enabling Constructs in Educational/Environmental Diagnosis and Evaluation
  - PROCEED: Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development
Change Management: Change Theories

• **PRECEDE-PROCEED** (*Community ToolBox*, 2016)
  – PRECEDE: 4 phases
    1. Identify ultimate desired result
    2. Identify obstacles or gaps to achieve that result
    3. Identify predisposing, enabling, reinforcing elements of obstacles or gaps
    4. Identify mechanisms to remove barriers and bridge gaps
Change Management: Change Theories

• PRECEDE-PROCEED (Community ToolBox, 2016)
  – PROCEED: 4 phases
    1. Design and implementation of change
    2. Process evaluation (Is workflow moving as expected?)
    3. Impact evaluation (Change has the expected impact?)
    4. Outcome evaluation
       – Does the planned outcome = actual outcome?
Change Management:
Change Theories

• **Social Influence Model of Technology Adoption** *(Vannoy, 2010)*
  – Conformance to subjective norms play a central role in technology adoption
  – Social influence is at the confluence of 4 social computing phenomena
    • Action, consensus, cooperation, authority
Change Management: Change Theories

- **Complex Adaptive Systems** *(Rouse, 2008)*
  - Characteristics
    - Nonlinear and dynamic
    - Composed of independent agents
    - Goals and behaviors often conflict
    - Intelligent agents
    - Adaptation and learning → self-organization
    - No single point of control
  - E.g., healthcare, internet, embryo
Change Management: Change Theories

• **Complex Adaptive Systems** *(Rouse, 2008)*
  – Analyzes complex relationships between components of a system
  – Ease of access to information will improve performance of the complex adaptive system
  – Incentives are essential to productivity and wellness
Change Management: Change Theories

• **Diffusion of Innovation Theory** *(Hagg, 2008)*
  – Innovation = change
  – Five most influential characteristics of innovations for affected end-users
    1. Perceived benefit of change
    2. Observability of the innovation
    3. Compatibility of the change with current organizational culture and personal beliefs
    4. Level of simplicity of the innovation
    5. Trialability of the innovation (can you test it?)
Change Management: Change Theories

- Diffusion of Innovation Theory (Hagg, 2008)

Change Management: Change Theories

- For some end-users, letting go of old workflows may cause significant grief
- **Kübler-Ross Grief Cycle ("dabda")**
  1. Denial
  2. Anger
  3. Bargaining
  4. Depression
  5. Acceptance
Change Management: Change Theories

- **Bridges’ Transition Theory**
  - “Managing Transitions” by William Bridges, PhD (1991)
  - Psychological transitions of people are more difficulty than the technology change itself
    - Think 80-20 rule (80% people; 20% technology)
  - Three phases of change
    - Ending, losing, letting go (Loss)
    - Neutral zone
      - Confusion, chaos, attempt to re-align to change
    - New beginning
      - Energy, purpose, embrace change
Change Management: Change Theories

- **Lewin’s Change Theory**
  - Kurt Lewin, 1930s
  - Unfreeze
    - Prepare for change, overcome inertia and resistance
  - Change
    - Uncomfortable confusion and transition
  - Re-freeze
    - Post-change circumstances crystallize; increasing comfort with outcome
CHANGE MANAGEMENT STRATEGIES
Change Management Strategies

Kotter and Schlesinger (Kotter, 2008)

• Diagnose resistance
  – Four most common reasons
    • Parochial self-interest
    • Misunderstanding and lack of trust
    • Different assessments of perceived benefit
    • Low tolerance for change
Change Management Strategies
Kotter and Schlesinger (Kotter, 2008)

• Deal with resistance
  – Education and communication
  – Participation and involvement
  – Facilitation and support
  – Negotiation and agreement
  – Manipulation
    • Co-optation
      – Form of manipulation
      – Giving a key role in change design or implementation
    – Explicit and implicit coercion
Change Management Strategies
Kotter and Schlesinger (Kotter, 2008)

• Choose your strategy - continuum
  – Fast vs. slow implementation
  – Factors affecting decision depend on data from organizational culture/behavior assessment
    • Amount and type of expected resistance
    • Power and political capital of initiators vs. resisters
    • The amount of energy needed to implement
    • Stakes (consequences of not making change)
Change Management Strategies

Change Management Strategies

**Phase 1: Creating a Climate for Change**
- Establish Sense of Urgency
- Build a Coalition (team to lead/guide change)
- Create a vision for the Future State

**Phase 2: Engaging & Enabling the Organization**
- Communicate Future State
- Empower others → action toward Future State
- Plan for and create short-term wins

**Phase 3: Implementing and Sustaining the Changes**
- Focus: problems, solutions, behavior change
- Training, retraining, technical assistance
- Celebrate Successes

STRATEGIES FOR ADOPTION AND USE...

SPECIFICALLY FOR INFORMATION SYSTEMS
Strategies for Adoption and Use of Clinical Information Systems

- Kruse et al 2016 systematic review ([Kruse, 2016](#))
  - Percent of studies citing barriers and facilitators to adoption are listed below

<table>
<thead>
<tr>
<th>Barriers to Adoption</th>
<th>17%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td></td>
</tr>
<tr>
<td>Time consuming</td>
<td>6%</td>
</tr>
<tr>
<td>Perceived lack of utility</td>
<td>6%</td>
</tr>
<tr>
<td>Transition of data</td>
<td>6%</td>
</tr>
<tr>
<td>Facility characteristics (e.g., small)</td>
<td>6%</td>
</tr>
<tr>
<td>Implementation issues</td>
<td>5%</td>
</tr>
<tr>
<td>User/patient resistance</td>
<td>5%</td>
</tr>
<tr>
<td>Lack of technical experience/help</td>
<td>5%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Facilitators to Adoption</th>
<th>12%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficiency</td>
<td></td>
</tr>
<tr>
<td>Organization size (e.g., large)</td>
<td>9%</td>
</tr>
<tr>
<td>Improved quality</td>
<td>9%</td>
</tr>
<tr>
<td>Access to patient care</td>
<td>7%</td>
</tr>
<tr>
<td>Perceived utility</td>
<td>6%</td>
</tr>
<tr>
<td>Ability to transfer information</td>
<td>6%</td>
</tr>
<tr>
<td>Incentives</td>
<td>5%</td>
</tr>
<tr>
<td>Error reduction</td>
<td>4%</td>
</tr>
</tbody>
</table>
Strategies for Adoption and Use of Clinical Information Systems

• Qualis Health experience in primary care settings (Hummel, 2012)
  – Six barriers to effective implementation (adoption)
    • Leadership issues
    • Workflow issues
    • Provider issues
    • Training issues
    • Data interface issues
    • User interface issues
Strategies for Adoption and Use of Clinical Information Systems

- Qualis Health experience in primary care settings (Hummel, 2012)

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Mitigation Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leadership</td>
<td>Engagement, clear communication, dedicated time</td>
</tr>
<tr>
<td>Workflow</td>
<td>Standardize BEFORE implementation, allocate time for process redesign, appropriate assignment of data entry responsibilities</td>
</tr>
<tr>
<td>Provider</td>
<td>Champions, engagement, reduce waste, avoid errors</td>
</tr>
<tr>
<td>Training</td>
<td>Allocate enough people and time, realistic scenarios</td>
</tr>
<tr>
<td>Data Interface</td>
<td>Must have full lab interface, scan/migrate only what is needed</td>
</tr>
<tr>
<td>User Interface</td>
<td>Use templates/favorites/order sets for faster entry, testing is critical, prioritize fixes after go-live</td>
</tr>
</tbody>
</table>
Strategies for Adoption and Use of Clinical Information Systems

- Meaningful use established a national program of **regional extension centers** (RECs) to help with small practice EHR implementation
- **Torda et al.**: REC experience with small practice barriers and facilitators of adoption
Question: The terms early adopters and laggards are most commonly associated with which Change Management Theory?

A. Diffusion of Innovations
B. Transition Theory
C. Social Influence
D. Kubler-Ross Grief Cycle
Answer: The terms early adopters and laggards are most commonly associated with which Change Management Theory?

A. Diffusion of Innovations  
B. Transition Theory  
C. Social Influence  
D. Kubler-Ross Grief Cycle
Question: Which of the following are among Kotter and Schlesinger’s change management strategies to deal with resistance?

A. Innovation, Communication channels, Time, Social system
B. Manipulation and Co-optation
C. Unfreeze, Change, Freeze
D. Compliance, Identification, Internalization, Conformity
Answer: Which of the following are among Kotter and Schlesinger’s change management strategies to deal with resistance?

A. Innovation, Communication channels, Time, Social system
B. Manipulation and Co-optation
C. Unfreeze, Change, Freeze
D. Compliance, Identification, Internalization, Conformity
Additional suggested readings: Workflow Analysis and Process Redesign


- Graban M. Lean Healthcare and Lean Design. 2011;  

  https://www.ncbi.nlm.nih.gov/books/NBK43727/
Additional suggested readings: Change Management

  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC61464/

  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4909978/
Answer: Petri-nets are distinct from other types of workflow analysis because they

A. Require the use of process mining

B. Require the use of software to capture data

C. Are better than other approaches at detecting interpersonal and non-system related elements of workflow

D. Are a computer science-based approach

Petri-nets are computer science-based approach which requires system use data and a workflow management system (software) to understand workflow. There is limited detection of interpersonal or non-system related elements of workflow. While process mining can be used as part of this approach, it is not required. Other computer science-based approaches also exist (e.g., contextual design).
Answer: Which workflow analysis approach is specifically designed for software designers to understand the individual human's actions in the workflow for which they are trying to design software?

A. Petri-nets
B. Computer-Supported Cooperative Work
C. Lean technology
D. Contextual design

Petri-nets are more focused on capturing data from the system that is being used rather than human actions within a specific context. Computer-Supported Cooperative Work (CSCW) has the primary goal of understanding activities of groups engaged in collaborative work for the purposes of software design. While activity theory (a component of CSCW) can be used for individuals, neither it nor Lean technology are specifically designed for that purpose.
Answer: A swim lane flowchart differs from a simple flowchart in that it:

A. Focuses on the value stream
B. Is a physical map of movements of people in the workflow
C. Visually represents the actions taken by various roles
D. Maps out the steps in the process

A swim lane flowchart visually represents the actions taken by various roles, and it is the roles that are represented by swim lanes. Both swim lane flowcharts and simple flow charts map out the steps in the process. A value stream map focuses on the value stream, while a spaghetti diagram is a physical map of movements of people in the workflow.
Answer: The terms early adopters and laggards are most commonly associated with which Change Management Theory?

A. Diffusion of Innovations

B. Transition Theory
C. Social Influence
D. Kubler-Ross Grief Cycle

The terms “early adopters” and “laggards” are most commonly associated with Everett Rogers’s Diffusion of Innovations theory which describes people within a social system as falling into one of 5 categories with respect to adoption of innovations: Innovators, Early adopters, Early Majority, Late Majority, and Laggards.
Answer: Which of the following are among Kotter and Schlesinger’s change management strategies to deal with resistance?

A. Innovation, Communication channels, Time, Social system

B. Manipulation and Co-optation

C. Unfreeze, Change, Freeze

D. Compliance, Identification, Internalization, Conformity

Kotter and Schlesinger describe six ways of dealing with resistance: Education and communication, Participation and involvement, Facilitation and support, Negotiation and agreement, Manipulation and Co-optation, and Explicit and implicit coercion.
References

All references are freely available online except for references to Shortliffe's Biomedical Informatics book.


Systematic Reviews of Lean in Healthcare


4F: Change Management

References

All references are freely available online except for references to Shortliffe’s Biomedical Informatics book.

2C-2: Healthcare Quality Improvement

Bimal R. Desai, MD, MBI, FAAP
The Children’s Hospital of Philadelphia
Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
   1.1.1. The discipline of informatics
   1.1.2. Key informatics concepts, models, and theories
   1.1.3. Clinical informatics literature
   1.1.4. International clinical informatics practices
   1.1.5. Ethics and professionalism
   1.1.6. Legal and regulatory issues
   1.2. The Health System
   1.2.1. Determinants of individual and population health
   1.2.2. Primary domains, organizational structures, cultures, and processes
   1.2.3. The flow of data, information, and knowledge within the health system
   1.2.4. Policy & regulatory framework
   1.2.5. Health economics and financing
   1.2.6. Forces shaping health care delivery
   1.2.7. Institute of Medicine quality components

2. Clinical Decision Making and Care Process Improvement
   2.1. Clinical Decision Support
   2.1.1. The nature and cognitive aspects of human decision making
   2.1.2. Decision science
   2.1.3. Application of clinical decision support
   2.1.4. Transformation of knowledge into clinical decision support tools
   2.1.5. Legal, ethical, and regulatory issues
   2.1.6. Quality and safety issues
   2.1.7. Supporting decisions for populations of patients
   2.2. Evidence-based Patient Care
   2.2.1. Evidence sources
   2.2.2. Evidence grading
   2.2.3. Clinical guidelines
   2.2.4. Implementation of guidelines as clinical algorithms
   2.2.5. Information retrieval and analysis
   2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
   2.3.1. Methods of workflow analysis
   2.3.2. Principles of workflow re-engineering
   2.3.3. Quality improvement principles and practices

3. Health Information Systems
   3.1. Information Technology Systems
   3.1.1. Computer Systems
   3.1.2. Architecture
   3.1.3. Networks
   3.1.4. Security
   3.1.5. Data
   3.1.6. Technical approaches that enable sharing data
   3.2. Human Factors Engineering
   3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
   3.2.2. HCI Evaluation, usability testing, study design and methods
   3.2.3. Interface design standards and design principles
   3.2.4. Usability engineering
   3.3. Health Information Systems and Applications
   3.3.1. Types of functions offered by systems
   3.3.2. Types of settings where systems are used
   3.3.3. Electronic health/medical records systems as the foundational tool
   3.3.4. Telemedicine
   3.4. Clinical Data Standards
   3.4.1. Standards development history and current process
   3.4.2. Data standards and data sharing
   3.4.3. Transaction standards
   3.4.4. Messaging standards
   3.4.5. Nomenclatures, vocabularies, and terminologies
   3.4.6. Ontologies and taxonomies
   3.4.7. Interoperability standards
   3.5. Information System Lifecycle
   3.5.1. Institutional governance of clinical information systems
   3.5.2. Clinical information needs analysis and system selection
   3.5.3. Clinical information system implementation
   3.5.4. Clinical information system testing, before, during and after implementation
   3.5.5. Clinical information system maintenance
   3.5.6. Clinical information system evaluation

4. Leading and Managing Change
   4.1. Leadership Models, Processes, and Practices
   4.1.1. Dimensions of effective leadership
   4.1.2. Governance
   4.1.3. Negotiation
   4.1.4. Conflict management
   4.1.5. Collaboration
   4.1.6. Motivation
   4.1.7. Decision making
   4.2. Effective Interdisciplinary Teams
   4.2.1. Human resources management
   4.2.2. Team productivity and effectiveness
   4.2.3. Group management processes
   4.2.4. Managing meetings
   4.2.5. Managing group deliberations
   4.3. Effective Communications
   4.3.1. Effective presentations to groups
   4.3.2. Effective one-on-one communication
   4.3.3. Writing effectively for various audiences and goals
   4.3.4. Developing effective communications program to support system implementation
   4.4. Project Management
   4.4.1. Basic principles
   4.4.2. Identifying resources
   4.4.3. Resource allocation
   4.4.4. Project management tools (non-software specific)
   4.4.5. Informatics project challenges
   4.5. Strategic and Financial Planning for Clinical Information Systems
   4.5.1. Establishing mission and objectives
   4.5.2. Environmental scanning
   4.5.3. Strategy formulation
   4.5.4. Action planning and strategy implementation
   4.5.5. Capital and operating budgeting
   4.5.6. Principles of managerial accounting
   4.5.7. Evaluation of planning process
   4.6. Change Management
   4.6.1. Assessment of organizational culture and behavior
   4.6.2. Change theories
   4.6.3. Change management strategies
   4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core Content Covered

2.3.3 Quality improvement principles and practice
Key Topics

• Define healthcare quality from the standpoint of a patient, a healthcare provider, a society/community, and a payor; understand that these definitions are sometimes challenging to reconcile.

• Distinguish healthcare quality indicators – structure, process, and outcomes.

• Understand that there are numerous well-established quality improvement (QI) frameworks in use in healthcare, such as Toyota Lean, Six Sigma, and Associates for Process Improvement (API); describe high-level concepts associated with each.

• Describe how Ishikawa/fishbone diagrams and Pareto charts can be used to identify targets for QI efforts.

• Describe a Plan-Do-Study-Act cycle.

• Understand the applicability of Control Charts to evaluation of healthcare QI efforts.

• Distinguish Control Charts from evaluation methods based on hypothesis testing, such as randomized trials.
2C-2 Healthcare Quality Improvement

• Why and what do we need to improve?
• Definitions of quality
• Indicators of quality
• QI Concepts & Historical Perspective
• QI Tools
• QI Frameworks and Methodologies
Healthcare in America is Unsafe

• Medical errors are harmful and costly
  – 98,000 deaths and 1 million injuries annually, at a cost of $29 billion (IOM, “To Err is Human” 1999)

  – 597,689 Heart Disease
  – 574,743 Cancer
  – 138,080 Chronic lower respiratory diseases
  – 129,476 Stroke
  – 120,859 Accidents
  – 98,000 Deaths Due to Medical Error
  – 83,494 Alzheimer’s disease
  – 69,071 Diabetes
Healthcare in America is Unsafe

– Two seminal works
  • IOM 1999, “To Err is Human”
  • IOM 2001, “Crossing the Quality Chasm”

– Adverse Drug Events (ADE)
  • Hospital Adverse Drug Events:
    – Classen 1997: “380,000 preventable adverse drug events annually”
    – Bates 1995: “450,000 preventable ADEs”
  • Long-term Care Facilities
    – Gurwitz 2005: “800,000 ADE’s annually”
  • Outpatient Care
    – Gurwitz 2003: “Among Medicare patients alone, 530,000 ADEs”

– Impact of ADEs
  • $3.6 Billion in additional expenses due to hospital ADEs
IOM Types of Errors

• Diagnostic
  – Error or delay in diagnosis
  – Failure to employ indicated tests
  – Use of outmoded tests or therapy
  – Failure to act on results of monitoring or testing

• Treatment
  – Error in the performance of an operation, procedure, or test
  – Error in administering the treatment
  – Error in the dose or method of using a drug
  – Avoidable delay in treatment or in responding to an abnormal test
  – Inappropriate (not indicated) care

IOM Types of Errors

• **Preventive**
  – Failure to provide prophylactic treatment
  – Inadequate monitoring or follow-up of treatment

• **Other**
  – Failure of communication
  – Equipment failure
  – Other system failure

Delivers Inconsistent Value

• Value = Level of Quality / Cost
  – Care can have poor value if it either delivers poor quality or has excess cost (or both)

• Compared to other developed countries, US healthcare system lags in many markers of healthcare value
US spends two-and-a-half times the OECD average

Total health expenditure per capita, public and private, 2010 (or nearest year)

USD PPP

1. In the Netherlands, it is not possible to clearly distinguish the public and private share related to investments.
2. Total expenditure excluding investments.
Information on data for Israel: http://dx.doi.org/10.1787/888932315602.

Source: OECD Health Data 2012.
At 17.6% of GDP in 2010, US health spending is one and a half as much as any other country, and nearly twice the OECD average.

Total health expenditure as a share of GDP, 2010 (or nearest year)

1. In the Netherlands, it is not possible to clearly distinguish the public and private share related to investments.
2. Total expenditure excluding investments.
Information on data for Israel: http://dx.doi.org/10.1787/888932315602.

Source: OECD Health Data 2012.
Healthcare Spending per capita vs. Average Life Expectancy Among OECD Countries

Source: Forbes, 2012
OECD: Organization for Economic Cooperation & Development
US spends much more on health than what might be expected by its GDP per capita

2010 (or latest year available)

Source: OECD Health Data 2012.
US prices for a set of hospital services are over 60% higher than the average of 12 OECD countries

Comparative price levels for total inpatient hospital services, 2007

Source: Koechlin et al. (2010).
Cancer system is generally performing well

**Breast cancer, 5-year survival rate**

<table>
<thead>
<tr>
<th>Country</th>
<th>5-year Survival Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States (2003-08)</td>
<td>89.3</td>
</tr>
<tr>
<td>Japan (2000-05)</td>
<td>87.3</td>
</tr>
<tr>
<td>Canada (2002-07)</td>
<td>86.6</td>
</tr>
<tr>
<td>OECD (16 countries)</td>
<td>83.5</td>
</tr>
<tr>
<td>Germany (2003-08)</td>
<td>83.3</td>
</tr>
<tr>
<td>France (1997-2002)</td>
<td>82.8</td>
</tr>
<tr>
<td>United Kingdom (2004-09)</td>
<td>81.3</td>
</tr>
</tbody>
</table>

**Colorectal cancer, 5-year survival rate**

<table>
<thead>
<tr>
<th>Country</th>
<th>5-year Survival Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan (2000-05)</td>
<td>68.0</td>
</tr>
<tr>
<td>United States (2003-08)</td>
<td>64.5</td>
</tr>
<tr>
<td>Canada (2002-07)</td>
<td>63.4</td>
</tr>
<tr>
<td>Germany (2003-08)</td>
<td>60.4</td>
</tr>
<tr>
<td>OECD (16 countries)</td>
<td>59.9</td>
</tr>
<tr>
<td>France (1997-2002)</td>
<td>57.0</td>
</tr>
<tr>
<td>United Kingdom (2004-09)</td>
<td>53.3</td>
</tr>
</tbody>
</table>

*Note: 95% confidence intervals are represented by H.*

*Source: OECD Health Data 2012.*
Primary care sector is not performing so well

Asthma hospital admission

- Canada (2009): 15.7
- Italy (2009): 19.2
- Germany (2009): 20.8
- France (2007): 43.4
- OECD (28 countries): 51.8
- United Kingdom (2009): 73.7
- United States (2008): 120.6

COPD hospital admission

- France (2007): 179
- Italy (2009): 126
- Canada (2009): 183
- OECD (28 countries): 198
- Germany (2009): 201
- United Kingdom (2009): 213
- United States (2008): 230

Note: 95% confidence intervals are represented by H.
Source: OECD Health Data 2012.
Healthcare is Inequitable

• Example: healthcare disparities (population-specific differences in quality and access to health care services) between 2003 and 2006 cost us $229 billion
  – Infants born to African-American women 1.5-3 times more likely to die than others
  – African-American men >2x as likely to die of prostate cancer
  – Hispanic women >2x as likely to be diagnosed with cervical cancer
Definition of Quality

“The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”

IOM Quality Domains

- **Safe**
  - 1st IOM Report “To Err is Human” (1999): 1M injured, 44K-98K die annually

- **Effective / Reliable**
  - Care is evidence-based; benefits outweigh risks
  - Care is consistent – patients receive the same standard of care regardless of where, when, and from whom

- **Patient-centered**
  - Meet individual needs, incorporates values/preferences
  - Tailored to language, level of education
  - Focus on emotional support, pain relief, attention to suffering, family support

- **Efficient**
  - avoid wastefulness and redundancy, match access to demand

- **Timely**
  - avoid long waits, scheduling delays, barriers to care

- **Equitable**
  - at population and individual level
  - reduce disparities attributable to age, gender, race, education, disability, sexual orientation, etc.
Stakeholders and National Activity

- **CMS – Center for Medicare & Medicaid Services**
  - Have published clinical quality measures (CQMs) that define appropriate use of EHR technology to support clinical practice
  - Submitting CQM data is required in order to receive Meaningful Use incentive in Stage 1 and Stage 2
  - Derived from NQF measures
  - Administers the EHR Incentive Program, total funds ~ $21 billion

- **NQF – National Quality Forum**
  - Collects and standardizes quality measures in a tool known as QPS or Quality Positioning System
  - Each NQF-endorsed measure has an NQF number, defined steward, and update / revision cycle
NQF Example

- NQF #0002 – Appropriate Test for Children with Pharyngitis
  - Measure Steward – NCQA
  - Measure description – “percentage of children 2-18 who received a diagnosis of pharyngitis, had strep testing, and received abx”
  - Numerator – “a group A strep test was performed in the 7 day period from 3 days before to 3 days after index episode”
  - Denominator – “children age 2 to 18 as of 6mo prior to measurement period who had an outpatient or ED visit with only a diagnosis of pharyngitis”
  - Exclusions
  - Risk Adjustment
  - Additional Classifications (condition, care setting, data source, etc)
Stakeholders and National Activity

• **NCQA – National Committee for Quality Assurance**
  – Publish and maintain Health Effectiveness Data and Information Set (HEDIS) performance measures
  – Intent is to allows consumers to benchmark health plans
  – Process of physician and hospital accreditation
  – HEDIS measures are required of CMS “Medicare Advantage” subcontractors, like HMOs

• **ONC – Office of the National Coordinator for Healthcare IT**
  – Established in 2004 by legislative order, mandated in 2009 in the HITECH Act (Title XIII of ARRA, “the stimulus package”)
  – Oversees national activities to promote HIT and healthcare information exchange
  – Established certification criteria for EHR
  – Established HIE standards
Stakeholders and National Activity

- **Joint Commission**
  - Non-profit that accredits US healthcare organizations
  - Established National Patient Safety Goals (NPSG)
    - Ex: reduction of MDRO, catheter-related bloodstream infections, surgical site infections

- **Leapfrog Group**
  - Voluntary program that described “4 leaps” that would improve safety and quality of US healthcare system
    - CPOE – recommend a list of CPOE functions/safeguards
    - Evidence-based hospital referral – recommend referring complex cases to high volume and high quality health care facilities
    - ICU Physician Staffing – recommend staffing ICU with intensivists
    - Leapfrog Safe Practice Score (a list of NQF-endorsed safe practices)
Error-Proofing Concepts

- High Reliability Systems
- Checklists
- James T. Reason’s “Swiss Cheese” Model
  - Latent and active failures are like “holes in the cheese”
  - Processes, safeguards, and workflows are “layers of cheese”
  - Accidents / errors occur when the latent and active failures in different layers line up, allowing hazards to lead to losses.

### World Health Organization Surgical Safety Checklist

**Available at:** [http://who.int/patientsafety/safesurgery/ss_checklist/en/](http://who.int/patientsafety/safesurgery/ss_checklist/en/)

<table>
<thead>
<tr>
<th>SIGN IN</th>
<th>TIME OUT</th>
<th>SIGN OUT</th>
</tr>
</thead>
</table>
| PATIENT HAS CONFIRMED  
  - IDENTITY  
  - SITE  
  - PROCEDURE  
  - CONSENT | CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE | NURSE VERBALLY CONFIRMS WITH THE TEAM: |
| SITE MARKED/NOT APPLICABLE | SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM  
  - PATIENT  
  - SITE  
  - PROCEDURE | THE NAME OF THE PROCEDURE RECORDED |
| ANAESTHESIA SAFETY CHECK COMPLETED | ANTIQUE CRITICAL EVENTS  
  - SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS? | THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE) |
| PULSE OXIMETER ON PATIENT AND FUNCTIONING | ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS? | HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME) |

**DOES PATIENT HAVE A:**

<table>
<thead>
<tr>
<th>KNOWN ALLERGY?</th>
<th>DIFFICULT AIRWAY/ASPIRATION RISK?</th>
<th>RISK OF &gt;500ML BLOOD LOSS (7ML/KG IN CHILDREN)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>YES</td>
<td>YES, AND EQUIPMENT/ASSISTANCE AVAILABLE</td>
<td>YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?</th>
<th>IS ESSENTIAL IMAGING DISPLAYED?</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>NOT APPLICABLE</td>
<td>NOT APPLICABLE</td>
</tr>
</tbody>
</table>
WHO Surgical Checklist


- 1750 consecutively enrolled patients > 16 years old at 8 hospitals across the world

“The complication rate was 18.4% (n=151) at baseline and 11.7% (n=102) after the checklist was introduced (P=0.0001). Death rates dropped from 3.7% to 1.4% following checklist introduction (P=0.0067). Adherence to 6 measured safety steps improved from 18.6% to 50.7% (P<0.0001).”
Analysis of a Medication Error

No bedside safety check
No standard concentrations
Imprecise CPOE
Outdated formulary

Losses

Hazards

Hazardous Medication

Adverse Drug Event

Failure Mode & Effects Analysis

• “FMEA”
  – Devised by the US Military in 1949
  – Used in aerospace, automotive industry
  – Later adopted for healthcare use

• Modes of failure in a process can be risk-prioritized according to severity of the failure, frequency of occurrence, and detectability
Failure Mode & Effects Analysis

- **Step 1:** Create detailed flow diagram of a process
- **Step 2:** For each step, describe what happens if process fails
- **Step 3:** Rate each failure on a standardized scale x 3
  - Severity of harm if failure occurs (S)
    - 1 = none; 5 = fatal
  - Likelihood of occurrence (O)
    - 1 = rare; 5 = common
  - Inability of existing controls to detect failure (D)
    - 1 = easily detectable; 5 = failure would not be evident
- **Step 4:** Calculate Risk Priority Number \( (RPN = S \times O \times D) \)
- **Example:** A fatal, but rare and detectable error = 5 x 1 x 1
Donabedian Quality Framework

• **Structure** – Attributes of setting in which care occurs
  – Number of specialists for a given patient population
  – Number of clinical guidelines implemented

• **Process** – How care is actually given and received
  – Proportion of diabetic patients who are screened for proteinuria
  – Proportion of children with otitis media who are treated appropriately with narrow-spectrum penicillins

• **Outcome** – Effects of care on patient status
  – Intermediate measures
    • HbA1c results for diabetic patients
    • Lipid profile results for patients with hyperlipidemia
  – End measures
    • Quality of life for patients with degenerative joint disease
    • Functional status for stroke patients
    • Patient satisfaction

Example of Quality Framework

Goal: “All emergency department rooms should be stocked with equipment for bag-mask ventilation”

- **Structure:** “does your hospital have a policy or standard that specifies what equipment should be in every room in the ED”?
- **Process:** “In weekly audits of ED rooms, what percent of the time is a room found to be improperly stocked?”
- **Outcome:** “How many occurrences are there annually of trauma/resuscitation events in the ED where a bad outcome was attributed to missing airway equipment?”
Lagging vs. Leading Indicators

- **Leading Indicator**: An indicator that anticipates future events, changes detectable before the events occur.
  - Examples: physical activity, weight, immunizations, antibiotics given prior to surgery, timely corticosteroid treatments for acute asthma, etc.

- **Lagging Indicator**: An indicator that follows an event.
  - Examples: infections (lagging) caused by hand washing rate (leading); ventilator acquired pneumonia; complication rates, asthma hospitalization or revisit rates

- Compare “Leading” to “Process”, “Lagging” to “Outcome”
  - **Process/Leading**: rate of pediatric immunization
  - **Outcome/Lagging**: rates of pertussis and measles in a community
Attributes of Good Indicators

• Definitions are agreed upon
• Optimally sensitive and specific
• Valid – does the indicator discriminate between good and bad quality?
• Reliable – are repeated measurements stable, reproducible, consistent?
• Relates to identifiable user events
• Permits useful comparison
• Evidence-based
QI Historical Perspective

- Informed by work in manufacturing, process control

- **1890s – Frederick Taylor**
  - “Scientific Management” movement
  - By modern standards, he thought poorly of workers
    - “In the majority of cases this man deliberately plans to do as little as he safely can”
    - "When he tells you to pick up a pig and walk, you pick it up and walk, and when he tells you to sit down and rest, you sit down. You do that right through the day. And what's more, no back talk”

- **1930s – Walter Shewhart, Western Electric Co.**
  - Statistical Process Control
  - Creator of control charts
QI Historical Perspective

• 1950s – Taiichi Ohno
  – Developed Toyota Production System, aka “Toyota Lean”
  – System focuses on removing all activity that has no value, contributes to waste or “muda”

• 1970s – W. Edwards Deming
  – Theory of Improvement
  – Plan-Do-Study-Act cycle for learning and improvement
  – Hired as consultant to improve production methods in post-WWII Japan
Control Charts

• Not a hypothesis test
• Definitions of “common cause” and “special cause” are based in statistics
• When monitored over time, an indicator will fluctuate around an average value, defined by upper and lower control limits
Control Charts

- UCL and LCL calculated from Standard Error (Sdev / sqrt(n))
- UCL and LCL defined as 3-sigma from center line (99% of events)
- Upper & Lower Warning Limits are 2-sigma from center line (95% of events)

Control Chart Center Line

• “Common Cause” Fluctuation
  – Within UCL and LCL (99.73% of random fluctuation should fall within 3-sigma)
  – **AND** has no unnatural patterns

• “Special Cause” Fluctuation
  – Falls outside UCL or LCL
  – **OR** meets criteria for any “Special Cause” pattern
Special Cause Patterns

- They all describe statistically improbable events or series of events
- Definitions differ, but some commonly accepted patterns:
  - Any single point outside 3-sigma
  - Two out of three points between 2 and 3-sigma
  - Four out of five consecutive points beyond 1-sigma on the same side of the centerline
  - Eight consecutive points on the same side of the centerline
  - Six in a row continually increasing or decreasing (drift)
  - And the list goes on…
How many special patterns can you identify in this graph?
Special Cause Examples

Any single point beyond 3-sigma is due to “special cause”
Special Cause Examples

Two out of 3 points between 2- and 3-sigma
Special Cause Examples

Eight consecutive on the same side of center line

- UCL = 99
- UWL = 96
- LWL = 83
- LCL = 80

Center = 89.6
Other Special Cause Terminology

- **Shift** – “a run of 6 or more points on same side of center line”
- **Trend** – “five consecutive points going in same direction”
- **Run** - “too few or too many events crossing the center line”
- **Cycle** – periodicity in data suggests special cause
  - Eg: “difference in STAT lab delays during night shift”
- **Pattern** – cycles in data attributable to other factors besides time
  - Eg: “higher override rates when a specific pharmacist is on duty”
For a QI project, you’re trending defects in a process over time.

After 11 months, you calculate the mean to be about 21 defects/month.

You choose a target for improvement that is 10% less, or about 18.
Oh no! For the next 8 months, you exceed your goal # of process defects. Your executives are unhappy at the backsliding metric.
Value of Using Control Charts

Process Defects

What if we had included control limits from the start?

UCL = 34
LCL = 7

mean

Courtesy Ron Keren, MD • Used with permission
Now it’s clear the variation is due to common cause, cannot be attributed to special cause.
Other QI Tools

- Flowchart
  - Graphically represent a process step-by-step
  - Model of workflow and cognitive steps with inputs, decisions, outputs

- Cause-Effect / Ishikawa / Fishbone diagram
  - Identify possible targets for improvement
  - Trace back to root cause by asking “Five Whys”
  - Represent as an outcome (head) and domains (bones)

- Pareto Chart
  - Frequency-sorted graph of events with a cumulative percent line
  - Origin of the “80:20” rule
  - Used commonly to identify the most valuable targets for improvement

- Key Driver Diagram
  - Establishes a causal pathway between the intervention and the aim
  - Work backwards from Outcomes to Drivers to Changes
  - User to identify measurable tests of change
Ishikawa Example

- EHR
  - No order set or accelerators for Supercillin
- Ordering Provider
  - Education re: dose by indication
  - Recent dose change
  - Formulary outdated
  - Communication gap
- Pharmacy

Supercillin Dosing errors
Pareto Chart Example

Causes of Errors Related to Antibiotics for Urinary Tract Infections

- Wrong empiric antibiotic
- Wrong dose of antibiotic
- Delay in ordering antibiotic
- Contaminated specimen
- Misidentification of morphology

Event Count vs. Cumulative %
Five Whys Example
(source: http://en.wikipedia.org/wiki/Five_whys)

- Problem: The vehicle won’t start
  - 1st Why? The battery is dead
  - 2nd Why? The alternator is not functioning
  - 3rd Why? The alternator belt is broken
  - 4th Why? The alternator belt was well beyond its useful service life and not replaced
  - 5th Why? **The vehicle was not maintained according to the recommended service schedule** (Root Cause)
    - Solution: start to maintain according to schedule
  - 6th Why? Replacement parts are not available because of the extreme age of the vehicle
    (optional footnote)
    - Solution: purchase a different vehicle that is easier to maintain
Improvement Methodologies

• PDSA = “Plan – Do – Study – Act”
  – (you may also see this as PDCA or “Plan – Do – Check – Act”)

• Six-Sigma

• Toyota Lean and related strategies

Plan Do Study Act

- Key to improvement is small, repeated cycles to select targets, improve on a small scale, implement widely, and measure outcome
- IHI reference: [http://www.ihi.org/knowledge/Pages/HowtoImprove/](http://www.ihi.org/knowledge/Pages/HowtoImprove/)
- Steps:
  - Form the team
  - Set Aims – time specific and measurable
  - Establish measures (ideally, these should be good indicators)
  - Select target for change/improvement (use FMEA, Pareto, Fishbone, and other techniques to identify targets)
  - **Plan** – Establish objectives, processes, expectations
  - **Do** – Implement the plan, collect data for analysis
  - **Study / Check** – look at the results and compare against expected results
  - **Act** – request corrective actions, disseminate results to all areas
Example in Practice

A children’s hospital wants to encourage appropriate 1\textsuperscript{st} line antibiotic prescribing for community acquired pneumonia

1: Form a team: hospitalists, ED, ID, pharmacist, and others

2: Develop aims: increase percent of patients admitted with community acquired pneumonia (CAP) on appropriate antibiotics from baseline of 0\% to 80\%

Ambroggio et al, Pediatrics 2013
Example in Practice

3: Create a process map to understand current workflows

**FIGURE 1**
Process map of antibiotic prescribing for a patient being admitted for CAP. Amox amoxicillin; PNA, pneumonia.

Ambroggio et al, Pediatrics 2013
Example in Practice

4: Conduct FMEA and determine key drivers

We will increase the percent of otherwise healthy patients admitted to the general pediatric service at the Burnet campus diagnosed with uncomplicated CAP* who receive appropriate evidence-based first-line antibiotic therapy** from 0% in the ED and 30% on the HM service to 80%.

*Children, >3 months, with age-appropriate vaccinations, who are immunocompetent and who do not have complex chronic conditions
**As outlined by the PIDS/IDSA pediatric pneumonia guidelines

Global Aim
Reduce variation in the management of CAP in children by implementing evidence-based guidelines

Key Drivers
- Increased provider buy-in
- Effective communication between care providers
- Accurate knowledge of guidelines
- Accurate order entry

Interventions
- Guideline Seminar, Grand Rounds, Antibiotic Recommendations in the Medical Staff Update LOR*: 1
- Charge Nurse Flag Cards LOR*: 1
- Index card with appropriate first-line antibiotic information for ED physicians and inpatient residents and resident report LOR*: 1
- H&P template and order set in EMR and link to PIDS/IDSA Guideline LOR*: 2

Figure 2
Key driver diagram summarizing the project aim and interventions implemented to achieve the study aim. H&P, history and physical examination note; LOR, level of reliability.

Ambroggio et al, Pediatrics 2013
Example in Practice

5: Plan and do the intervention(s)
- Educational seminars re: ID guidelines
- 4x6 index card with recommendations in bullet points
- Included recommendations in housestaff guide
- Incorporate CAP guidelines into an existing CAP orderset, with links to guidelines
  • Default orderset to recommended 1st-line antibiotics
- Update EHR note templates to reflect guideline-based plan of care

Ambroggio et al, Pediatrics 2013
Example in Practice

6: Measure the change using run chart

First-line Antibiotic Prescribing on HM Resident Teams
May 2011–July 2012

Ambroggio et al, Pediatrics 2013
Six Sigma

• Developed by Motorola in the 1980s
• Name comes from ideal of having a process in control within six-sigma ("perfect" process) – 3.4 defects per million opportunities, or 99.999% error free.
• Steps – DMAIC (note some similarities to PDSA/PDCA)
  – **Define** – project charter, needs, scope, goals
  – **Measure** – data collection plan, sources of data to measure defects, design control charts to monitor process
  – **Analyze** – identify deviation from standards, sources of process variation
  – **Improve** – identify creative solutions, implement plans
  – **Control** – process is updated; policies, guidelines, error-proofing put in place
Lean Methodology

• Taiichi Ohno, Toyota Motor Corporation Engineer in 1950s

• Remove all non-value added activities
  – *Muda* – “uselessness, wastefulness”
  – *Mura* – “irregularity, unevenness”
  – *Muri* – “unreasonable, burdensome work”
Seven Types of *Muda*

- Overproduction / underproduction
- Inventory (ex: having too much inventory of a perishable good in stock)
- Repairs / rejects (assembly mistakes)
- Motion (poor work area ergonomics)
- Processing (e.g. outdated policies, procedures)
- Waiting (patients languishing in a waiting room)
- Transport (transporting patients unnecessarily)
Lean: Value Stream Mapping

- Graphical depiction of inputs, throughputs, outputs
- Highlights opportunities for improvement
- Frontline staff bring forth ideas for improvement
- Tests of change implemented as “kaizens” or “change for the better” – small improvements, rapid adaptation to results, continuous quality improvement
Lean: Kaizen

- Standardize operational activities
- Measure operation
- Compare measurements to requirements
- Engage frontline staff in identifying opportunities to improve
- When improvements work, make them the new standard
- Repeat
Lean: Supporting Conventions

- **Kanban cards**
  - Visual indicators that a supply is empty
  - Ex: red flip tabs on the top of hand sanitizer dispensers

- **Andon**
  - Visual indication that indicates production status / alerts when assistance is needed
  - Ex: “X-Ray In Progress” light

- **Poka-yoke**
  - “mistake avoiding” in design or process
  - Intentional incompatibility of refill spouts for inhaled anesthetics
  - Color-coding of medical gases - yellow for air, green for oxygen
  - The notch on your SIM card that only allows it to be inserted in one c
Your Homework

• Review the PDSA Tutorial on the Ohio Perinatal Quality Collaborative website
  (https://www.opqc.net/projects/improvement%20resources)

• Pick a hypothetical clinical quality improvement project of your choosing and use the guide to design a PDSA project (you can stop at the “PLAN” stage for this exercise).
End of Lecture
Suggested Additional Reading


- **How to Improve** [Internet]. Cambridge (MA): Institute for Healthcare Improvement; [updated 2012 Dec 04; cited 2012 Jan 14]. Available from: [http://www.ihi.org/knowledge/Pages/HowtoImprove/](http://www.ihi.org/knowledge/Pages/HowtoImprove/)

Supplemental Materials

• Institute for Healthcare Improvement Open School
  – http://www.ihi.org/Pages/default.aspx
  – https://www.youtube.com/user/IHIOpenSchool/videos

• Example of QI tools in action
Health Information Systems & Applications

Lecture 3C

Thomas H Payne, MD, FACMI
University of Washington
Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
      1.1.1. The discipline of informatics
      1.1.2. Key informatics concepts, models, and theories
      1.1.3. Clinical informatics literature
      1.1.4. International clinical informatics practices
      1.1.5. Ethics and professionalism
      1.1.6. Legal and regulatory issues
   1.2. The Health System
      1.2.1. Determinants of individual and population health
      1.2.2. Primary domains, organizational structures, cultures, and processes
      1.2.3. The flow of data, information, and knowledge within the health system
      1.2.4. Policy & regulatory framework
      1.2.5. Health economics and financing
      1.2.6. Forces shaping health care delivery
      1.2.7. Institute of Medicine quality components

2. Clinical Decision Making and Care Process Improvement
   2.1. Clinical Decision Support
      2.1.1. The nature and cognitive aspects of human decision making
      2.1.2. Decision science
      2.1.3. Application of clinical decision support
      2.1.4. Transformation of knowledge into clinical decision support tools
      2.1.5. Legal, ethical, and regulatory issues
      2.1.6. Quality and safety issues
      2.1.7. Supporting decisions for populations of patients
   2.2. Evidence-based Patient Care
      2.2.1. Evidence sources
      2.2.2. Evidence grading
      2.2.3. Clinical guidelines
      2.2.4. Implementation of guidelines as clinical algorithms
      2.2.5. Information retrieval and analysis
   2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
      2.3.1. Methods of workflow analysis
      2.3.2. Principles of workflow re-engineering
      2.3.3. Quality improvement principles and practices

3. Health Information Systems
   3.1. Information Technology Systems
      3.1.1. Computer Systems
      3.1.2. Architecture
      3.1.3. Networks
      3.1.4. Security
      3.1.5. Data
      3.1.6. Technical approaches that enable sharing data
   3.2. Human Factors Engineering
      3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
      3.2.2. HCI Evaluation, usability testing, study design and methods
      3.2.3. Interface design standards and design principles
      3.2.4. Usability engineering
   3.3. Health Information Systems and Applications
      3.3.1. Types of functions offered by systems
      3.3.2. Types of settings where systems are used
      3.3.3. Electronic health/medical records systems as the foundational tool
      3.3.4. Telemedicine
   3.4. Clinical Data Standards
      3.4.1. Standards development history and current process
      3.4.2. Data standards and data sharing
      3.4.3. Transaction standards
      3.4.4. Messaging standards
      3.4.5. Nomenclatures, vocabularies, and terminologies
      3.4.6. Ontologies and taxonomies
      3.4.7. Interoperability standards
   3.5. Information System Lifecycle
      3.5.1. Institutional governance of clinical information systems
      3.5.2. Clinical information needs analysis and system selection
      3.5.3. Clinical information system implementation
      3.5.4. Clinical information system testing, before, during and after implementation
      3.5.5. Clinical information system maintenance
      3.5.6. Clinical information system evaluation

4. Leading and Managing Change
   4.1. Leadership Models, Processes, and Practices
      4.1.1. Dimensions of effective leadership
      4.1.2. Governance
      4.1.3. Negotiation
      4.1.4. Conflict management
      4.1.5. Collaboration
      4.1.6. Motivation
      4.1.7. Decision making
   4.2. Effective Interdisciplinary Teams
      4.2.1. Human resources management
      4.2.2. Team productivity and effectiveness
      4.2.3. Group management processes
      4.2.4. Managing meetings
      4.2.5. Managing group deliberations
   4.3. Effective Communications
      4.3.1. Effective presentations to groups
      4.3.2. Effective one-on-one communication
      4.3.3. Writing effectively for various audiences and goals
      4.3.4. Developing effective communications program to support system implementation
   4.4. Project Management
      4.4.1. Basic principles
      4.4.2. Identifying resources
      4.4.3. Resource allocation
      4.4.4. Project management tools (non-software specific)
      4.4.5. Informatics project challenges
   4.5. Strategic and Financial Planning for Clinical Information Systems
      4.5.1. Establishing mission and objectives
      4.5.2. Environmental scanning
      4.5.3. Strategy formulation
      4.5.4. Action planning and strategy implementation
      4.5.5. Capital and operating budgeting
      4.5.6. Principles of managerial accounting
      4.5.7. Evaluation of planning process
   4.6. Change Management
      4.6.1. Assessment of organizational culture and behavior
      4.6.2. Change theories
      4.6.3. Change management strategies
      4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core Content Covered

3.3 Health Information Systems and Applications
3.3.1 Types and functions offered by systems
3.3.2 Types of settings where systems are used
3.3.3 Electronic health/medical records systems as the foundational tool
3.3.4 Telemedicine
Key topics

• Architecture, technical and computing infrastructure underlying health information systems (HIS).
• Breadth of HIS functionality and topics historically challenging to physicians.
• Telemedicine application areas and types.
Core Content Covered

3.3 Health Information Systems and Applications

3.3.1 Types and functions offered by systems

3.3.2 Types of settings where systems are used

3.3.3 Electronic health/medical records systems as the foundational tool

3.3.4 Telemedicine
Examples of clinical computing system functionality commonly used

**Electronic medical record system**
- Results review
- Documentation
- CPOE
- Decision support
- Messaging

**Departmental systems**
- Laboratory
- Radiology
- Pharmacy
- Pathology
- PACS
- Facility billing
- Professional fee billing

**Financial systems**
- ADT
- Registration
- Master Patient Index
- Materials management
- Workforce management

**Foundational systems**
- Workforce management
Foundational systems

- Admission/Discharge/Transfer
- Master Patient Index
- Registration
- Materials management
- Workforce management
Departmental systems

- Laboratory
  - Clinical pathology
  - Anatomic pathology
  - Blood bank
- Radiology
  - PACS
  - RIS
- Pharmacy
  - Unit dose
  - Retail
- Cardiology (ECG, echo, cath, PACS)
- Dietary
- Neurology (EMG, NCV)
- Pulmonary (PFT)
- GI endoscopy
Financial systems

- Facility fee
- Professional fee
- Financial and strategic decision support
Layers of infrastructure

<table>
<thead>
<tr>
<th>Layer</th>
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</thead>
<tbody>
<tr>
<td>Care delivery, clinical mission, quality</td>
</tr>
<tr>
<td>Results review, documentation, CPOE</td>
</tr>
<tr>
<td>EMR with interfaces</td>
</tr>
<tr>
<td>Point-of-care devices</td>
</tr>
<tr>
<td>Network, fixed and wireless</td>
</tr>
<tr>
<td>Power, HVAC</td>
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</table>
Infrastructure – Physical

- **Data Center** is a dedicated and protected facility with specific requirements of electricity, humidity, and air conditioning
  - Usually one per campus or institution
  - Houses hundreds of servers, appliances, and disk storage
  - These are placed on racks, and are physically measured in “rack units”
  - Physically protected, electrically fed
Data Center Classes

- **Tier I** (Basic) - Single path for power and cooling distribution, without redundancy (99.671% availability).
- **Tier II** (Redundancy) - Single path for power and cooling distribution (99.741% availability).
- **Tier III** (Concurrently maintainable) - Multiple active power and cooling paths, but only one path active; has redundancy (99.982% availability).
- **Tier IV** (Fault tolerant) - Multiple active power and cooling distribution paths; has redundancy (99.995% availability).

From: Turner, Seader, and Brill. The Uptime Institute (http://www.uptime.com/file_downloads/PDF/Tier_Classification.pdf) Slide courtesy of Dave Chou
The most accurate statement regarding health IT infrastructure is:

A. UPS provide electrical power for the duration of most power outages.
B. The phrase “dual-homed” indicates routers connect to both fiber and wire cabling.
C. Cloud storage is inherently less secure than local storage.
D. Data center protections for power and cooling can be considered security measures.
Infrastructure – Physical – Data Center issues

- **Uninterruptible Power Supplies (UPS)** provide 30 minutes of backup power using storage batteries to be replaced every 3-5 years.
- A fully loaded rack may weigh 2000 lbs. 100 racks require ensuring proper structural integrity.
- Too many physical servers and other equipment → Virtualization.
Infrastructure Physical – Data Center issues

• **Expensive** to build, hence often outsourced where space and electricity are cheaper

• **Redundancy** in air conditioning, power, networking

• **Heat**– A fully loaded rack could consume 20kw, and require 6 tons of cooling. 100 racks require 2Mw electricity, and may need water-cooled air conditioning

Slide courtesy of Soumitra Sengupta
Infrastructure – Network design

- Dual-homed Floor Switch-Routers
- Dual-Homed Building Switch-Routers
- Redundant Backbone Core Switch-Routers
- Internet
- WAN Locations

Slide courtesy of Soumitra Sengupta
In the ISO/OSI model, TCP/IP can be considered at what levels?

A. 1 and 2
B. 2
C. 3 and 4
D. 4
Infrastructure – Physical – Cabling

- **Data closet** is a smaller space, typically on each floor, which houses networking equipment and cable ends
  - Standards - IEEE
- **Cable plant** is a topographical layout of physical cables connecting desktops to the equipment in the closets and cables interconnecting closets and the data center.
  - Standards

Slide courtesy of Soumitra Sengupta
Which of the following accurately describes increasing complexity of these network devices?

A. Bridges are simpler than hubs
B. Routers are simpler than switches
C. Bridges are more complex than switches
D. Routers are more complex than hubs
Infrastructure – Physical cabling issues

- Closets may not have adequate HVAC
- Cables are laid, old ones are almost never taken out – a weight issue
- Fire codes must be followed going across floors and buildings
- New cables in ICU and OR require utmost caution
- Cables can be outdated, unable to support higher bandwidth
- Labor costs of cabling outweighs other hardware and software purchases
- Security of closets and cables are suspect; closets may be shared
Architecture terminology

Client Server
- Desktop clients handle user interaction. More powerful servers handle data requests

Thin Client
- User device runs simple application software which is connected to powerful server

Application Service Provider (ASP) model
- Business that provides computer services over the internet
Health Information System Archetypal Architectures

• **Integrated systems**: Those in which patient data exist in the same database used by all clinical applications.

• **Interfaced systems**: Those in which data are communicated between separate applications with different databases, usually by means of an interface using HL7 protocol.

“Best of breed”

In practice most organizational clinical computing systems are a mixture, with varying degrees of both.
Archetypal architectures

Integrated

Clinical Informatics Board Review Course
Interface engines

An Interface Engine (a.k.a. message broker, application-level router) is a middleware application used to transform, route, clone and translate messages. A HL7 interface engine is an interface or integration engine built specifically for the healthcare industry. [HL7]

Can “play back” messages when unavailable receiving system comes back online.

Useful, common, fallible.

\[ \frac{n(n-1)}{2} \]

This formula demonstrates potential reduction in point-to-point interfaces
<table>
<thead>
<tr>
<th>Component</th>
<th>Problems</th>
<th>Clinical consequence</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPI</td>
<td>Application failure</td>
<td>Newly enrolled patients not transmitted to departmental systems and EMR; patient misidentification</td>
</tr>
<tr>
<td>Power and HVAC</td>
<td>Loss of power or environmental controls</td>
<td>Shutdown of all hosts in affected room, major outage</td>
</tr>
<tr>
<td>Network hubs, routers, switches, fiber, cables</td>
<td>Denial of service attack, spanning tree problems, cable disruption</td>
<td>Local or widespread unavailability of applications</td>
</tr>
<tr>
<td>Interface engine</td>
<td>Application failure</td>
<td>New results and MPI information not transmitted to departmental systems preventing new results, orders</td>
</tr>
<tr>
<td>Departmental applications</td>
<td>Failure of disks, controllers, application or operating system</td>
<td>New clinical data generated by department not available</td>
</tr>
<tr>
<td>Repository and EMR</td>
<td>Database corruption, application failure, faulty patch or upgrade</td>
<td>Impaired performance or application unavailability</td>
</tr>
<tr>
<td>Terminal server</td>
<td>Memory leaks, host failure</td>
<td>Partial or widespread loss of access to EMR</td>
</tr>
<tr>
<td>Workstations</td>
<td>Misconfiguration, local drive failure, virus</td>
<td>Partial or widespread loss of access to EMR</td>
</tr>
</tbody>
</table>
Methods to improve interoperability between HIT systems

1. Interfaces (HL7, other)
2. Communicate results in paper; scan into foreign EMR
3. Reciprocal access
4. Embedded applications
5. Context sharing—CCOW (Clinical Context Object Workgroup), other
6. Build separate application with data from both
Core Content Covered

3.3 Health Information Systems and Applications
3.3.1 Types and functions offered by systems
3.3.2 Types of settings where systems are used
3.3.3 Electronic health/medical records systems as the foundational tool
3.3.4 Telemedicine
Settings where EMRs are used

- Ambulatory (clinic)
- Free standing surgical center
- Emergency room
- Operating room
- Skilled nursing facility
- Long-term acute care facility
- Home

- Inpatient
  - Acute care
  - Psychiatry
  - Rehabilitation service
  - ICU
    - Trauma/surgical
    - Pulmonary Medicine
    - Cardiology
    - Neurology/neurosurgery
    - Neonatal
    - Remote ICU
Core Content Covered

3.3 Health Information Systems and Applications
3.3.1 Types and functions offered by systems
3.3.2 Types of settings where systems are used
3.3.3 Electronic health/medical records systems as the foundational tool
3.3.4 Telemedicine
Electronic health/medical record systems as the foundational tool

- Evolution from department-focused to patient-focused
  - Tab metaphor for data remains common
- Goal of problem-oriented medical record remains largely elusive
- Most visible system to clinicians and patients
- Target of federal incentive programs
## Electronic health record functionality

**[IOM 2003]**

### Box 2. Core Functionalities for an Electronic Health Record System

- Health information and data
- Results management
- Order entry/management
- Decision support
- Electronic communication and connectivity

- Patient support
- Administrative processes
- Reporting & population health management

IOM Committee on Data Standards for Patient Safety, 2003 http://www.nap.edu/books/NI00427/html/
EMR functionality. 1

• Message box (proprietary names vary but functionality similar)
• Results review (lab, path, imaging, notes)
• Documentation (direct entry, structured/unstructured, dictation, mixed)
• Order management
• Patient summary displays
• Medication administration record
  – Bar code medication administration
EMR functionality. 2

- Patient lists, schedule, rounding/handoff tools
- Patient monitoring review
- Quality metrics, dashboards
- Billing
  - Professional fee
  - Facility fee
- Patient support
- Administrative
- Electronic communication
  - With team
  - With patients
EMR functionality. 3

• Population health
• External resources
• Aspects of all functionality:
  – Compliance
  – Decision support
The HIMSS EMR adoption model:

A. Lists population health in Stage 7
B. Is directly incorporated into Meaningful Use
C. Lists 7 stages of EMR adoption
D. Does not describe steps in adoption for many hospitals.
## HIMSS EMR Adoption Model

<table>
<thead>
<tr>
<th>Stage</th>
<th>Cumulative Capabilities</th>
<th>2009 Final</th>
<th>2010 Q1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 7</td>
<td>Complete EMR; CCD transactions to share data; Data warehousing; Data continuity with ED, ambulatory, OP</td>
<td>0.7%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Stage 6</td>
<td>Physician documentation (structured templates), full CDSS (variance &amp; compliance), full R-PACS</td>
<td>1.6%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Stage 5</td>
<td>Closed loop medication administration</td>
<td>3.8%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Stage 4</td>
<td>CPOE, Clinical Decision Support (clinical protocols)</td>
<td>7.4%</td>
<td>7.7%</td>
</tr>
<tr>
<td>Stage 3</td>
<td>Nursing/clinical documentation (flow sheets), CDSS (error checking), PACS available outside Radiology</td>
<td>50.9%</td>
<td>50.0%</td>
</tr>
<tr>
<td>Stage 2</td>
<td>CDR, Controlled Medical Vocabulary, CDS, may have Document Imaging; HIE capable</td>
<td>16.9%</td>
<td>16.5%</td>
</tr>
<tr>
<td>Stage 1</td>
<td>Ancillaries - Lab, Rad, Pharmacy - All Installed</td>
<td>7.2%</td>
<td>6.9%</td>
</tr>
<tr>
<td>Stage 0</td>
<td>All Three Ancillaries Not Installed</td>
<td>11.5%</td>
<td>11.4%</td>
</tr>
</tbody>
</table>

Data from HIMSS Analytics™ Database © 2010

Clinical Informatics Board Review Course
Documentation using EMRs
[Rosenbloom 2007]

4 factors influence satisfaction with electronic documentation tools:

• Time efficiency
• Availability/accessibility
• Expressivity
• Quality
Issues to confront

- Time spent writing notes (4-14 min per Mamykina 2012)
- “Electronic notes are harder to understand.”
- Copying and pasting
- Time spent writing notes
- Note loss, notes in wrong chart, notes with wrong title, notes on wrong encounter
- Billing and compliance
Study on copying & pasting in an EMR
[Hammond 2003]

Copying and pasting severity scale

1. Artifact, not misleading, no risk
2. Artifact, minimally misleading, minimal risk
3. Human, not misleading, no risk
4. Human, minimally misleading, minimal risk
5. Human, misleading, some risk
6. Human, clinically misleading, major risk
Conclusions from Hammond study

[Hammond 2003]

• One in ten electronic charts contained an instance of high-risk copying.

• Clear policies, practitioner consciousness-raising and development of effective monitoring procedures are recommended to protect the value of electronic patient records.
Documentation tools

Click in a template

Mixture of click and type

Type in a text editor

Hybrid dictation

Dictation

Structured

Unstructured

Age: 53
Gender: M

Problems: HEART FAILURE, UNSPECIFIED [428.9]
ROS: Dyspnea [267036007]

Chest pain [29857009]

“This 53 y.o. male with congestive heart failure presents with dyspnea, chest pain...”
Definition of CPOE

Computerized practitioner order entry is defined as a process which allows the ordering practitioner to use a computer to directly enter medical orders.
Reduction in serious medication errors

[Bates et al, JAMA, 1998]

<table>
<thead>
<tr>
<th>Category</th>
<th>Phase 1 Rate (Events/1000 Patient-Days, Mean)</th>
<th>Phase 2 Rate (Events/1000 Patient-Days, Mean)</th>
<th>% Reduction</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonintercepted serious medication errors</td>
<td>10.7</td>
<td>4.86</td>
<td>-55%</td>
<td>.01</td>
</tr>
<tr>
<td>Preventable ADEs</td>
<td>4.69</td>
<td>3.88</td>
<td>17%</td>
<td>.37</td>
</tr>
<tr>
<td>Nonintercepted potential ADEs</td>
<td>5.99</td>
<td>0.98</td>
<td>84%</td>
<td>.002</td>
</tr>
<tr>
<td>All ADEs</td>
<td>16.0</td>
<td>15.2</td>
<td>0%</td>
<td>.77</td>
</tr>
<tr>
<td>Nonpreventable ADEs</td>
<td>11.3</td>
<td>11.3</td>
<td>0%</td>
<td>.99</td>
</tr>
<tr>
<td>All potential ADEs</td>
<td>11.7</td>
<td>3.38</td>
<td>71%</td>
<td>.02</td>
</tr>
<tr>
<td>Intercepted potential ADEs</td>
<td>5.67</td>
<td>2.4</td>
<td>58%</td>
<td>.15</td>
</tr>
</tbody>
</table>

*Paired comparison between phase 1 and 2 made using t test including only the 6 units in both phases.
†Sum of nonintercepted potential ADEs and preventable ADEs.
In three published studies on effect of CPOE on mortality in pediatric hospitals

A. No conclusion can be drawn regarding the effect of CPOE on mortality from these studies
B. CPOE was demonstrated to reduce mortality in all.
C. In some, but not all, CPOE caused increased mortality.
D. No studies of CPOE and mortality have been completed.
Protocol
is built of
Order sets
is built of
Preconfigured orders
is built from
Order dialog
The Rationale for Order Sets

[Payne 2003]

- Reduce the time required to enter orders
- Reduce errors and increase accuracy during order entry
- Increase completeness of orders
- “Built in” decision support and evidence driven care
- Reduce variability in the care process and enhance compliance with “best practices”

Slide courtesy of Matt Eisenberg, MD
Mortality rates pediatric hospitals before and after CPOE

Fig 1. Observed mortality rates (presented as a normalized % of predicted mortality) during the 18-month study period are plotted according to quarter of year. Observed mortality rates were consistently better than predicted before CPOE implementation, but this relationship did not remain after CPOE implementation. *P < .05 and 1P = .07 (observed vs predicted mortality, z statistic). Q, quarter.

FIGURE 1
Hospital-wide mortality rate per 100 discharges according to month (excluding the obstetrical population). The pre-EMR period was between January 1, 2001, and October 31, 2007, and the postintervention period was between November 1, 2007, and April 30, 2009.

<table>
<thead>
<tr>
<th>TABLE 2</th>
<th>Mortality Rates of PICU Patients Before or After CPOE Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Patients, n</td>
<td>Survivors, n</td>
</tr>
<tr>
<td>All patients</td>
<td>2533</td>
</tr>
<tr>
<td>Before CPOE</td>
<td>1232</td>
</tr>
<tr>
<td>After CPOE</td>
<td>1301</td>
</tr>
<tr>
<td>Transfers</td>
<td>284</td>
</tr>
<tr>
<td>Before CPOE</td>
<td>125</td>
</tr>
<tr>
<td>After CPOE</td>
<td>159</td>
</tr>
<tr>
<td>Congenital cardiovascular disease</td>
<td>432</td>
</tr>
<tr>
<td>Before CPOE</td>
<td>203</td>
</tr>
<tr>
<td>After CPOE</td>
<td>229</td>
</tr>
</tbody>
</table>
## CPOE effects on workflow

[Niazkhani 2009]

<table>
<thead>
<tr>
<th>Beneficial</th>
<th>Detrimental</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order turn around time</td>
<td>Time spend entering orders</td>
</tr>
<tr>
<td>Remote access</td>
<td>In-person communication</td>
</tr>
<tr>
<td>Time for antibiotics to reach patient</td>
<td>Usability</td>
</tr>
<tr>
<td>Improved order legibility</td>
<td>Shifting responsibilities</td>
</tr>
<tr>
<td>Reduction in verbal orders</td>
<td>Communication of STAT orders</td>
</tr>
<tr>
<td>Ordering practitioner known</td>
<td></td>
</tr>
<tr>
<td>Routing of results to Inbox</td>
<td></td>
</tr>
</tbody>
</table>
Unintended consequences of CPOE

[Ash JAMIA 2007]

• More/New Work Issues
• Workflow Issues
• Never Ending Demands
• Paper Persistence
• Communication Issues

• Emotions
• New Kinds of Errors
• Changes in the Power Structure
• Overdependence on Technology
Core Content Covered

3.3 Health Information Systems and Applications

3.3.1 Types and functions offered by systems

3.3.2 Types of settings where systems are used

3.3.3 Electronic health/medical records systems as the foundational tool

3.3.4 Telemedicine
Telemedicine

• Clinical use cases
  – Teleconsultation
    » Psychiatry
    » Dermatology
    » Pathology
    » ENT
    » Retinography
  – Teleradiology
  – Telesurgery
  – Remote retinal imaging
  – Remote monitoring
  – Remote ICU
  – Remote procedures

• Economic considerations
  – Payer policies
  – Bundled payment
Telemedicine media & timing

• Synchronous teleconferencing
  – Dedicated hardware
  – Broadly available tools
    • (e.g. Skype)
    • Conferencing applications
• Asynchronous telemedicine
  – Store & forward
  – Electronic mail
  – Other
Additional suggested readings


• See also References
Clinical Informatics for Pathology and Laboratory Medicine

Alexis B. Carter, MD
Children’s Healthcare of Atlanta
Core Content Covered in this Lecture

1. Fundamentals
1.1. Clinical Informatics
1.1.1. The discipline of informatics
1.1.2. Key informatics concepts, models, theories
1.1.3. Clinical informatics literature
1.1.4. International clinical informatics practices
1.1.5. Ethics and professionalism
1.1.6. Legal and regulatory issues
1.2. The Health System
1.2.1. Determinants of individual and population health
1.2.2. Primary domains, organizational structures, cultures, and processes
1.2.3. The flow of data, information, and knowledge within the health system
1.2.4. Policy & regulatory framework
1.2.5. Health economics and financing
1.2.6. Forces shaping health care delivery
1.2.7. Institute of Medicine quality components

2. Clinical Decision Making and Care Process Improvement
2.1. Clinical Decision Support
2.1.1. The nature and cognitive aspects of human decision making
2.1.2. Decision science
2.1.3. Application of clinical decision support
2.1.4. Transformation of knowledge into clinical decision support tools
2.1.5. Legal, ethical, and regulatory issues
2.1.6. Quality and safety issues
2.1.7. Supporting decisions for populations of patients
2.2. Evidence-based Patient Care
2.2.1. Evidence sources
2.2.2. Evidence grading
2.2.3. Clinical guidelines
2.2.4. Implementation of guidelines as clinical algorithms
2.2.5. Information retrieval and analysis
2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
2.3.1. Methods of workflow analysis
2.3.2. Principles of workflow re-engineering
2.3.3. Quality improvement principles and practices

3. Health Information Systems
3.1. Information Technology Systems
3.1.1. Computer Systems
3.1.2. Architecture
3.1.3. Networks
3.1.4. Security
3.1.5. Data
3.1.6. Technical approaches that enable sharing data
3.2. Human Factors Engineering
3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
3.2.2. HCI Evaluation, usability testing, study design and methods
3.2.3. Interface design standards and design principles
3.2.4. Usability engineering
3.3. Electronic health/medical records systems as the foundational tool
3.3.1. Types of functions offered by systems
3.3.2. Types of settings where systems are used
3.3.3. Telemedicine
3.4. Clinical Data Standards
3.4.1. Standards development history and current process
3.4.2. Data standards and data sharing
3.4.3. Transaction standards
3.4.4. Messaging standards
3.4.5. Nomenclatures, vocabularies, and terminologies
3.4.6. Ontologies and taxonomies
3.4.7. Interoperability standards
3.5. Information System Lifecycle
3.5.1. Institutional governance of clinical information systems
3.5.2. Clinical information needs analysis and system selection
3.5.3. Clinical information system implementation
3.5.4. Clinical information system testing, before, during and after implementation
3.5.5. Clinical information system maintenance
3.5.6. Clinical information system evaluation

4. Leading and Managing Change
4.1. Leadership Models, Processes, and Practices
4.1.1. Dimensions of effective leadership
4.1.2. Governance
4.1.3. Negotiation
4.1.4. Conflict management
4.1.5. Collaboration
4.1.6. Motivation
4.1.7. Decision making
4.2. Effective Interdisciplinary Teams
4.2.1. Human resources management
4.2.2. Team productivity and effectiveness
4.2.3. Group management processes
4.2.4. Managing meetings
4.2.5. Managing group deliberations
4.3. Effective Communications
4.3.1. Effective presentations to groups
4.3.2. Effective one-on-one communication
4.3.3. Writing effectively for various audiences and goals
4.3.4. Developing effective communications program to support system implementation
4.4. Project Management
4.4.1. Basic principles
4.4.2. Identifying resources
4.4.3. Resource allocation
4.4.4. Project management tools (non-software specific)
4.4.5. Informatics project challenges
4.5. Strategic and Financial Planning for Clinical Information Systems
4.5.1. Establishing mission and objectives
4.5.2. Environmental scanning
4.5.3. Strategy formulation
4.5.4. Action planning and strategy implementation
4.5.5. Capital and operating budgeting
4.5.6. Principles of managerial accounting
4.5.7. Evaluation of planning process
4.6. Change Management
4.6.1. Assessment of organizational culture and behavior
4.6.2. Change theories
4.6.3. Change management strategies
4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core content covered

Supplemental information
3.3 Health Information Systems and Applications
• 3.3.1. Types of functions offered by systems
• 3.3.2. Types of settings where systems are used
• 3.3.3. Electronic health/medical records systems as the foundational tool
• 3.3.4. Telemedicine

The Pathology Perspective as it applies to EHRs
## Abbreviations and Terminology

<table>
<thead>
<tr>
<th>EHR</th>
<th>Electronic Health Record</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIS</td>
<td>Laboratory Information System*</td>
</tr>
<tr>
<td>Lab</td>
<td>Any laboratory performing clinical testing on a patient. Includes:</td>
</tr>
<tr>
<td></td>
<td>• Anatomic Pathology (Surgical pathology, cytology, autopsy)</td>
</tr>
<tr>
<td></td>
<td>• Clinical Laboratories</td>
</tr>
<tr>
<td></td>
<td>• Specialized laboratories</td>
</tr>
<tr>
<td></td>
<td>• Reference laboratories</td>
</tr>
</tbody>
</table>

*Another, less frequently used, abbreviation is LIMS (laboratory information management system). LIMS usually, but not always, refers to an information system used in a research (not clinical) laboratory.*
Key topics

• The EHR-LIS relationship
  – EHR-LIS Architectures
  – Support Models for LISs
  – Laboratory Regulations and Standards that may impact EHRs

• The Laboratory as an Automation Driver
  – Interfaces and automation lines
  – Barcodes
  – Radiofrequency Identification Tags (RFID)

• Basics of digital imaging
  – Telepathology
Key topics

• Genomic data
  – Impact on clinical informatics
  – Next-generation sequencing and bioinformatics
  – Genomic data privacy

• Big data

• Computational pathology
Why Learn about the LIS?

- The LIS is one of the largest contributors of objective data into an EHR
  - Think about the impact when your LIS is down
- Larger laboratories are highly automated
  - Can inform the use of automation in other areas
- Laboratories and LISs highly regulated by federal law
- Three pathologists helped develop the Clinical Informatics board exam questions 😊
- Pathology now has teaching toolkits for pathology residents
  - Expected to inform future ACGME Pathology requirements
EHR-LIS Architectures

• Integrated LIS
  – LIS is an integrated module/component of the EHR
  – LIS shares tables with the EHR (e.g., patient tables)

• Interfaced LIS
  – Separate from the EHR
  – Communications only occur through HL7 interfaces
  – With reference to the EHR:

<table>
<thead>
<tr>
<th>Internal LIS</th>
<th>LIS and EHR are both owned and managed by the same health care entity</th>
</tr>
</thead>
<tbody>
<tr>
<td>External LIS</td>
<td>LIS is owned and managed by a different health care entity than the EHR (i.e., reference lab)</td>
</tr>
</tbody>
</table>
Integrated LIS

**Advantages**
- May be less expensive at contract signature (short-term)
- No interfaces
- Same hardware platform (usually)
- May allow for unique functionality that is hard to do with standard HL7 interfaces

**Disadvantages**
- Will not work when EHR is down
- Functionality may be limited
  - Workarounds, safety issues
- May be more expensive long-term
- May not be usable for highly complex labs
  - HLA (transplant testing), Cytogenetics, Fluorescence *In Situ* Hybridization (FISH), Molecular and Genomics, blood and tissue donors
- May not be usable by simpler labs
  - Microbiology
  - Blood Bank
- Assumption that EHR display doesn’t have to be validated (WRONG!)
- May not work in the absence of an EHR or with multiple EHRs
Interfaced (Separate) LIS

Advantages

• Works in absence of EHR or with multiple EHRs (downtime; reference laboratory)
• Often more amenable to laboratory workflow
  – Less workarounds or safety issues
  – Includes blood bank system
• Specialized LISs better support complex laboratories and tests
  – Genomic revolution
• May be less expensive in the long-term

Disadvantages

• May be more expensive at contract signature (short-term)
• HL7 interfaces and separate hardware have to be purchased and managed
• Some functionality may not be available with standard HL7 interfaces
LIS Management

• **Institutional Management**
  – Central IT staff for the health care entity manage the LIS as well as the EHR
  – Common model with integrated systems

• **Laboratory (Departmental) Management**
  – Laboratory manages the LIS
    • Hardware, software and networks

• **Hybrid Management**
  – IT staff that manage the EHR also manage some, but not all, components of the LIS
    • Hardware and/or networks
  – Laboratory manages the rest of the LIS
Pathologists and Clinical Informatics

• A CMIO is to an EHR what a Director of Pathology Informatics is to an LIS
  – A.k.a. Medical Director of LIS, Chief Pathology Information Officer (CPIO)
• Pathologist specializing in Clinical Informatics
  – Provides medical oversight for the LIS
  – Good resource for laboratory and IT regulations, practice and implementations
Pathologists as Clinical Informaticists

• Pathologists have a long history of clinical informatics practice
  – First publications of laboratory informatics in the 1940s
  – Laboratories were the first areas in hospitals to adopt computer systems
  – American Board of Pathology co-sponsored the application for the Clinical Informatics Exam with the American Board of Preventive Medicine
    • American Board of Pathology initiated the first request to the American Board of Medical Specialties for a subspecialty exam in Informatics the 1990s
  – As of December 2014, percent of all pathologists who are board certified in Clinical Informatics is three times the percent of all non-pathology physicians who are board certified in Clinical Informatics
    • Speaks to data-driven nature of laboratory and pathology practice
Laboratory Regulations and EHRs

• **CLIA**
  – Clinical Laboratory Improvement Amendments of 1988
  – Massive overhaul of Clinical Laboratories Improvement Act of 1967
  – Generated in response to public fury
    • deaths due to false negative Pap smear readings and other laboratory errors
  – Pertains to every laboratory in the USA

http://www.aapsonline.org/msas/clia.php
Laboratory Regulations and EHRs

• **CLIA** (cont.)
  – Requirements for reporting and notification of laboratory results
  – CLIA regulates laboratories, not EHRs
  – Some ambiguity exists regarding electronic laboratory reporting which may be rectified in the future
  – Not always clear where the laboratory’s reporting responsibility ends with relation to the EHR
Laboratory Regulations and EHRs

• **CLIA** (cont.) – 42 CFR § 493.1291(a)
  
  – The laboratory must have adequate manual or electronic systems in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:

  • Results reported from calculated data.
  • Results and patient-specific data electronically reported to network or interfaced systems.
  • Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.
Clinical Informatics Board Review Course

Laboratory Regulations and EHRs

- **CLIA** (cont.) – 42 CFR § 493.1291(c) and (d)
  - The test report must indicate the following:
    - For positive patient identification, either the patient's name and identification number, or an unique patient identifier and identification number.
    - The **name and address of the laboratory location where the test was performed**.
    - The test report date.
    - The test performed.
    - Specimen source, when appropriate.
    - The test result and, if applicable, the **units of measurement** or interpretation, or both.
    - Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.
  - **Pertinent “reference intervals” or “normal” values**, as determined by the laboratory performing the tests, **must** be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.
Laboratory Accreditation and EHRs

• Laboratories must be accredited by CLIA or a CLIA-deemed agency every two years

• College of American Pathologists (CAP) accredits most laboratories in the United States and the world
  – GEN.48500 – Phase II
    • There is a procedure to verify that patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to patient reports (whether paper or electronic).

• Others (AABB, ASHI, COLA, TJC)
Patient Access to Lab Results

HIPAA (before Omnibus Rule)
- Requires a covered entity to provide an individual with a copy of the health information in his/her “designated record set” in the form and format requested by the individual
- **Included exceptions with regard to laboratory results and CLIA, specifically…**
  - this requirement did **NOT** apply to PHI maintained by a covered entity subject to CLIA (**Laboratory**) or exempt from CLIA (**CLIA-exempt laboratory**)  

ONC reported…
- Outcry from patients about lack of access to their own laboratory data
- Outcry from others who perceived CLIA as imposing barriers to health information exchange
Impact of Patient Lack of Access to Laboratory Data

- Rate of failure to inform or document informing the patient of abnormal test results

  7.1%

Patient Access Rule

- SUPERSEDES all state laws on release of laboratory results to patients
- Applies to ALL CLIA laboratories and CLIA-exempt laboratories who...
  - Perform even just ONE HIPAA financial transaction
Patient Access Rule

- Patient can now request a copy of their laboratory results contained within the “designated record set” directly from the laboratory.
- Requirements to comply with request are the same as for health care entities.
- Labs may refer the patient to medical records to comply with the rule IF…
  - Medical records has ALL the requested laboratory results for that patient AND
  - Medical Records is complying with HIPAA regulations for release of information.
- There is NO requirement for the laboratory to interpret the test results for the patient.
- The patient does not have to get permission from the ordering provider to receive the results.
- Reports must be compliant with CLIA reporting requirements.

Clinical Informatics Board Review Course
Other Special Requirements

• **Transfusion (blood bank) systems** are regulated by the FDA
  – High risk (Class III) medical device
  – System makes determinations on what products/organs get transfused/transplanted
  – Guidance on Software validation
    • Has good recommendations for validation of health software in general

Guidelines and Standards

• Clinical and Laboratory Standards Institute
  – www.clsi.org
  – International standards development organization for laboratories
  – Consensus-driven (reflect equal representation from government, industry, and health care professions)

  • AUTO01-A: Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard
  • AUTO02-A: Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition
  • AUTO03-A: Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition
  • AUTO04-A: Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard
  • AUTO05-A: Laboratory Automation: Electromechanical Interfaces; Approved Standard
  • AUTO07-A: Laboratory Automation: Data Content for Specimen Identification; Approved Standard
  • AUTO08-A: Managing and Validating Laboratory Information Systems; Approved Guideline
  • AUTO09-A: Remote Access to Clinical Laboratory Diagnostic Devices via the Internet; Approved Standard
  • AUTO10-A: Autoverification of Clinical Laboratory Test Results; Approved Guideline
  • AUTO11-A: Information Technology Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard—Second Edition
  • AUTO12-A: Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard
  • LIS01-A2: Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition
  • LIS02-A2: Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard—Second Edition
  • LIS03-A: Standard Guide for Selection of a Clinical Laboratory Information Management System
  • LIS04-A: Standard Guide for Documentation of Clinical Laboratory Computer Systems
  • LIS05-A: Standard Specification for Transferring Clinical Observations Between Independent Computer Systems
  • LIS06-A: Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems; Approved Standard
  • LIS07-A: Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory
  • LIS08-A: Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems
LIS-to-EHR Communication

• Challenges for laboratories
  – Personnel may not have access to the EHR
    • Additional barriers if the lab is outside the covered entity for the EHR
  – Too many EHRs
  – EHRs with results from multiple laboratories
  – EHR manipulations of laboratory data \textit{after} result is posted
  – Lab manipulations of laboratory data with unseen downstream impact to EHR
LIS-to-EHR Communication

• For non-lab EHR users and administrators
  – May not recognize how complex or highly regulated the laboratory is
  – May not know they can be cited for non-compliance
  – Are less likely to know when laboratory data is inaccurately displayed during display validation
  • Fail to prevent common errors
Laboratory Automation

• System interfaces
  – Used to communicate information between two databases
  – >99% of laboratory interfaces are HL7 interfaces
    • Real-time for clinical patient care activities
    • Nightly for billing, data warehousing
  – Few “flat-file” interfaces
HL7 Orders Interface

EHR
- Translate to HL7
- Send HL7 msg(s)
- Queue orders

HL7

LIS
- Receive HL7 msg(s)
- Translate to DB records
- Use data
HL7 Results Interface
“Bidirectional” Interfaces

• Information flows in both directions
• Can be complicated to set up

• **Symmetrical**
  – Type of information exchanged in both directions is the **same**
  – Example: ADT messages

• **Asymmetrical**
  – Information flows in both directions, but type of information is **different**
  – Example: Orders in one direction; Results in another
“Unidirectional” Interfaces

- Information flows in **one direction only**
- Often considered less tricky to implement, but often drive...
  - Workflow (e.g., specimen labels)
  - Faxes and printed jobs (e.g., quality review)
  - Movement of specimens down a robotic line
- When broken, can be very problematic
  - Lack of normal workflow triggers
Laboratory Interfaces

- LISs communicate via interfaces with...
  - One to multiple EHRs (internal and/or external)
  - One to multiple outside LISs
    - Reference laboratories (LIS sends orders out)
    - Outreach laboratories (LIS receives orders in)
  - One to multiple middleware servers
    - Automation line servers
    - Point of Care device management
    - Blood typing instrument management
    - Autoverification management
  - Many, many laboratory instruments
  - Billing systems
Automation Line

• Robotically operated specimen track which moves specimens from point of entry to the instrument that will perform the test
  – Scans specimen label barcode
  – Uses accession # from barcode to query LIS for pending orders
  – Sends the sample to the appropriate instrument for testing
Autoverification

- Process whereby computer-based algorithms automatically perform actions on a defined subset of laboratory results without the need for manual intervention by a medical technologist, laboratorian or pathologist.
- Results that fall within certain reference ranges may be automatically verified (signed and released) by the middleware instead of a person.
- Can do 10x as many laboratory tests with the same number of employees.
  - When it isn’t working, volume may quickly outpace staff’s ability to keep up.

Barcodes

• Code used to represent alphanumeric characters, like an accession number or encounter number
• Can be “read” by a barcode scanner and decoded into the original data
• Advantages
  – Reduces manual typing errors
  – Improves speed of data entry
• Strong recommendations supported by guidelines: ensure that the human-readable version of the encoded data is always printed next to the barcode
# Linear Barcodes

<table>
<thead>
<tr>
<th>Code</th>
<th>0123456789</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code 39</td>
<td>0123456789</td>
</tr>
<tr>
<td>Code 128A</td>
<td>0123456789</td>
</tr>
<tr>
<td>Code 128B</td>
<td>0123456789</td>
</tr>
<tr>
<td>Code 128C</td>
<td>0123456789</td>
</tr>
</tbody>
</table>
Linear (1D) barcodes

• Disadvantages
  – Very space intensive (take up a lot of real estate) for the amount of data encoded
  – Damage and misprints can result in substitution errors (data decoded is not what was intended for printing) at an alarmingly high rate (1 in 88,000 barcodes on armbands)
  – No way to know what piece of data was encoded into the barcode
    • Is it an MRN, Financial number or Master Patient Index?

2D Barcodes

- Encoded data represented in two dimensions
- Two major types
  - Stacked 1D
    - e.g., PDF417
  - Matrix
    - QR code
    - DataMatrix
    - Aztec

• “The AMIA Clinical Informatics Board Review Course”

PDF417

DataMatrix

QR code
## Barcodes

<table>
<thead>
<tr>
<th>Type of Error</th>
<th>Estimated Unrecognized Character Error Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual Entry</td>
<td>1 in 300</td>
</tr>
<tr>
<td>1D barcode</td>
<td>1 in (90,000^*) to 37 million</td>
</tr>
<tr>
<td>2D/matrix barcode</td>
<td>1 in sextillions ((10^{21}))</td>
</tr>
</tbody>
</table>

## Linear (1D) vs. 2D barcodes

<table>
<thead>
<tr>
<th>Feature</th>
<th>1D Barcode</th>
<th>2D Barcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data density – amount of data it can contain</td>
<td>Usually only 1 identifier</td>
<td>Multiple identifiers</td>
</tr>
<tr>
<td>Can encode redundancy of data</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Damage/Printer Error Correction and Detection Algorithms</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Number of data integrity checks</td>
<td>0 (most 1D barcodes) OR 1 (Code 128 only)</td>
<td>&gt;1</td>
</tr>
<tr>
<td>Ease of installation</td>
<td>Easy</td>
<td>Harder</td>
</tr>
</tbody>
</table>
RFID

• **Radio Frequency Identification**
  – Uses radio waves to broadcast data from an electronic tag mounted on an object to a scanner/reader
  – Some can be read from several meters away and beyond the line of sight of the reader
  – Bulk reading is possible
  – U.S. Passports and many other items now have RFIDs
RFID

• Two types (and a hybrid)
  – **Passive RFID**
    • does *not* use a battery
  – **Active RFID**
    • has an on-board battery
    • *always* broadcasts or beacons its signal
  – **Battery-assisted passive (BAP) RFID**
    • small battery on board
    • activated when in the presence of a RFID reader
## Barcodes vs. RFID

<table>
<thead>
<tr>
<th>Item</th>
<th>Barcodes</th>
<th>RFID tags</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item must be in scanner’s line of sight</td>
<td>Yes</td>
<td>Not always</td>
</tr>
<tr>
<td>Bulk scanning possible</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Prone to damage</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Can be used to locate a missing specimen?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Discarded items can be scanned in error?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Easy to make HIPAA compliant</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Cost</td>
<td>Cheap</td>
<td>Expensive</td>
</tr>
<tr>
<td>Interference problem with multiple items next to each other?</td>
<td>No</td>
<td>Yes (items closer than 1 cm will interfere with the signal)</td>
</tr>
</tbody>
</table>
Question: According to the Patient Access Rule, which of the following is correct:

A. Patients must go to medical records to obtain a copy of their laboratory data
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A. Barcode readers know what data is encoded in a 2D barcode automatically but they don’t with 1D barcodes.

B. 2D barcodes never require special software in the laboratory information system to read them (unlike 1D barcodes).

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Basics of Digital Imaging

• **Pixel**
  – Smallest component of an image
  – Print vs. digital

• **Image Size**
  – Overall size of the image in its final form (digital or printed)
  – Width by height
  – Contains no information on image resolution
  – Important to know if need to decide on resolution
Basics of Digital Imaging

• **Image resolution**
  – A.k.a *pixel density*
  – Commonly referenced as **Dots per inch (DPI)**
    • The number of pixels per inch of screen
    • The number of printed pixels per inch of print medium
    • Average computer screen DPI = 96
    • Average printed DPI = 300 (can vary significantly)
Basics of Digital Imaging

• Image resolution (continued)
  – Gross images → low resolution OK
  – Microscopic images → high resolution desired
  – NOTE: Balance resolution against the final image size desired
    • Small image size → low resolution
    • Large image size → high resolution
Image Compression

• To compress or not to compress…
  – **Image Compression**
    • Reducing the amount of memory that an image occupies by various mathematical algorithms
    • May be lossy or lossless
Image Compression

- **Lossless** image compression
  - Memory (file size) is reduced but...
  - All original image data can be recovered
  - Examples: PNG and GIF

- **Lossy** image compression
  - Some original data in the photo is gone forever
  - Amount of compression is proportional to the amount of loss
  - Well-designed → substantial data reduction without obvious loss to the end-user
  - Example: standard JPG

- Example file types using either type of compression: TIFF, MNG, some JPG

- Lossy and lossless compression algorithms can also be used for audio (e.g., MP3) and video (e.g., MPEG)
Image Compression

• How compression works (the really over-simplified model...)

The decision to use lossy vs. lossless may depend on the media type
Telepathology

• Has a specific meaning compared to all other forms of digital pathology

• Diagnosis which results in a report is rendered from a digital microscopic image ONLY
  – No cheating and looking at the glass slides
Telepathology

• Differs from teleradiology in that the image cannot be acquired directly from the specimen/patient
Definitions in Telepathology

• **Static Telepathology**
  – Entire image is captured then transmitted
  – Transmission can be *in toto* or in pieces (tiling)

• **Dynamic Telepathology**
  – Live video feed
  – With or without remote control of scanner

• **Hybrid telepathology** systems do both
Telepathology Regulations

- Vary from state to state
- Not the same as for teleradiology
- CLIA still applies to laboratories
- College of American Pathologists has telepathology standards for laboratory accreditation
- FDA
  - Whole slide imaging devices are Class III
  - Require premarket approval when intended to be used for primary diagnosis
  - Draft guidance issued on February 25, 2015 regarding technical performance assessment of WSI systems for regulatory evaluation

NGS - Overview

• Next-generation sequencing
• Better term: massively parallel sequencing
• DNA is sequenced in short overlapping fragments then aligned to the reference and variants detected
DNA Testing – Next Generation Sequencing

Integrated Genomics Viewer  https://www.broadinstitute.org/software/igv/download

Clinical Informatics of Genomic Information

• Next-generation sequencing
  – High-throughput genetic analysis
  – Analysis requires intensive computational processing
  – Results not decipherable without computational algorithms
    • no electropheresis gel or electropherogram to look at
  – People are rarely talking about anything else
  – Good example of big data analysis
  – US Federal Government scrutiny
DNA Testing – More bases for $$$

http://core-genomics.blogspot.com/2015/01/the-not-so-rapid-decreasing-costs-of.html
DNA Testing – Today vs. Before

Previously
- Testing each gene required many tests
- Expensive to do more than one gene
- Could not test entire DNA

Today (Next-Generation)
- Can sequence many, many genes at one time
- Cost per amount of DNA has decreased a lot
- Can find more variants with less money
NGS Bioinformatics Pipeline

• Bioinformatics pipeline
  – Multiple sets of one or more computational algorithms performed in series to analyze biological data
  – Not limited to NGS data
• Critical to collect and check quality metrics along the way
• Many, many software packages with variable quality

Raw sequence data → Demultiplexing
• Packaging into FASTQ files

FASTQ file
• Align sequences to reference genome
• Generate SAM file; Compress to BAM File

BAM file
• Computation to detect variants from reference

VCF file

Interpretation

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Big Data

• So what is big data? Why do we care?
• High quality Computational Pathology is rooted in sound principles of analyzing and using big data
• Characterized by three Vs:

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Big Data

• So what is big data? Why do we care?
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• Characterized by **three** Vs:

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</tr>
</thead>
<tbody>
<tr>
<td><strong>Variety</strong></td>
<td>Many different types of data</td>
</tr>
<tr>
<td><strong>Velocity</strong></td>
<td>Constantly accumulating new data</td>
</tr>
</tbody>
</table>

Big Data

• Many people think big data refers to:
  – Next generation sequencing
    • FASTQ, BAM and VCF files have volume but lack velocity and variety unless…
      – Multi-patient exome/genome level sequences acquired on an ongoing basis from different analyzers
    • Is definitely big data, regardless of input, when you are trying to interpret variants produced
    • Online genomic references to help determine significance of variants are
      – Are constantly being updated by multiple (often anonymous) sources
      – Data may be unstructured
      – Data often uncurated
Big Data

• Many people think big data refers to:
  – Whole slide imaging
    • Imaging files similarly have volume (per file) but generally lack velocity and variety unless…
      – Continuous acquisition of whole slide images from multiple patients and sites on different whole slide imaging instruments
    • Most laboratories are not producing as many whole slide images as slides per day (nowhere close)
    • From a limited set of instruments
Big Data

• Many people think big data refers to:
  – Image analysis
    • Clinical use relatively restricted (ER, PR, HER2 and a few others)
    • Is only big data when uses multiple algorithms developed by different programmers for various features with secondary interpretation
Big Data

• Other (less commonly thought of) examples of big data:
  – Laboratory Information System (LIS)
  – Electronic Health Record (EHR)
  – Why?

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</tbody>
</table>
Small data

Structured data

Knowledge

Tools

ACTIONABLE
BIG data

Unstructured BIG data

Structured data

Tools

Knowledge

ACTIONABLE

Clinical Informatics Board Review Course
### Privacy and Genetic Information

<table>
<thead>
<tr>
<th>Federal Law</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIPAA Final Security Rule</td>
<td>Apr 21, 2003</td>
</tr>
<tr>
<td>Health Information Technology for Economic and Clinical Health Act (HITECH)</td>
<td>Feb 17, 2009</td>
</tr>
<tr>
<td>Genetic Information Non-discrimination Act (GINA)</td>
<td>May 21, 2009</td>
</tr>
<tr>
<td>HIPAA Omnibus Rule</td>
<td>Sep 23, 2013</td>
</tr>
</tbody>
</table>
GINA

- Genetic Information Nondiscrimination Act of 2008 (GINA)
- Generally prohibits group health plans and health insurance issuers from
  - discriminating based on genetic information
  - requesting or requiring genetic testing
  - collecting of genetic information
GINA

• Defined “genetic information”
  – **Genetic services**: genetic tests, genetic counseling, or genetic education
  – **Genetic tests**: analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes
    • Does **not** include an analysis of proteins or metabolites directly related to a manifested disease, disorder, or pathological condition
HIPAA Omnibus

• In effect September 23, 2013
• Requires “Genetic Information” (as defined by GINA) to be treated as PHI under HIPAA
  – Genetic information must first be individually identifiable
  – HUGE implications for research on genetic material
  – i.e., Genetic information cannot be de-identified
That’s a wrap!

- The EHR-LIS relationship
  - EHR-LIS Architectures
  - Support Models for LISs
  - Laboratory Regulations and Standards that may impact EHRs
- The Laboratory as an Automation Driver
  - Interfaces and automation lines
  - Barcodes
  - Radiofrequency Identification Tags (RFID)
- Basics of digital imaging
  - Telepathology
That’s a wrap!

• Genomic data
  – Impact on clinical informatics
  – Next-generation sequencing and bioinformatics
  – Genomic data privacy
• Big data
• Computational pathology
Additional Suggested Readings

Answer: According to the Patient Access Rule, which of the following is correct:

A. Patients must go to medical records to obtain a copy of their laboratory data
B. Patients are entitled to their laboratory results immediately after requesting them
C. Patients can request only verified results directly from the laboratory
D. Patients have to get permission from their physician to request a copy of their lab results

Patients may request laboratory results directly from a laboratory. This rule supersedes all state laws regarding release of laboratory results directly to patients from laboratories. Laboratories have up to 30 days to comply with the patient’s request, and patients do not have to get permission from their ordering provider to make this request from the laboratory.
**Answer:** **Two-dimensional (2D) barcodes are superior to linear (one-dimensional or 1D) barcodes because:**

A. Barcode readers know what data is encoded in a 2D barcode automatically but they don’t with 1D barcodes.

B. 2D barcodes never require special software in the laboratory information system to read them (unlike 1D barcodes).

C. **2D barcodes can contain multiple data elements where 1D barcodes can usually only just contain one data element.**

D. 2D barcodes are easier to setup and install than 1D barcodes.

Because of their significantly greater data density, two-dimensional barcodes may contain multiple data elements where one-dimensional barcodes, in most cases in healthcare, only contain one data element such as an accession number for a laboratory specimen or medical record number on a patient’s armband. Similar to one-dimensional barcodes, two-dimensional barcodes by themselves do not indicate what type of data is encoded. Because two-dimensional barcodes have significantly higher data density, descriptors can be included in the encoded content, but these descriptors still require software to interpret them. Both one-dimensional and two-dimensional barcodes may require special software in order to read them, particularly if they encode more than one data element. Outside of ISBT 128 barcodes, linear barcodes rarely contain more than one data element, whereas it is more common to find multiple data elements encoded in two-dimensional barcodes. Therefore, the need for additional software to interpret multi-element data can make set up of two-dimensional barcodes more difficult than non-ISBT 128 linear barcodes.
P1 - Pathology Informatics

References

Free online resources


Additional Resources (not free)
2A-3: Knowledge Acquisition and Use for Clinical Decision Support

William Hersh, MD, FACP, FACMI
Oregon Health & Science University
Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
      1.1.1. The discipline of informatics
      1.1.2. Key informatics concepts, models, and theories
      1.1.3. Clinical informatics literature
      1.1.4. International clinical informatics practices
      1.1.5. Ethics and professionalism
      1.1.6. Legal and regulatory issues
   1.2. The Health System
      1.2.1. Determinants of individual and population health
      1.2.2. Primary domains, organizational structures, cultures, and processes
      1.2.3. The flow of data, information, and knowledge within the health system
      1.2.4. Policy & regulatory framework
      1.2.5. Health economics and financing
      1.2.6. Forces shaping health care delivery
      1.2.7. Institute of Medicine quality components

2. Clinical Decision Making and Care Process Improvement
   2.1. Clinical Decision Support
      2.1.1. The nature and cognitive aspects of human decision making
      2.1.2. Decision science
      2.1.3. Application of clinical decision support
   2.1.4. Transformation of knowledge into clinical decision support tools
   2.1.5. Legal, ethical, and regulatory issues
   2.1.6. Quality and safety issues
   2.1.7. Supporting decisions for populations of patients
   2.2. Evidence-based Patient Care
      2.2.1. Evidence sources
      2.2.2. Evidence grading
      2.2.3. Clinical guidelines
      2.2.4. Implementation of guidelines as clinical algorithms
      2.2.5. Information retrieval and analysis
   2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
      2.3.1. Methods of workflow analysis
      2.3.2. Principles of workflow re-engineering
      2.3.3. Quality improvement principles and practices

3. Health Information Systems
   3.1. Information Technology Systems
      3.1.1. Computer Systems
      3.1.2. Architecture
      3.1.3. Networks
      3.1.4. Security
      3.1.5. Data
      3.1.6. Technical approaches that enable sharing data
      3.1.7. Human Factors Engineering
      3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
      3.2.2. HCI Evaluation, usability testing, study design and methods
      3.2.3. Interface design standards and design principles
      3.2.4. Usability engineering
      3.3. Health Information Systems and Applications
      3.3.1. Types of functions offered by systems
      3.3.2. Types of settings where systems are used
      3.3.3. Electronic health/medical records systems as the foundational tool
      3.3.4. Telemedicine
      3.4. Clinical Data Standards
      3.4.1. Standards development history and current process
      3.4.2. Data standards and data sharing
      3.4.3. Transaction standards
      3.4.4. Messaging standards
      3.4.5. Nomenclatures, vocabularies, and terminologies
      3.4.6. Ontologies and taxonomies
      3.4.7. Interoperability standards
   3.5. Information System Lifecycle
      3.5.1. Institutional governance of clinical information systems
      3.5.2. Clinical information needs analysis and system selection
      3.5.3. Clinical information system implementation
      3.5.4. Clinical information system testing, before, during and after implementation
      3.5.5. Clinical information system maintenance
      3.5.6. Clinical information system evaluation

4. Leading and Managing Change
   4.1. Leadership Models, Processes, and Practices
      4.1.1. Dimensions of effective leadership
      4.1.2. Governance
      4.1.3. Negotiation
      4.1.4. Conflict management
      4.1.5. Collaboration
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      4.1.7. Decision making
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      4.6.2. Change theories
      4.6.3. Change management strategies
      4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core content covered

2.1.4. Transformation of knowledge into clinical decision support tools
   2.1.4.1 Knowledge generation
   2.1.4.2 Knowledge acquisition
   2.1.4.3 Knowledge modeling
   2.1.4.4 Knowledge representation
   2.1.4.5 Knowledge management and maintenance
2.1.5 Legal, ethical, and regulatory issues
2.1.6 Quality and safety issues
2.1.7 Supporting decisions for populations of patients
Key topics

• Approaches to representing knowledge in clinical decision support systems from the past and present
• Known problems of safety with health IT systems and how they can be minimized
• Current legal and regulatory framework for clinical decision support
2A-3: Knowledge Acquisition and Use for Clinical Decision Support

- Knowledge generation
- Knowledge acquisition
- Knowledge modeling
- Knowledge representation
- Knowledge management and maintenance
- Legal, ethical, and regulatory issues
- Quality and safety issues
- Supporting decisions for populations of patients
Knowledge generation (Hersh, 2009)

Secondary publications → Original research → Public data repository

Original research → Publish → Revisit

Revisit → Peer review

Peer review → Submit for publication

Submit for publication → Write up results

Write up results → Publish

Publish → Relinquish copyright

Relinquish copyright → Reject

Reject → Accept
Knowledge acquisition (Hersh, 2009)

All literature → Possibly relevant literature → Definitely relevant literature → Structured knowledge

Information retrieval

Information extraction, text mining
Knowledge modeling and representation

- Functions of systems tightly linked to methods for knowledge representation
- Four general approaches
  - Clinical algorithms
  - Bayesian statistics
  - Production rules
  - Scoring and heuristics
- Current approaches take advantage of modern EHRs and other advances
Clinical algorithms

• Follow path through “flow chart”
• Elements in chart are nodes
  – Data is gathered at information nodes
  – Decisions are made at decision nodes
Clinical algorithms (cont.)

• Benefits
  – Knowledge is explicit
  – Knowledge is easy to encode

• Limitations
  – No accounting for prior results
  – Inability to pursue new etiologies, treatments, etc.
  – New knowledge difficult to generate

• Forerunner of modern clinical practice guidelines
Bayesian statistics

• Based on Bayes’ theorem, which calculates probability based on prior probability and new information

• Assumptions of Bayes’ theorem
  – Conditional independence of findings – no relationship between different findings for a given disease
  – Mutual exclusivity of conditions – one finding can only explain one disease
Bayes’ Theorem generalized form

• Probability of disease i in the face of evidence E, out of a set of possible j diseases is:

\[
P(D_i | E) = \frac{P(D_i) P(E | D_i)}{\sum_{j} P(D_j) P(E | D_j)}
\]

• Translation of formula: probability of a disease given one or more findings can be calculated from
  – The prior probability of the disease – sometimes can be estimated from prevalence of disease
  – The probability of findings occurring in the disease
Implementation and limitations of Bayesian approach

• Leeds Abdominal Pain System (de Dombal, 1975)
  – Most successful implementation, used in diagnosis of acute abdominal pain
  – Performed better than physicians – accuracy 92% vs. clinicians 65-80%, better in 6 of 7 disease categories
  – But difficult to use and not transportable to other locations (Berg, 1997)

• Limitations of Bayesian statistics
  – Findings in a disease are usually not conditionally independent
  – Diseases themselves may not be mutually exclusive
  – When multiple findings important in diagnosis, reaches high computational complexity quickly
Production rules

- Knowledge encoded as IF-THEN rules
- System combines evidence from different rules to arrive at a diagnosis
- Two types of rule-based ESs:
  - Backward chaining – System pursues goal and ask questions to reach goal
  - Forward chaining – Similar to clinical algorithms, with computer following proscribed path to reach answer
- Generic rule: IF test-X shows result-Y THEN conclude Z (with certainty p)
The first rule-based ES in medicine: MYCIN

- PhD dissertation of Shortliffe (1975) and one of the first applications in medical informatics
- Major features
  - Diagnosed the infectious diseases, meningitis and bacteremia
  - Used backward chaining approach
  - Asked questions (relentlessly!) in an attempt to reach diagnosis
- Evaluation of MYCIN (Yu, 1979)
  - 10 cases of meningitis assessed by physician experts and MYCIN; output judged by other physician experts
  - Recommendations of experienced physicians judged acceptable 43-63% of the time, compared with 65% of the time for MYCIN
  - In no cases did MYCIN fail to recommend an antibiotic that would cover the infection (even if it was not optimal choice)
Limitations of rule-based systems

• Depth-first searching could lead to focus in wrong area
• Rule bases were large and difficult to maintain
  – MYCIN had 400 rules covering two types of bacterial infection
  – Approach worked better in constrained domains, such as pulmonary function test interpretation
• Systems were slow and time-consuming to use
  – Rule-based goal seeking could take long time
  – System also developed prior to era of modern computers and graphical user interfaces, making data entry time-consuming
Scoring and heuristics

- Knowledge is represented as profiles of findings that occur in diseases
- There are measures of importance and frequency for each finding in each disease
- Found to be most “scalable” approach for comprehensive decision support systems
- Examples – INTERNIST-1/QMR, Dxplain, Iliad
History of systems using scoring and heuristics approach

• INTERNIST-1
  – Original approach, aimed to develop an expert diagnostician in internal medicine (Miller, 1982)
  – System originally designed to mimic the expertise of an expert diagnostician at the University of Pittsburgh, Dr. Jack Meyers
  – Evolved into Quick Medical Reference (QMR) where goal changed to using knowledge base explicitly (Miller, 1986)

• DxPlain used principles of INTERNIST-1/QMR but developed more disease coverage (Barnett, 1987)
  – Only system still available: http://www.lcs.mgh.harvard.edu/dxplain.asp

• Iliad attempted to add Bayesian statistics to the approach (Warner, 1989)
INTERNIST-1/QMR knowledge representation

- Disease profiles – findings known to reliably occur in the disease
- Findings – from history, exam, and laboratory
- Import – each finding has a measure of how important it is to explain (e.g., fever, chest pain)
- Properties – e.g., taboos, such as a male cannot get pregnant and a female cannot get prostate cancer
Findings in diseases

• For each finding that occurs in each disease, there are two measures
  – Evoking strength – the likelihood of a disease given a finding
    • Scored from 0 (finding non-specific) to 5 (pathognomonic)
  – Frequency – the likelihood of a finding given a disease
    • Scored from 1 (occurs rarely) to 5 (occurs in all cases)
# Disease profile for acute myocardial infarction

## Dx: MYOCARDIAL INFARCTION ACUTE

<table>
<thead>
<tr>
<th>Finding</th>
<th>Ev</th>
<th>Fr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Past Medical History...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptoms of Current Illness...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chest Pain Substernal At Rest</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Chest Pain Substernal Lasting 20 Minute(s) Or Gtr</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Chest Pain Substernal Unrelieved By Nitroglycerin</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Onset Abrupt</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Chest Pain Substernal Crushing</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Chest Pain Substernal Radiating To Neck And/Or Upper Extremity(ies)</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Chest Pain Substernal Severe</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Abdomen Pain Acute</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Abdomen Pain Epigastrium</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Abdomen Pain Epigastrium Unrelieved By Antacid</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Abdomen Pain Exacerbation With Exercise</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Abdomen Pain Non Colicky</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Abdomen Pain Present</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Abdomen Pain Severe</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
INTERNIST-1/QMR scoring algorithm

• Initial positive and negative findings are entered by user
• A disease hypothesis is created for any disease that has one or more of the positive findings entered
• Each disease hypothesis gets a score
  – Positive component based on evoking strengths of all findings
  – Negative component of score based on frequency from findings expected to occur but which are designated as absent
• A diagnosis is made if the top-ranking diagnosis is >80 points (one pathognomonic finding) above the next-highest one
  – When diagnosis made, all findings for a disease are removed from the list, and subsequent diagnoses are made
• Performed as well as experts in NEJM clinical cases (Miller, 1982)
Limitations of INTERNIST-1 and evolution to QMR

• Limitations
  – Long learning curve
  – Data entry time-consuming
  – Diagnostic dilemmas not a major proportion of clinician information needs
  – Knowledge base incomplete

• Evolution to QMR (Miller, 1986)
  – Less value in “case” mode
  – More value in knowledge exploration mode, e.g.,
    • Rule diseases in and out
    • Obtain differential diagnoses
    • Link to more detailed information
  – Became commercial product but did not succeed in marketplace
Toward the modern era

• By the late 1980s and early 1990s, it was apparent that
  – Diagnostic process was too complex for computer programs
  – Systems took long time to use and did not provide information that clinicians truly needed
  – “Greek Oracle” model was inappropriate to medical usefulness (Miller, 1990)

• Recent studies still demonstrate limited utility for expertise-based artificial intelligence
  – Best systems still cannot pass eighth-grade science tests (Knight, 2016)
  – Systematic review of differential diagnosis generators shows that, while accurate, they generate limited value (Riches, 2015)

• Decision support evolved in the 1990s with recognition of its value within EHR
  – Rules and algorithms most useful in this context
  – Evolution from broad-based diagnostic decision support to more focused CDS
Where are we headed now?

- Evolved to “clinical decision support” (CDS) in the 1990s with recognition of their value within EHR
  - Production rules → simpler rules
  - Algorithms → clinical practice guidelines
- Many grand challenges remain (Sittig, 2008)
- Now being implemented on wider scale in operational EHRs (Osheroff, 2012)
- Should FDA regulate? View so far is that systems akin to textbooks, with humans between patient and system, but could change
Although the quest for diagnostic decision support continues

- Isabel (www.isabelhealthcare.com) – “Second generation” approach uses
  - Natural language processing to map entered text into findings
  - List of differential diagnosis with 30 most likely diagnoses grouped by body system, not probability

- Performance studies
  - In ED, displayed correct diagnosis 95% of time and 90% of time showed “must-not-miss” diagnoses (Ramnarayan, 2007)
  - In internal medicine, pasting in text from NEJM case reports had correct diagnosis suggested in 48 of 50 cases for key text and 37 of 50 cases for all text (Graber, 2008)
  - In UK primary care, 36% of uses led to broadened differential diagnosis, 29% led to no specialist referral being needed, and 36% made referral more appropriate (Maude, 2010)
  - But still too time-consuming to use in clinical practice routinely (Henderson, 2013)
Other continuing approaches

• “Googling” for a diagnosis? Large quantity of text in Google may hold latent knowledge
  – Found in a case study to make diagnosis of a rare condition (Greenwald, 2005)
  – When text of NEJM cases entered, 15 of 26 had correct diagnosis in top three suggested (Tang, 2006)
• “Patients like my patient” in EHR may yield similar cases that can inform decisions (Shirts, 2013)
• Patient symptom-checkers – analysis of 23 found deficiencies in triage and diagnosis, often advising care when self-care is reasonable (Semigran, 2013)
Knowledge management (KM) and maintenance

- Many healthcare organizations and EHR systems maintain knowledge assets in different ways (Wright, 2011)
- Recommended practices for CDS and KM include attention to 1) workflow; 2) knowledge management; 3) data as a foundation for CDS; 4) user-computer interaction; 5) measurement and metrics; 6) governance; 7) translation for collaboration; 8) the meaning of CDS; 9) roles of special, essential people; and 10) communication, training, and support (Ash, 2012)
- Commercial solutions the answer?
  - e.g., Zynx, Lexicomp, EHR vendors, etc.
Other knowledge acquisition and use issues

- Legal, ethical, and regulatory issues – many complex issues, but CDS still viewed as “open loop” system, i.e., clinician between patient and system (Bates, 2011)

- Quality and safety issues – recognized need to view health IT as potentially dangerous (Sittig, 2009; Sittig, 2012; IOM, 2012)

- Supporting decisions for populations of patients – CDS applied to population health management (Gauthier, 2014)
Additional suggested readings

• Key

• Supplemental


3A-1: Computer Programming & Methods of Software Development

Bimal R. Desai, MD, MBI, FAAP

The Children’s Hospital of Philadelphia
Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
      1.1.1. The discipline of informatics
      1.1.2. Key informatics concepts, models, and theories
      1.1.3. Clinical informatics literature
      1.1.4. International clinical informatics practices
      1.1.5. Ethics and professionalism
      1.1.6. Legal and regulatory issues
      1.2. The Health System
         1.2.1. Determinants of individual and population health
         1.2.2. Primary domains, organizational structures, cultures, and processes
         1.2.3. The flow of data, information, and knowledge within the health system
         1.2.4. Policy & regulatory framework
         1.2.5. Health economics and financing
         1.2.6. Forces shaping health care delivery
         1.2.7. Institute of Medicine quality components

2. Clinical Decision Making and Care Process Improvement
   2.1. Clinical Decision Support
      2.1.1. The nature and cognitive aspects of human decision making
      2.1.2. Decision science
      2.1.3. Application of clinical decision support
      2.1.4. Transformation of knowledge into clinical decision support tools
      2.1.5. Legal, ethical, and regulatory issues
      2.1.6. Quality and safety issues
      2.1.7. Supporting decisions for populations of patients
      2.2. Evidence-based Patient Care
         2.2.1. Evidence sources
         2.2.2. Evidence grading
         2.2.3. Clinical guidelines
         2.2.4. Implementation of guidelines as clinical algorithms
         2.2.5. Information retrieval and analysis
      2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
         2.3.1. Methods of workflow analysis
         2.3.2. Principles of workflow re-engineering
         2.3.3. Quality improvement principles and practices

3. Health Information Systems
   3.1. Information Technology Systems
      3.1.1. Computer Systems
      3.1.2. Architecture
      3.1.3. Networks
      3.1.4. Security
      3.1.5. Data
      3.1.6. Technical approaches that enable sharing data
      3.2. Human Factors Engineering
      3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
      3.2.2. HCI Evaluation, usability testing, study design and methods
      3.2.3. Interface design standards and design principles
      3.2.4. Usability engineering
      3.3. Health Information Systems and Applications
      3.3.1. Types of functions offered by systems
      3.3.2. Types of settings where systems are used
      3.3.3. Electronic health/medical records systems as the foundational tool
      3.3.4. Telemedicine
      3.4. Clinical Data Standards
      3.4.1. Standards development history and current process
      3.4.2. Data standards and data sharing
      3.4.3. Transaction standards
      3.4.4. Messaging standards
      3.4.5. Nomenclatures, vocabularies, and terminologies
      3.4.6. Ontologies and taxonomies
      3.4.7. Interoperability standards
      3.5. Information System Lifecycle
      3.5.1. Institutional governance of clinical information systems
      3.5.2. Clinical information needs analysis and system selection
      3.5.3. Clinical information system implementation
      3.5.4. Clinical information system testing, before, during and after implementation
      3.5.5. Clinical information system maintenance
      3.5.6. Clinical information system evaluation

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Core Content Covered

3.1 Information Technology Systems

3.1.1 Computer Systems

3.1.1.1 Programming

3.1.1.2 Data and control structures

3.1.1.3 Software development methods
  (e.g., agile, waterfall, spiral, rapid prototyping)

3.1.1.4 System integration

3.1.1.5 Quality
Key Topics

• Understand binary representation, simple examples of Boolean algebra, and how these can be used to perform calculation.
• Distinguish low-level and high-level programming languages, distinguish RISC and CISC instructions
• Understand differences between imperative, procedural, and object-oriented programming languages.
• Give examples of common data structures; use the example of date representations to illustrate how choice of data structure influences its use.
• Using pseudo-code, be able to define a clinical rule using each of the following control structures: “IF-THEN-ELSE”, “CASE”, “FOR loop”, and “WHILE loop”.
• Recognize that different software development methodologies exist and that each has different approaches to requirement gathering, scope definition, and risk mitigation.
• Understand how software systems may be integrated through interfaces, messaging standards, and web services.
• Distinguish “black-box” and “white-box” software testing; software verification and software validation.
• Give clinical examples of software testing strategies such as beta testing, testing, and regression testing following system enhancement.
3A-1 Computer Programming & Software Development Methods

- Binary, Bits, Bytes, and Boolean Algebra
- Levels of programming languages
- Programming paradigms
- Data Structures
- Control Structures
- Software Development Methodologies
- System Integration
- Quality Assurance & Testing
Binary, Bits, and Bytes

• Computers represent data in binary
  – Ex: text is encoded in ASCII, which can be represented as 8-bit binary (ISO 8859-1, or ISO Latin-1)
  – Contrast ASCII/ISO 8859-1 (8-bit) to Unicode (16-bit), which allows encoding of most of the world’s languages
  – Because 16 is a power of 2, base-16 (hexadecimal) is a compact way of relaying binary information. An 8-bit binary ASCII-encoded character can be represented as a 2-digit HEX
    • ASCII: “informatics”
    • HEX: “69 6e 66 6f 72 6d 61 74 69 63 73”
    • BIN: “01101001 01101110 01100110 01101111 01110010 01101101 01100001 01110100 01101001 01100011 01110011”

• Bit = contraction of “binary digit”, also convenient for logical and algebraic information (Boolean “true”/”false”, pos/neg)
• Byte = 8 bits
From Bits to Boole

- George Boole (1815-1864) was an English mathematician, logician
  - Invented “Boolean algebra”, basis for digital computation

<table>
<thead>
<tr>
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<th>Notation(s)</th>
<th>Venn Diagram</th>
<th>Logic Gate Diagram</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conjunction (AND)</td>
<td>$a \land b$</td>
<td>$A \cap B$</td>
<td><img src="image" alt="AND gate" /></td>
</tr>
<tr>
<td></td>
<td>$a \cdot b$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disjunction (OR)</td>
<td>$a \lor b$</td>
<td>$A \cup B$</td>
<td><img src="image" alt="OR gate" /></td>
</tr>
<tr>
<td></td>
<td>$a + b$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negation (NOT)</td>
<td>$\neg a$</td>
<td>$\overline{A}$</td>
<td><img src="image" alt="NOT gate" /></td>
</tr>
<tr>
<td></td>
<td>$\sim a$</td>
<td></td>
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<tr>
<td></td>
<td>$\sim a$</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Digital Logic Gates

- Digital circuits can mimic Boolean algebra
- Logic gate diagrams show idealized versions of these circuits
- Combining these circuits allows for complex calculation
- Let’s look at a few more Boolean operations and logic gate diagrams
  - XOR (exclusive OR) – returns TRUE if either A or B is true, but not both
  - NAND (NOT AND) – returns TRUE unless both A and B are TRUE
  - NOR (NOT OR) – returns TRUE only when both A and B are FALSE

How Computers Add Binary Numbers

- Imagine A and B are 1-bit binary values. We can model the output of this logic gate circuit with a Truth Table.
- If C (carry) and S (sum) represent the $2^1$ and $2^0$ positions of a 2-bit binary number, note that this series of logic gates, with one “XOR” gate and one “AND” gate, is performing a simple addition function.
- This digital circuit is called a “half adder”. There are, of course, more complicated versions that can perform more complicated math.

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C (A AND B)</th>
<th>S (A XOR B)</th>
<th>Binary calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>$1 + 1 = 10$</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>$1 + 0 = 1$</td>
</tr>
<tr>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>$0 + 1 = 1$</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>$0 + 0 = 0$</td>
</tr>
</tbody>
</table>
Transistors and Integrated Circuits

- Transistors, invented in 1947, replaced vacuum tubes as the fundamental building block of electronic devices.
- Make use of silicon semiconductors to make a switch with no moving parts that can be controlled with a small current.
- Can be combined to build logic gates - a single logic gate might need 20 transistors.
- These days, transistors, resistors, diodes and capacitors are prepackaged onto integrated circuits (ICs).
- Your smartphone has 100 million transistors, your PC has over a billion, and each is only 22 nanometers wide.
- At some point, will reach theoretical size limit. The end of Moore’s law? Not quite – there are a few tricks left, like 3D instead of planar transistors.
Why More Transistors is Better

- **Moore’s law** predicts that the number of transistors on an integrated circuit doubles every two years, and therefore so will speed.
- Allows computers to do billions of calculations per second.
- **FLOP** is measure of computational speed = Floating-point Operations Per Second.
- A giga-FLOP (GFLOP) is a billion floating point operations.

*Image credit: [http://upload.wikimedia.org/wikipedia/commons/0/00/Transistor_Count_and_Moore%27s_Law_-_2011.svg](http://upload.wikimedia.org/wikipedia/commons/0/00/Transistor_Count_and_Moore%27s_Law_-_2011.svg)*
Computers Are Faster and Cheaper Than Ever
A GFLOP is 69 trillion-times cheaper than it was 50 years ago

<table>
<thead>
<tr>
<th>Date</th>
<th>Cost per GFLOP ($US)</th>
<th>Cost per GFLOP (adjusted 2013 $)</th>
<th>Platform</th>
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<tr>
<td>1961</td>
<td>$1,100,000,000,000,000 ($1.1 trillion)</td>
<td>US $8.3 trillion</td>
<td>About 17 million IBM 1620 units costing $64,000 each</td>
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<td>1984</td>
<td>$15,000,000</td>
<td>$33,000,000</td>
<td>Cray X-MP</td>
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<td>1997</td>
<td>$30,000</td>
<td>$42,000</td>
<td>Two 16-processor Beowulf clusters with Pentium Promicroprocessors</td>
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<tr>
<td>Apr-00</td>
<td>$1,000</td>
<td>$1,300</td>
<td>Bunyip Beowulf cluster</td>
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<tr>
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<td>$640</td>
<td>$836</td>
<td>KLAT2</td>
</tr>
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<td>Aug-03</td>
<td>$82</td>
<td>$100</td>
<td>KASY0</td>
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<td>Aug-07</td>
<td>$48</td>
<td>$52</td>
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<td>Mar-11</td>
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<td>HPU4Science</td>
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<td>Aug-12</td>
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<td>$0.73</td>
<td>Quad AMD7970 GHz System</td>
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<td>Jun-13</td>
<td>$0.22</td>
<td>$0.22</td>
<td>Sony Playstation 4</td>
</tr>
<tr>
<td>Nov-13</td>
<td>$0.16</td>
<td>$0.16</td>
<td>AMD Sempron 145 + GeForce GTX 760 System</td>
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<tr>
<td>Dec-13</td>
<td>$0.12</td>
<td>$0.12</td>
<td>Pentium G550 + Radeon R9 290 System</td>
</tr>
<tr>
<td>Jan-15</td>
<td>$0.08</td>
<td>$0.06</td>
<td>Celeron G1830 + Radeon R9 295X2 System</td>
</tr>
</tbody>
</table>

Source: http://en.wikipedia.org/wiki/FLOPS
Low Level Programming Languages

• Machine Code
  – Unique to the CPU (why code for SPARC, ARM, and X86 are fundamentally different)
  – Series of binary digits – not intended to be human interpretable
  – Ex: “10110000 01100001” or “B0 61” in hexadecimal

• Assembly language
  – Shortcut mnemonics for machine language routines
  – Still tedious to use, not “readable”
  – Ex: “MOV AL, 61h” → instruction to move contents of a memory register from one location to another
High Level Programming Languages

• Written in English-like phrases
• Compiled before execution (converted from source code to object code, usually assembly language or machine code)
• Ex: C/C++, Java, VisualBasic, etc.
• Fourth-generation languages
  – Further abstraction of complex tasks
  – May automate report generation, interaction with a database
  – Often are very task or domain-specific
    • Ex: Mathematica, SPSS
Programming Paradigms

- Distinct styles of programming that influence performance, maintainability, length of code, memory requirements, etc.
- Key examples:
  - Imperative / Procedural
  - Object-Oriented
Imperative & Procedural Programming

- Ex: FORTRAN, BASIC, Pascal, C, C++
- Programs are a list of tasks, subroutines
- Like a recipe: each step is a sequenced instruction
- Procedural languages allow programmer to define functions, subroutines (procedures) and reuse throughout the program
Object-Oriented Programming

• Ex: Java, Objective-C, VisualBasic.NET

• Programs are a collection of interacting objects

• **Objects** can have independent functions, characteristics, and states

• A **Class** is a “blueprint” for an object – it describes the functions and characteristics that all objects in that class share in common
  – Ex: “the class of all dogs”

• A specific member of a class is an **Instance**
  – Ex: “a beagle is an instance of a dog”
OOP Terminology

- Objects have **Attributes** (adjectives) and **Methods** (verbs)
- **Instantiation** involves creating a new object and setting initial parameters for the **Attributes** and **Methods**
- Ex: the class of “Dog” may have attributes for “fur color”, “name”, “breed” and methods for “bark” and “roll over”
- Classes can demonstrate **Encapsulation**: can keep their attributes and methods private; control access to other parts of the program; either allow or restrict external invocation / modification
OOP Terminology

• Composition
  – Objects can be composed from smaller objects
  – Ex: if you have a class that defines a “Point” as an X,Y coordinate, you can create a class for “Line” by reusing two “Point” objects

• Inheritance
  – Objects can inherit their structure from parent objects and extend their functionality
  – Ex: Two classes for “Manager” and “Staff” may inherit the same basic structure of a parent class “Employee”.
OOP Terminology

• **Polymorphism**
  – Objects can override their parent attributes/methods
  – Details of the subclass implementation will determine which attribute/method is invoked
  – Ex: class “Animal” may have a “makeNoise” method. SubClasses of “Animal” (Dog, Cat, Mouse) will all have a “makeNoise” method, but may implement it differently and can override the parent method

• **Accessors** ("getters") are methods used to retrieve variable state

• **Mutators** ("setters") are methods used to change variable state
OOP Class Example (Java)

```java
public class Dog extends Mammal {
    private String name;
    private String furColor;
    private String breed;
    private String noise = "Woof!";

    public void setName(String n) {
        name = n;
    }

    public void setFurColor(String f) {
        furColor = f;
    }

    public void setBreed(String b) {
        breed = b;
    }

    //continued
    public String getName() {
        return name;
    }

    public String getFurColor() {
        return furColor;
    }

    public void bark() {
        System.out.println(noise);
    }
}
```

- **Inheritance**: Dog extends Mammal class
- **Encapsulation**: no way to see or modify name, furColor, breed without using “get” and “set” methods
- **Composition**: Dog uses “String” class and “System.out” class
- **Polymorphism**: Subclasses of Dog do not have to say “Woof!”
public static void main(String[] args) {
    Dog myDog = new Dog();
    myDog.setName("Amia");
    myDog.setFurColor("brown");

    System.out.println("My dog’s name is "+myDog.getName());

    myDog.bark();
}
Types of Qualitative Data

• **Nominal** aka “Categorical”
  – Think “data with names”
  – Mutually exclusive, unordered, discrete categories of data, such as patient smoking status
  – **Mode** (most frequently occurring value) is the only measure of central tendency

• **Ordinal**
  – Think “ordered data”
  – Data that have a natural ordering
  – Ex: “Small”, “Medium”, “Large”
  – Ex: Asthma severity (“Intermittent”, “Mild Persistent”, “Moderate Persistent”, “Severe Persistent”)
  – Ex: Likert scales of patient satisfaction, Pain scales
  – **Median** (middle-ranked value) and **Mode** can be used to measure central tendency
Types of Quantitative Data

- **Interval**
  - Data where the intervals between values represent the same distance
  - Example: Year, Temperature. The difference between 32°F and 33°F is the same as the difference between 76°F and 77°F
  - **Arithmetic mean, median, and mode** can be used as measures of central tendency

- **Ratio**
  - Allows for additional comparison because “zero” means something and is not arbitrarily chosen
  - Ex: Area, distance. Temperature in Kelvin is a ratio (because 300K has twice as much heat as 150K), but temperature in Fahrenheit is not (because zero Fahrenheit does not mean zero heat)
  - **Geometric mean** \((n)\text{th root of the product of } n \text{ values})\), **arithmetic mean, median** and **mode** are allowed
Data Transformations

• **Interval → Ratio**
  – Your application stores a value for “year diagnosed with cancer” – that’s an Interval
  – In your software, you convert this to “years since diagnosis of cancer” – that’s a Ratio

• **Interval → Interval or Ratio → Ratio**
  – Example: Image processing, scaling an image: take every 2x2 cluster of pixels and calculate the average color value, assign it to a single 1x1 pixel.

• **Interval → Ordinal**
  – Can group ranges of variable using “Binning” techniques, commonly used to smooth effects of minor observation errors
  – Take a continuous variable like “age in years”, group them into categories such a “Neonate”, “Infant”, “Toddler”, “Child”, “Adolescent”, “Adult” (implied order)

Be aware what you gain or lose when you transform data.

When you compress image / audio files by downsampling, you can lose data
When you bin continuous data into ordinal buckets, you lose data.
Data Structures

- **Primitives**
  - Boolean
  - Char
  - Float / Double
  - Int

- **Array & Composite structures (e.g. multidimensional arrays)**

- **Strings**

- **Date**
  - most programming languages have a special class for dates
  - most RDBMS have a special data type for dates
  - Could store as a string, but that could impact reuse
  - Ex: Oracle SQL – define a column of type VARCHAR and store value “01/13/12”. How would you perform math on this value?

- **Time**
Control Structures

- **Primitive**
  - Labels (line numbers)
  - GOTO statements – instructs program to “jump” to another label
  - Subroutine – GOSUB label → [do some stuff] → RETURN

- **Choice**
  - IF – THEN – ELSE
    
    IF (age > 12 && sex = female) THEN (show pregnancy risk warning) ELSE (do nothing)
  
  - CASE – WHEN statements

    CASE
    
    WHEN (age < 8) → (recommend amoxicillin instead of doxycycline)
    WHEN (age >= 8 && age < 60) → (recommend doxycycline)
    WHEN (age >= 60) → (recommend cephalosporin)
    
    END
Control Structures

- Loop
  - Count-controlled loop with iterator (FOR – NEXT)
    
    ```
    FOR (i=1; i<20; i=i+1){ DO SOMETHING; }
    ```
  - Condition-controlled loops (WHILE)
    
    ```
    WHILE (i<20) {
      DO SOMETHING;
      i=i+1;
    }
    ```
  - Collection-controlled loops (FOR EACH IN…)
    
    ```
    var Patients=["John","Martha","Alice","Carlos"]; 
    for(var i in Patients){
      DO SOMETHING;
    }
    ```
Apple Basic Example

```
10  FOR T = 1 TO 10
20   HOME : HGR
30  FOR N = 1 TO 100
40     X = INT(280 * RND(1))
50     Y = INT(192 * RND(1))
60     C = INT(7 * RND(1))
70   HCOLOR = C
80  HLINE (280 / 2), (192 / 2) TO X, Y
90   NEXT N
100  NEXT T
110  TEXT : HOME
```

- Set a variable “T” and iterate it from 1 to 10, start the loop at T=1
- Clear the screen, change to high resolution graphics mode (“HGR”)
- Set a variable “N” and iterate it from 1 to 100, start at N=1
- Define variables X, Y, and C using the random number function (“RND(1)”)
- Set the pen color to the value of variable C
- Plot a line from the center of the screen to the coordinates X,Y
- Increment N by 1 and repeat steps 40 through 80 until N = 100
- Increment T by 1 and repeat steps 20 through 90 until T=10
- Exit HGR mode, go back to TEXT mode, and clear the screen

Apple Basic Example

So, this program will draw a random starburst pattern of “N” lines a total of “T” times

Pseudocode & Trace Tables

- The last example was easy enough that we could “do it in our heads”
- But often, you want to keep track of variable assignments, loops, and operators.
- You can use **pseudocode** for this and check your code using **trace tables**
- Pseudocode is not a real programming language (but there is a “standard”)
- You use normal English expressions to represent common computer functions
  - Variable assignment
  - Control / loop structures
  - Logic functions
  - Inputs / Outputs / Database functions
- Goal is to represent an algorithm in a way that can be implemented in any computer program, simply to convey program flow and logic
- It’s also a way to check algorithms before you start coding
Pseudocode & Trace Tables

1. \( x = 10 \)
2. \( y = 2 \)
3. `print x+y`
4. `print x/y`
5. `for i = 1 to 3`
6. `x = x-1`
7. `print x`
8. `next i`
9. `print “I love AMIA!”`

<table>
<thead>
<tr>
<th>line</th>
<th>x</th>
<th>y</th>
<th>i</th>
<th>output</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>2</td>
<td></td>
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</tr>
<tr>
<td>3</td>
<td></td>
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</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Class Exercise

- The “modulo” function returns the remainder when you divide 2 numbers.
  - Ex: 13 mod 5 = 3
  - 5 goes into 13 twice, with 3 left over
- Let’s make a trace table for this program

```
// pseudocode example
01 let n = 2
02 while (n < 10) do the following:
03   t= “true”
04   let i = 2; for every number i < n:
05     if (n mod i) is not 0 then increase i by 1
06     else t = “false” and then exit for loop
07     if t is still “true” then print n
08 increase n by 1
```

Class Questions:
- How many numbers will it output?
- What do these numbers have in common?
// pseudocode example

01 let n = 2
02 while (n < 10) do the following:
03   t = “true”
04   let i = 2; for every number i < n:
05     if (n mod i) is not 0 then increase i by 1
06     else t = “false” and then exit for loop
07     if t is still “true” then print n
08   increase n by 1

*Note that “t” and “i” get reset in each loop

<table>
<thead>
<tr>
<th>n</th>
<th>n&lt;10?</th>
<th>i</th>
<th>i&lt;n?</th>
<th>n mod i</th>
<th>t</th>
<th>Output</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
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<td></td>
<td></td>
<td></td>
<td>true</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
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<td>2</td>
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<td>1</td>
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<td>3</td>
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<tr>
<td>4</td>
<td>yes</td>
<td>2</td>
<td>yes</td>
<td>0</td>
<td>false</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>yes</td>
<td>2</td>
<td>yes</td>
<td>1</td>
<td>true</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>yes</td>
<td>3</td>
<td>yes</td>
<td>2</td>
<td>true</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>yes</td>
<td>4</td>
<td>yes</td>
<td>3</td>
<td>true</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
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<td>no</td>
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<td>true</td>
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<tr>
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<td>0</td>
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<td>1</td>
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<td>3</td>
<td>yes</td>
<td>0</td>
<td>false</td>
<td></td>
</tr>
</tbody>
</table>
Here’s an implementation of the same algorithm in Javascript.

The website [http://repl.it/](http://repl.it/) features a browser-based Javascript console where you can test code.

The left half of the screen is your code. When you press the “play” triangle icon, you can run the program in a virtual console on the right.

Note that the output is the same as our trace table (the numbers 2, 3, 5, and 7 – all primes less than 10).

Also note the use of “for” loops instead of “while” loops.

Bonus question: what would you change to print all primes less than 100?
Some hints to understand this Javascript snippet:

- Good practice to use indentation as a visual cue re: nested loops and controls
- Open/Close brackets must match – use this to tell where a loop ends if you get lost.
- “for...next” loops follow this syntax: `for (start; until; increment)`
- New variable declarations start with the word “var”
- The percent sign “%” is the modulo operator
- “!” means “not”, and “==” is a test of equality
  - So “!=0” means “is not equal to zero”
- “continue” and “break” allow you to iterate within or exit out of a “for” loop
- The variable “t” is a Boolean
Programming questions on the exam?

Likely to be Tested

• Interpreting a pseudocode algorithm
• Understanding control structures, loops, operators, variable assignment
• Completing a trace table

Not likely to be tested

• You are not likely to be tested on a specific computer programming language except SQL (in the database lecture)
• If you are tested on a real language, the syntax will probably be very “human interpretable” – so treat it just like pseudocode
Hash Functions

• Algorithm that maps data of arbitrary length to data of fixed length, an example of “binning”
• Returned value is known as “hash value”, “hash code”, “hash sum”, or “checksum”
• Uses in data integrity:
  – Checking that a file was not tampered with or downloaded incompletely (“MD5 Hash”)
  – Checking that a keystroke error did not occur (National Provider Identifier and Luhn Algorithm, where last digit is a checksum)
Hash Functions

\[
\text{md5( "The patient has evidence of hypertrophy") =}
\text{ "65dc36d7011f96c757ca96e87bd0ff9e"}
\]

\[
\text{md5( "the patient has evidence of hypertrophy") =}
\text{ "611a64303cffc9232c05022500fe4b9a"}
\]

- Uses in Cryptography
  - Websites should not store unencrypted passwords
  - Rule of thumb: if you click ‘forgot password’ on a website and they email you the password, they’re probably storing them unencrypted, which is a no-no

- Uses in Indexing (as in databases)
  - Takes text strings and, via a hash, places them into “buckets”
  - Retrieving info is faster since program only has to look in that bucket
Software Development Methodologies

• Aka Software Development Life Cycle (SDLC)

• Need for standard approach to
  – Determine scope
  – Organize programming tasks
  – Determine testing requirements
  – Manage resources & time commitments
  – Deliver software on a reproducible schedule
Basic Phases of SDLC

• **Planning**
  – Gather requirements, determine scope and priority of work

• **Implementation**
  – Actual development process

• **Testing – Verification vs. Validation**
  – **Verification** - “are you building the software right?” (does it meet specification, is the code high quality, defect-free, etc.)
  – **Validation** - “are you building the right software?” (does it meet customer’s expectation, satisfy their needs, do what it’s supposed to)

• **Documentation**
  – critical for future enhancement, debugging, maintainability

• **Deployment**
  – Install, customize, train, evaluate

• **Maintenance**
  – Process to collect new defects or enhancements, support users in ongoing fashion
SDLC Methodologies: Waterfall

- Move to next phase only when prior phase is done
- Option to revisit decisions, but usually go through a formal change control process
- Highly structured, relatively inflexible
- Good for projects with stable requirements
- **Advantages:** defects are found sooner, when they’re less costly to fix
- **Disadvantage:** a late-breaking requirement can be expensive or prohibitive
SDLC Methodologies: Spiral

- “Risk oriented” software development
  - One example of risk is poorly understood requirements
- Development broken into smaller efforts
- Each subproject designed to tackle an area of high-risk
- Traditional phases
  - Determine objectives, alternatives, constraints
  - Identify and resolve risks
  - Evaluate alternatives
  - Develop deliverables for a given iteration and verify they are correct
  - Plan the next iteration
  - Commit to an approach for subsequent iteration
- **Advantages:** highest risk is tackled early on, when change is less expensive
SDLC Methodologies: Agile

- High focus on very small steps, frequent loops
- Extreme Programming (XP) and Scrum are two popular Agile variations
- Feedback provides regular testing and release of software
SDLC Methodologies: Agile

- **Scrum Terminology**
  - **Product Owner** – person who represents client requirements. Writes user stories (brief statement that captures “who”, “what”, “why” of a simple requirement) and adds to backlog.
  - **Development team** – 3-9 programmers who are cross-functional (can tradeoff coding, testing, documentation)
  - **Scrum Master** – rule enforcer and remover of impediments
  - **Sprint** – basic unit of development, predefined in duration and scope, chosen from list of backlog
  - **Daily Scrum** – what happened yesterday? What will happen today? Any obstacles?

- **Advantage**: Extremely flexible; assumes that clients will change requirements and is equipped to adapt to unpredicted challenges
System Integration

- Process of linking subsystems in software architecture
  - requires combination of software, hardware, interface sills
- Facilitated by strong understanding of standards
  - HL7, Web Services, Networking
- Methods
  - Vertical Integration
    - Group systems by function into silos
    - Integrate within a silo, but not necessarily between
  - Star Integration
    - Unique connection to each system that requires it
    - High overhead for complex systems
  - Horizontal Integration (via Enterprise Service Bus)
    - One connection per system to ESB. ESB handles downstream connections
    - Replacing a single system is much easier
Quality Assurance / Testing

- Goal: to mitigate project risk as early as possible, release good products
- Cost of fixing a defect is a function of project phase

<table>
<thead>
<tr>
<th>Phase of Defect</th>
<th>Cost to fix a defect</th>
<th>Time detected</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Requirements</td>
<td>Architecture</td>
</tr>
<tr>
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<td>3x</td>
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<tr>
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<td>-</td>
<td>1x</td>
</tr>
<tr>
<td>Construction</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
**THERAC-25**

- Radiation therapy machine
- Responsible for 6 accidents, 3 deaths due to massive radiation overdose from 1985-1987
- Attributed to failure to detect a “race condition” in software
- Poor design of error messages (“MALFUNCTION” followed by a number from 1 to 64)
- Personnel didn’t believe patient’s complaints
**PATIENT NAME : JOHN DOE**

**TREATMENT MODE : FIX**

**BEAM TYPE: X**

**ENERGY (MeV): 25**

<table>
<thead>
<tr>
<th></th>
<th>ACTUAL</th>
<th>PRESCRIBED</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNIT RATE/MINUTE</td>
<td>0</td>
<td>200</td>
</tr>
<tr>
<td>MONITOR UNITS</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>TIME (MIN)</td>
<td>0.27</td>
<td>1.00</td>
</tr>
</tbody>
</table>

**GANTRY ROTATION (DEG)**

|                      | 0.0      | 0          | VERIFIED |

**COLLIMATOR ROTATION (DEG)**

|                      | 359.2    | 359        | VERIFIED |

**COLLIMATOR X (CM)**

|                      | 14.2     | 14.3       | VERIFIED |

**COLLIMATOR Y (CM)**

|                      | 27.2     | 27.3       | VERIFIED |

**WEDGE NUMBER**

|                      | 1        | 1          | VERIFIED |

**ACCESSORY NUMBER**

|                      | 0        | 0          | VERIFIED |

**DATE : 84-OCT-26**

**SYSTEM : BEAM READY**

**OP. MODE : TREAT AUTO**

**TIME : 12:55.8**

**TREAT : TREAT PAUSE**

**X-RAY 173777**

**OPR ID : T25VO2-RO3**

**REASON : OPERATOR**

**COMMAND :**
Testing Approaches

- Static testing – reviewing code itself
- Dynamic testing – apply test cases to code
- Test case development approaches
  - **White Box** – tests inner workings of a program (ex: was an order sent/received correctly between systems)
    - **Code Coverage** is an example of White Box testing – programmer will develop a set of test conditions for all scenarios, all variables, all possible inputs with awareness of the internal design of the system.
  - **Black Box** – tests functionality from end-user standpoint (ex: if user enters an order, does EHR display the order is active and signed).
    - Ex: **specification testing**, which may be insufficient to capture all defects
Levels of Testing

• **Unit Test**
  – white box
  – code coverage
  – developer driven, can be semi-automated

• **Integration Test**
  – white box
  – interfaces/API’s
  – developer-driven

• **System Test**
  – Black box
  – Test against documented requirements (verification)

• **Acceptance Test**
  – Black box
  – Request for user sign-off (validation)
  – Ex: “beta testing”, solicit input from a small group of users
Regression Testing

• Regression is a new defect revealed with the addition of a new functionality

• Ex: you add a new feature to a program, now an older feature stops working as intended – that’s a regression

• Regression testing: when you add new functionality, go-back and repeat all prior tests, retest all previously-reported and fixed defects
End of Lecture
Suggested Additional Reading

Self Directed Learning

• “Standard” pseudocode: http://users.csc.calpoly.edu/~jdalbey/SWE/pdl_std.html
• Repl.it browser-based Javascript console: https://repl.it/languages/JavaScript
• Javascript tutorial
  – http://www.w3schools.com/js/default.asp
  – Sections of interest:
    • Syntax, Statements, Variables, Operators, Arithmetic, Assignment, Data Types, Functions, Objects, Scope, Strings, Numbers, Arrays, Booleans, Comparisons, Conditions, Switch, Loop For / While
• YouTube pseudocode tutorial
  – https://www.youtube.com/watch?v=Rg-fO7rDsd
• TraceTable example on YouTube
  – https://www.youtube.com/watch?v=UhziRgmVKuQ
3A-2: Systems, Databases, Networks

Bimal R. Desai, MD, MBI, FAAP
The Children’s Hospital of Philadelphia
Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
      1.1.1. The discipline of informatics
      1.1.2. Key informatics concepts, models, and theories
      1.1.3. Clinical informatics literature
      1.1.4. International clinical informatics practices
      1.1.5. Ethics and professionalism
      1.1.6. Legal and regulatory issues
   1.2. The Health System
      1.2.1. Determinants of individual and population health
      1.2.2. Primary domains, organizational structures, cultures, and processes
      1.2.3. The flow of data, information, and knowledge within the health system
      1.2.4. Policy & regulatory framework
      1.2.5. Health economics and financing
      1.2.6. Forces shaping health care delivery
      1.2.7. Institute of Medicine quality components

2. Clinical Decision Making and Care Process Improvement
   2.1. Clinical Decision Support
      2.1.1. The nature and cognitive aspects of human decision making
      2.1.2. Decision science
      2.1.3. Application of clinical decision support
      2.1.4. Transformation of knowledge into clinical decision support tools
      2.1.5. Legal, ethical, and regulatory issues
      2.1.6. Quality and safety issues
      2.1.7. Supporting decisions for populations of patients
   2.2. Evidence-based Patient Care
      2.2.1. Evidence sources
      2.2.2. Evidence grading
      2.2.3. Clinical guidelines
      2.2.4. Implementation of guidelines as clinical algorithms
      2.2.5. Information retrieval and analysis
   2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
      2.3.1. Methods of workflow analysis
      2.3.2. Principles of workflow re-engineering
      2.3.3. Quality improvement principles and practices

3. Health Information Systems
   3.1. Information Technology Systems
      3.1.1. Computer Systems
      3.1.2. Architecture
      3.1.3. Networks
      3.1.4. Security
      3.1.5. Data
      3.1.6. Technical approaches that enable sharing data
      3.2. Human Factors Engineering
      3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
      3.2.2. HCI Evaluation, usability testing, study design and methods
      3.2.3. Interface design standards and design principles
      3.2.4. Usability engineering
      3.3. Health Information Systems and Applications
      3.3.1. Types of functions offered by systems
      3.3.2. Types of settings where systems are used
      3.3.3. Electronic health/medical records systems as the foundational tool
      3.3.4. Telemedicine
      3.4. Clinical Data Standards
      3.4.1. Standards development history and current process
      3.4.2. Data standards and data sharing
      3.4.3. Transaction standards
      3.4.4. Messaging standards
      3.4.5. Nomenclatures, vocabularies, and terminologies
      3.4.6. Ontologies and taxonomies
      3.4.7. Interoperability standards
   3.5. Information System Lifecycle
      3.5.1. Institutional governance of clinical information systems
      3.5.2. Clinical information needs analysis and system selection
      3.5.3. Clinical information system implementation
      3.5.4. Clinical information system testing, before, during and after implementation
      3.5.5. Clinical information system maintenance
      3.5.6. Clinical information system evaluation

4. Leading and Managing Change
   4.1. Leadership Models, Processes, and Practices
      4.1.1. Dimensions of effective leadership
      4.1.2. Governance
      4.1.3. Negotiation
      4.1.4. Conflict management
      4.1.5. Collaboration
      4.1.6. Motivation
      4.1.7. Decision making
   4.2. Effective Interdisciplinary Teams
      4.2.1. Human resources management
      4.2.2. Team productivity and effectiveness
      4.2.3. Group management processes
      4.2.4. Managing meetings
      4.2.5. Managing group deliberations
      4.3. Effective Communications
      4.3.1. Effective presentations to groups
      4.3.2. Effective one-on-one communication
      4.3.3. Writing effectively for various audiences and goals
      4.3.4. Developing effective communications program to support system implementation
   4.4. Project Management
      4.4.1. Basic principles
      4.4.2. Identifying resources
      4.4.3. Resource allocation
      4.4.4. Project management tools (non-software specific)
      4.4.5. Informatics project challenges
   4.5. Strategic and Financial Planning for Clinical Information Systems
      4.5.1. Establishing mission and objectives
      4.5.2. Environmental scanning
      4.5.3. Strategy formulation
      4.5.4. Action planning and strategy implementation
      4.5.5. Capital and operating budgeting
      4.5.6. Principles of managerial accounting
      4.5.7. Evaluation of planning process
   4.6. Change Management
      4.6.1. Assessment of organizational culture and behavior
      4.6.2. Change theories
      4.6.3. Change management strategies
      4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core Content Covered

3.1.1.6 Information systems design and analysis

3.1.2 Architecture

3.1.2.1 Systems
3.1.2.2 Networks
3.1.2.3 Data/database

3.1.3 Networks

3.1.3.1 Topologies
3.1.3.2 Telecommunications
Key Topics

• Distinguish hierarchical, relational, and object-oriented databases; advantages and disadvantages of each.
• Describe the logical schema of a database using a UML Entity Relationship (ER) diagram.
• Understand how the suite of UML diagrams are used to model a process and assist in software development and maintenance.
• Understand how update, insert, and deletion anomalies in databases are prevented through database normalization.
• Understand how denormalization of a database can be used to optimize certain queries, for example, in a clinical datamart.
• Describe some of the common network topologies, such as star, tree, and bus networks.
• Recognize the names and uses of common telecommunications standards.
3A-2 Systems, Databases, Networks

- Database definition
- Flat Files, Relational, Hierarchical, & Object DBs
- Unified Modeling Language
- Reliable DB transactions
- Normalization
- Data Warehouses and Datamarts
- Network Topologies
- Communication protocols and the TCP/IP Stack
- Telecommunications
Database

Any collection of related data (address book, spreadsheet, MS Access)

• Database Management System (DBMS)
  – Allows users to interact with DB and maintain structure, integrity
  – Common features of DBMS
    • Define data types, structures, constraints
    • Construct data tables, store data on a storage medium
    • Manipulate data to create (insert), retrieve (read), update (edit), delete
      (sometimes abbreviated “CRUD”)
    • Share data via permissions, user access control; control concurrency
    • Protect against inappropriate access, hardware/software failure
    • Maintain & Optimize data structures
Flat File

- Convenient, easy, ubiquitous
- May require redundant data (eg: Louise Chen – have to remember to indicate in each cell that she is deceased)
- Can’t represent 1-to-many relationships easily (Louise has 2 meds)
- Limited ability to enforce data integrity (multiple spellings of “yes” and “no”)
- Incomplete data represented as blank cells

<table>
<thead>
<tr>
<th>My Patients &amp; Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jose Patel</td>
</tr>
</tbody>
</table>
Relational Database

- Defines association within and between relations (relation ~ table)
- Each attribute (attribute ~ column) corresponds to a domain in the relation
- Each tuple (tuple ~ row) describes an ordered list of elements, the order is important
- Data elements (element ~ cell) have a data type that is consistent across that attribute. (VARCHAR, INT, DATE, LONG, etc)
- Attributes can also have constraints (non NULL, auto-incrementing, cascading delete, Primary Key, Foreign Key) beyond the type constraint
- Create and describe structure/constraints using "Data Definition Language" (DDL) which contains metadata (data about the data)
- Further describe the data using a Data Dictionary (not just FK/PK, constraints, but also definitions of each field and its intended use)
Relational Database

- The relation **schema** (table schema) is a description of the relation, its attributes, and the data types / rules associated with the relation.
- A specific table that uses that schema is an **instance of that schema**
- Adding new relations as easy as adding a table, add an attribute by adding a column
- In very simple terms these make it easy to know “everything that has one attribute”
Object-Relational Mapping (ORM)

- Parallelism between OOP and RDBMS is very useful programmatically
  - Object-oriented Class $\leftrightarrow$ DB Relation
  - Instance $\leftrightarrow$ Tuple (a specific row) in a Relation (table), where each row is a member of the class described by those attributes
  - Attribute $\leftrightarrow$ Attribute (column), where the Value of that attribute is the element (content of the cell)
  - Method (accessors, mutators) $\leftrightarrow$ database manipulation (CRUD) functions

- Many modern programming languages use Object-Relational Mapping (ORM) either built-in or available as an extension
  - Each class is mapped to a table
  - Each attribute is mapped to a column
  - Each method (getters/setters) mapped to a “CRUD” function
  - Ex: Creating a new instance of a class automatically creates a row and populates data
## Example Relational Schema

<table>
<thead>
<tr>
<th>PATIENT</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Key</td>
<td>Pat_ID</td>
<td>INT</td>
</tr>
<tr>
<td></td>
<td>First Name</td>
<td>VARCHAR(50)</td>
</tr>
<tr>
<td></td>
<td>Last Name</td>
<td>VARCHAR(50)</td>
</tr>
<tr>
<td></td>
<td>DOB</td>
<td>DATE</td>
</tr>
<tr>
<td></td>
<td>Is_Deceased</td>
<td>BOOLEAN</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ORDER</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Key</td>
<td>Order_ID</td>
<td>INT</td>
</tr>
<tr>
<td></td>
<td>Med Name</td>
<td>VARCHAR(50)</td>
</tr>
<tr>
<td>Foreign Key to Pat_ID in PATIENT table</td>
<td>Pat_ID</td>
<td>INT</td>
</tr>
</tbody>
</table>
# Example Relational Instance

<table>
<thead>
<tr>
<th>PATIENT</th>
<th>Pat_ID</th>
<th>First_Name</th>
<th>Last_Name</th>
<th>DOB</th>
<th>Is_Deceased</th>
</tr>
</thead>
<tbody>
<tr>
<td>1001</td>
<td>John</td>
<td>Smith</td>
<td></td>
<td>4/25/74</td>
<td>N</td>
</tr>
<tr>
<td>1002</td>
<td>Jane</td>
<td>Doe</td>
<td></td>
<td>8/12/58</td>
<td>N</td>
</tr>
<tr>
<td>1003</td>
<td>Jose</td>
<td>Patel</td>
<td></td>
<td>2/19/88</td>
<td>N</td>
</tr>
<tr>
<td>1004</td>
<td>Louise</td>
<td>Chen</td>
<td></td>
<td>12/8/69</td>
<td>Y</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ORDER</th>
<th>Order_ID</th>
<th>Med_Name</th>
<th>Pat_ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>991</td>
<td>1003</td>
<td>amoxicillin</td>
<td></td>
</tr>
<tr>
<td>992</td>
<td>1002</td>
<td>diphenhydramine</td>
<td></td>
</tr>
<tr>
<td>993</td>
<td>1004</td>
<td>acetaminophen</td>
<td></td>
</tr>
<tr>
<td>994</td>
<td>1004</td>
<td>topiramate</td>
<td></td>
</tr>
<tr>
<td>995</td>
<td>1001</td>
<td>propranolol</td>
<td></td>
</tr>
</tbody>
</table>
Structured Query Language

• “SQL” – a family of related languages with different dialects specific to the RBDMS (MS-SQL, Oracle SQL, MySQL)

• English-like with key words that allow for all functions common to DBMS (“CRUD” functions):
  - INSERT INTO [table] VALUES [tuple]
  - SELECT [columns] FROM [table] WHERE [constraints]
  - UPDATE [table] SET [column] = [value] WHERE [condition]
  - DELETE FROM [table] WHERE [column] = [value]
SQL Joins

- Consider two tables with a PK / FK relationship
- How do we write a **SELECT** statement that returns data from both tables?

<table>
<thead>
<tr>
<th>PATIENT</th>
<th>Pat_ID</th>
<th>First_Name</th>
<th>Last_Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1001</td>
<td>John</td>
<td>Smith</td>
<td></td>
</tr>
<tr>
<td>1002</td>
<td>Jane</td>
<td>Doe</td>
<td></td>
</tr>
<tr>
<td>1003</td>
<td>Jose</td>
<td>Patel</td>
<td></td>
</tr>
<tr>
<td>1004</td>
<td>Louise</td>
<td>Chen</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ORDER</th>
<th>Order_ID</th>
<th>Med_Name</th>
<th>Pat_ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>991</td>
<td></td>
<td>amoxicillin</td>
<td>1003</td>
</tr>
<tr>
<td>992</td>
<td></td>
<td>diphenhydramine</td>
<td>1002</td>
</tr>
<tr>
<td>993</td>
<td></td>
<td>acetaminophen</td>
<td>1004</td>
</tr>
<tr>
<td>994</td>
<td></td>
<td>topiramate</td>
<td>1004</td>
</tr>
<tr>
<td>995</td>
<td></td>
<td>propranolol</td>
<td>1001</td>
</tr>
</tbody>
</table>
SQL Joins

```
SELECT PATIENT.First_Name, PATIENT.Last_Name, ORDER.Med_Name
FROM PATIENT
INNER JOIN ORDER
ON PATIENT.Pat_ID = ORDER.Pat_ID
```
### SQL Joins

**SQL Query:**

```sql
SELECT PATIENT.First_Name, PATIENT.Last_Name, ORDER.Med_Name
FROM PATIENT
INNER JOIN ORDER
ON PATIENT.Pat_ID = ORDER.Pat_ID
```

**Tables: PATIENT and ORDER**

<table>
<thead>
<tr>
<th>PATIENT</th>
<th>Pat_ID</th>
<th>First_Name</th>
<th>Last_Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1001</td>
<td>John</td>
<td>Smith</td>
<td></td>
</tr>
<tr>
<td>1002</td>
<td>Jane</td>
<td>Doe</td>
<td></td>
</tr>
<tr>
<td>1003</td>
<td>Jose</td>
<td>Patel</td>
<td></td>
</tr>
<tr>
<td>1004</td>
<td>Louise</td>
<td>Chen</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ORDER</th>
<th>Order_ID</th>
<th>Med_Name</th>
<th>Pat_ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>991</td>
<td>amoxicillin</td>
<td>1003</td>
<td></td>
</tr>
<tr>
<td>992</td>
<td>diphenhydramine</td>
<td>1002</td>
<td></td>
</tr>
<tr>
<td>993</td>
<td>acetaminophen</td>
<td>1004</td>
<td></td>
</tr>
<tr>
<td>994</td>
<td>topiramate</td>
<td>1004</td>
<td></td>
</tr>
<tr>
<td>995</td>
<td>propranolol</td>
<td>1001</td>
<td></td>
</tr>
</tbody>
</table>

**Result:**

<table>
<thead>
<tr>
<th>First_Name</th>
<th>Last_Name</th>
<th>Med_Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>John</td>
<td>Smith</td>
<td>propranolol</td>
</tr>
<tr>
<td>Jane</td>
<td>Doe</td>
<td>diphenhydramine</td>
</tr>
<tr>
<td>Jose</td>
<td>Patel</td>
<td>amoxicillin</td>
</tr>
<tr>
<td>Louise</td>
<td>Chen</td>
<td>acetaminophen</td>
</tr>
<tr>
<td>Louise</td>
<td>Chen</td>
<td>topiramate</td>
</tr>
</tbody>
</table>
SQL Joins

- Note that this Join can also be written as a “WHERE” clause.
- These two statements have equivalent output:

```sql
SELECT PATIENT.First_Name, PATIENT.Last_Name, ORDER.Med_Name
FROM PATIENT
INNER JOIN ORDER
ON PATIENT.Pat_ID = ORDER.Pat_ID
```

```sql
SELECT PATIENT.First_Name, PATIENT.Last_Name, ORDER.Med_Name
FROM PATIENT, ORDER
WHERE PATIENT.Pat_ID = ORDER.Pat_ID
```

**NB:** If there is no match in ORDER for a specific Pat_ID, that PATIENT will not appear in the result set. That’s what is meant by the key word “INNER”
SQL Joins: Inner vs. Outer

• How do you join tables where there is no one-to-one equivalence (not every row in A has a match in B, not every row in B has a match in A)?

<table>
<thead>
<tr>
<th>Faculty</th>
<th>Interests</th>
</tr>
</thead>
<tbody>
<tr>
<td>User_ID</td>
<td>User_Name</td>
</tr>
<tr>
<td>54</td>
<td>Tom Payne</td>
</tr>
<tr>
<td>30</td>
<td>Diane Montella</td>
</tr>
<tr>
<td>41</td>
<td>Bill Hersh</td>
</tr>
<tr>
<td>29</td>
<td>Bimal Desai</td>
</tr>
<tr>
<td>12</td>
<td>Ben Munger</td>
</tr>
<tr>
<td>User_ID</td>
<td>Hobby</td>
</tr>
<tr>
<td>54</td>
<td>Painting</td>
</tr>
<tr>
<td>30</td>
<td>Wood Carving</td>
</tr>
<tr>
<td>41</td>
<td>Gardening</td>
</tr>
<tr>
<td>61</td>
<td>Home Improvement</td>
</tr>
<tr>
<td>12</td>
<td>Reading</td>
</tr>
</tbody>
</table>
### Inner Join

Only includes rows that match both tables

<table>
<thead>
<tr>
<th>Faculty</th>
<th>Interests</th>
</tr>
</thead>
<tbody>
<tr>
<td>User_ID</td>
<td>User_Name</td>
</tr>
<tr>
<td>54</td>
<td>Tom Payne</td>
</tr>
<tr>
<td>30</td>
<td>Diane Montella</td>
</tr>
<tr>
<td>41</td>
<td>Bill Hersh</td>
</tr>
<tr>
<td>29</td>
<td>Bimal Desai</td>
</tr>
<tr>
<td>12</td>
<td>Ben Munger</td>
</tr>
</tbody>
</table>

```sql
SELECT Faculty.User_Name, Interests.Hobby
FROM Faculty
INNER JOIN Interests
ON Faculty.User_ID = Interests.User_ID
```
Left Outer Join
Will include all rows in the left table, display blanks from right

```
SELECT Faculty.User_Name, Interests.Hobby
FROM Faculty
LEFT OUTER JOIN Interests
ON Faculty.User_ID = Interests.User_ID
```
Right Outer Join
Will include all rows in the right table, display blanks from left

```
SELECT Faculty.User_Name, Interests.Hobby
FROM Faculty
RIGHT OUTER JOIN Interests
ON Faculty.User_ID = Interests.User_ID
```
Full Outer Join
Includes all rows in both tables, blanks in both

```
SELECT Faculty.User_Name,
       Interests.Hobby
FROM Faculty
FULL OUTER JOIN Interests
ON Faculty.User_ID = Interests.User_ID
```
Cartesian (Cross) Join

- Rarely used – gives you the “cross product” of both tables
- Often arises by accident when joins don’t have correct constraints or if you omit a WHERE clause constraint
- Sometimes used to generate test data
- Uses SQL “CROSS JOIN” statement, omits the “ON” statement

```
SELECT Faculty.User_Name, Interests.Hobby
FROM Faculty
CROSS JOIN Interests
```

Probably not what you want...
Returns 25 rows.
Can you guess why?
## SQL Joins as Venn Diagrams

<table>
<thead>
<tr>
<th>Join Type</th>
<th>SQL Code</th>
<th>Diagram</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INNER</strong></td>
<td><code>select a.*, b.* from a inner join b on a.id = b.id</code></td>
<td><img src="venn_diagram.png" alt="Venn Diagram" /></td>
<td>Only returns rows present in both tables. No nulls in columns from A or B</td>
</tr>
<tr>
<td><strong>LEFT OUTER</strong></td>
<td><code>select a.*, b.* from a left outer join b on a.id = b.id</code></td>
<td><img src="venn_diagram.png" alt="Venn Diagram" /></td>
<td>Returns all of A, regardless of match in B (columns from B may be null)</td>
</tr>
<tr>
<td><strong>RIGHT OUTER</strong></td>
<td><code>select a.*, b.* from a right outer join b on a.id = b.id</code></td>
<td><img src="venn_diagram.png" alt="Venn Diagram" /></td>
<td>Returns all of B, regardless of match in A (columns from A may be null)</td>
</tr>
<tr>
<td><strong>FULL OUTER</strong></td>
<td><code>select a.*, b.* from a full outer join b on a.id = b.id</code></td>
<td><img src="venn_diagram.png" alt="Venn Diagram" /></td>
<td>Returns all cells from both, including nulls in A and B</td>
</tr>
</tbody>
</table>
Nested Subqueries in SQL

- Mimic an “inner join” using nested subquery syntax
- Substitute results of a subquery for “where [column] in” clause in place of a list
- Example: suppose you want all meds ordered for patients between ages 4 and 5. The data are in two tables, a “patients” table and “medications”, with “pat_id” as PK in patients, FK in medications
  - First, you identify all patients between 4 and 5 – this is the subquery
  - Then you pass the results of the subquery as a list of values to the “IN” operator

```sql
select * from medications
where pat_id in
  (select pat_id from patients
   where pat_age between 4 and 5)
```
Class Exercise

Two tables describe the customers and orders for an online shoe store. Orders.custId is a foreign key that refers to the column Customers.Id

Write a query that returns the orderId, name, and city of all customers who ordered “dancing shoes”
Write your “SELECT” statement first. Since we’re mixing columns from two tables, we need to qualify the table for each column using “dot” notation:

```
SELECT Orders.orderId, Customers.name, Customers.city
```

Now we have to choose a “FROM” table – it doesn’t matter which you choose in this example. If you choose Orders, you’ll have to join Customers. If you choose Customers, you’ll have to join Orders. Let’s choose Orders:

```
FROM Orders
```

Here comes the join – in this case, we want an “inner” join because we don’t care about nulls on either side (orders without customers or customers without orders). We link the tables on the PK/FK relation specified in the database schema:

```
INNER JOIN Customers
ON Orders.custId = Customers.Id
```
Class Exercise

So far, we have...

```
SELECT Orders.orderID, Customers.name, Customers.city
FROM Orders
INNER JOIN Customers
ON Orders.custID = Customers.Id
```

All we need now is a “where” clause to limit the results to customers who ordered “dancing shoes”. Voila! Our final query:

```
SELECT Orders.orderID, Customers.name, Customers.city
FROM Orders
INNER JOIN Customers
ON Orders.custID = Customers.Id
WHERE Orders.itemDesc = 'dancing shoes'
```

*note the single quotes around text strings in SQL*
SELECT Orders.orderId, Customers.name, Customers.city
FROM Orders
INNER JOIN Customers
ON Orders.custId = Customers.Id
WHERE Orders.itemDesc = 'Dancing shoes'

What is the result of this query?

<table>
<thead>
<tr>
<th>orderId</th>
<th>name</th>
<th>city</th>
</tr>
</thead>
<tbody>
<tr>
<td>66</td>
<td>Pesha</td>
<td>Bethesda</td>
</tr>
</tbody>
</table>
Class Exercise

```
SELECT Orders.orderId, Customers.name, Customers.city
FROM Orders
INNER JOIN Customers
ON Orders.custId = Customers.Id
WHERE Orders.itemDesc = 'Dancing shoes'
```

**Bonus questions (assume you still want to show the same 3 attributes):**

1) Can you modify the query to show only customers from Seattle?

2) Can you modify the query to show only customers from Seattle who did not order “golf cleats”?

3) Can you modify the query to show all order, including those where the customer is not listed in the Customers table?

4) Can you modify the query to show all customers whose first name starts with the letter “B” (even if they didn’t place an order)?

<table>
<thead>
<tr>
<th>Customers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Id (PK)</td>
</tr>
<tr>
<td>----------</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Orders</th>
</tr>
</thead>
<tbody>
<tr>
<td>orderId (PK)</td>
</tr>
<tr>
<td>----------</td>
</tr>
<tr>
<td>65</td>
</tr>
<tr>
<td>66</td>
</tr>
<tr>
<td>67</td>
</tr>
<tr>
<td>68</td>
</tr>
<tr>
<td>69</td>
</tr>
</tbody>
</table>
Class Exercise

Show only customers from Seattle:

```
SELECT Orders.orderId, Customers.name, Customers.city
FROM Orders
INNER JOIN Customers
ON Orders.custId = Customers.Id
WHERE Customers.city = 'Seattle'
```

What is the result of this query?

<table>
<thead>
<tr>
<th>orderId</th>
<th>name</th>
<th>city</th>
</tr>
</thead>
<tbody>
<tr>
<td>69</td>
<td>Tom</td>
<td>Seattle</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Id (PK)</th>
<th>name</th>
<th>city</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Alexis</td>
<td>Atlanta</td>
</tr>
<tr>
<td>2</td>
<td>Bimal</td>
<td>Philadelphia</td>
</tr>
<tr>
<td>3</td>
<td>Tom</td>
<td>Seattle</td>
</tr>
<tr>
<td>4</td>
<td>Bill</td>
<td>Portland</td>
</tr>
<tr>
<td>5</td>
<td>Pesha</td>
<td>Bethesda</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>orderId (PK)</th>
<th>custId (FK)</th>
<th>itemDesc</th>
</tr>
</thead>
<tbody>
<tr>
<td>65</td>
<td>2</td>
<td>flip flops</td>
</tr>
<tr>
<td>66</td>
<td>5</td>
<td>dancing shoes</td>
</tr>
<tr>
<td>67</td>
<td>7</td>
<td>clogs</td>
</tr>
<tr>
<td>68</td>
<td>1</td>
<td>hiking boots</td>
</tr>
<tr>
<td>69</td>
<td>3</td>
<td>golf cleats</td>
</tr>
</tbody>
</table>
Show only customers from Seattle who did not order golf cleats:

```sql
SELECT Orders.orderId, Customers.name, Customers.city
FROM Orders
INNER JOIN Customers
ON Orders.custId = Customers.Id
WHERE Customers.city = 'Seattle'
AND Orders.itemDesc <> 'golf cleats'
```

What is the result of this query?

<table>
<thead>
<tr>
<th>orderId</th>
<th>name</th>
<th>city</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 rows returned</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Class Exercise

All orders, including those with missing customer

SELECT Orders.orderID, Customers.name, Customers.city
FROM Orders
LEFT OUTER JOIN Customers
ON Orders.custID = Customers.Id

<table>
<thead>
<tr>
<th>orderId</th>
<th>name</th>
<th>city</th>
</tr>
</thead>
<tbody>
<tr>
<td>65</td>
<td>Bimal</td>
<td>Philadelphia</td>
</tr>
<tr>
<td>66</td>
<td>Pesha</td>
<td>Bethesda</td>
</tr>
<tr>
<td>67</td>
<td></td>
<td></td>
</tr>
<tr>
<td>68</td>
<td>Alexis</td>
<td>Atlanta</td>
</tr>
<tr>
<td>69</td>
<td>Tom</td>
<td>Seattle</td>
</tr>
</tbody>
</table>

Customers

<table>
<thead>
<tr>
<th>Id (PK)</th>
<th>name</th>
<th>city</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Alexis</td>
<td>Atlanta</td>
</tr>
<tr>
<td>2</td>
<td>Bimal</td>
<td>Philadelphia</td>
</tr>
<tr>
<td>3</td>
<td>Tom</td>
<td>Seattle</td>
</tr>
<tr>
<td>4</td>
<td>Bill</td>
<td>Portland</td>
</tr>
<tr>
<td>5</td>
<td>Pesha</td>
<td>Bethesda</td>
</tr>
</tbody>
</table>

Orders

<table>
<thead>
<tr>
<th>orderId (PK)</th>
<th>custID (FK)</th>
<th>itemDesc</th>
</tr>
</thead>
<tbody>
<tr>
<td>65</td>
<td>2</td>
<td>flip flops</td>
</tr>
<tr>
<td>66</td>
<td>5</td>
<td>dancing shoes</td>
</tr>
<tr>
<td>67</td>
<td>7</td>
<td>clogs</td>
</tr>
<tr>
<td>68</td>
<td>1</td>
<td>hiking boots</td>
</tr>
<tr>
<td>69</td>
<td>3</td>
<td>golf cleats</td>
</tr>
</tbody>
</table>
All customers whose first name starts with letter “B”, even those with no orders:

```
SELECT Orders.orderID, Customers.name, Customers.city
FROM Orders
RIGHT OUTER JOIN Customers
ON Orders.custID = Customers.Id
WHERE Customers.name like 'B%'
```
Another well-earned moment of Zen...
Hierarchical Database

- Structurally different from RDBMS
- Optimized for rapid transactions of hierarchical data
- In very simple terms, makes it easy to know “every attribute about one thing” (quickly retrieve all known information about patient 1001)
- Computationally easy to traverse the tree. Can only traverse tree from root (top parent) node
- Ex: “find all deceased patients who were ordered topiramate” would be “easier” in relational DB than hierarchical DB
- Child nodes can only have 1 parent
  - Difficult to model relationship between child nodes (many-to-many, recursive relationships)
Example Hierarchical DB

- PAT_ID = 1004
  - MRN = 9992321
  - DOB = ‘12/08/1969’
  - First_Name = ‘Louise’
  - Last_Name = ‘Chen’
  - Deceased = Y
  - Medications[
    - Order_ID = 993
      - Name = ‘acetaminophen’
    - Order_ID = 994
      - Name = ‘topiramate’
  ]
History of MUMPS

Design and Implementation of a Clinical Data Management System*

R. A. Greenes, A. N. Pappalardo, C. W. Marble, and G. Octo Barnett

Laboratory of Computer Science,
Massachusetts General Hospital,
Department of Medicine
Harvard Medical School,
Boston, Massachusetts 02114

Received March 10, 1969

Increasing activity in the use of computers for acquisition, storage, and retrieval of medical information has been stimulated by the growing complexity of medical care, and the needs for standardization, quality control, and retrievability of clinical data. Criteria for the design of a clinical data management system include flexibility in its interface with its environment, the capability of handling variable length text string data, and of organizing it in tree-structured files, the availability of this data to a multi-user environment, and the existence of a high-level language facility for programming and development of the system. The scale and cost of the computer configuration required to meet these demands must nevertheless permit gradual expansion, modularity, and usually duplication of hardware. The MGH Utility Multi-Programming System (MUMPS) is a compact time-sharing system on a medium-scale computer dedicated to clinical data management applications. A novel system design based on a reentrant high-level language interpreter has permitted the implementation of a highly responsive, flexible system, both for research and development and for economical, reliable service operation.
History of MUMPS

- Described in 1969 by Greenes, Pappalardo, Marble, and Barnett
- “MGH Utility Multi-Programming System”
- Design goals
  - Flexible interface (e.g. lab systems, notes, variable output format)
  - Variable length text-handling
  - Hierarchical design to support complexity of clinical data and update/retrieval methods
  - Multi-user access (original paper recognized potential for conflicting updates, need to have ACID transactions)
  - Large storage capacity
  - Low CPU usage
  - A high-level programming language to make interface design less time-consuming, more efficient
- MUMPS renamed “M” in 1993 by M Technology Association, recognized by ANSI in 1995
- MUMPS and its derivatives, such as Intersystems Caché, are among the most widely used transactional DBs for EHRs today
- Design of MUMPS predated, anticipated the “NoSQL” and “schema-less DB” movement
MUMPS as a Procedural Language

```mumps
WRITE 1
1.10 READ !,"UNIT NO. ",X
1.15 IF 'X:3N'"-"2N"-"2N TYPE " ILLEGAL" GOTO 1

DO 1
UNIT NO. 123-45-678 ILLEGAL
UNIT NO. 12-345-67 ILLEGAL
UNIT NO. 123-456-78 ILLEGAL
UNIT NO. 123-45-67
```

- This programming snippet reads user input from teletype at the prompt “Unit No.” and assigns the value to variable X.
- Line 1.15 uses a ternary operator (IF-THEN-ELSE) to validate the format of the string X, in this case, that it’s the form of 3 digits, a dash, 2 digits, a dash, and two digits.
- If the pattern does not match, it displays the phrase “ILLEGAL” and returns to 1.10.
Can you guess what these snippets do?  
(hint: imagine this code as the user interface for a lab information system)
MUMPS as a Hierarchical DB

Fig. 5. A simplified tree-structured patient file, stored in a global array, named “$A$”, used in the data retrieval program example of Fig. 6. The first level of the array indicates patient identification; the $I$th branch is expanded here to show the structure for the data of patient I. The next level is used to represent class of information. We are interested in field 7, diagnoses; the number of diagnoses present for the $I$th patient is indicated at this level. The diagnosis field is expanded at the third level, which contains a number of individual diagnostic statements.
MUMPS Global Variables

• “[H]ierachically organized, symbolically accessed” structure – KEY/VALUE database
• Local variables are defined in the scope of the program
• Global variables referenced by an up arrow symbol (later became a caret “^”)
• This code retrieves a patient in the Active Patient Record (APR) global that matches a local variable “UN” (hospital unit number, or location of patient) and assigns the name and age:

  \[
  \text{SET } ^\text{APR(UN, NAME)}=\text{“DOE, JOHN”}, \ ^\text{APR(UN, AGE)}=\text{“34”}
  \]

• This code traverses a patient’s record UN→CHEM→N (unit number, chemistry results, sodium), and assigns it a string value, concatenated from two local variables DATE and TEST:

  \[
  \text{SET } ^\text{APR(UN, CHEM,N)}=\text{DATE. , , TEST}
  \]
Object Databases

- Data represented as data objects
- Support for more data types (graphics, photo, video, webpages)
- Object DBs are usually integrated into programming language, so accessing data doesn’t require complex driver configuration
- Increased use recently with development of web applications, most web application frameworks support interaction with OODBMS
- Commercial example: Intersystems Caché – the OODBMS behind the Epic EHR
Unified Modeling Language

- Standard toolset for describing aspects of databases, software, business processes
- **Class diagram** to describe OO classes (name, hierarchies, attributes, methods)
- **Activity diagram** ~ process flowchart, stepwise description of decisions, consequences, inputs, outputs
Unified Modeling Language

- **Use Case diagram** – describes actors, goals, dependencies
- **Entity-Relationship diagram** – describes objects and their relationships
- ER diagram can then be used to define RDBMS logical schema, which DB programmers can use to build physical schema of a DB

UML Class Diagram

- Title of the class
- Attributes with type (optional default values)
- Methods with inputs or return types
- Inheritance indicated with a solid arrow pointing to parent class
“E-R” = Entity Relation

Note relationship between Customer and Purchase Order:

- A customer is an optional participant (the “O” symbol)
- Only one customer can participate (the “|” symbol)
- A customer can have multiple purchase orders (the three-pronged arrow symbol)
- Details the attributes of Customer and Purchase Order
Based on the E-R Diagram, a developer can:

- describe the logical schema for the database
- create physical schema and DDL/SQL code to create tables
- create object classes that map to database tables
- map object classes to DB tables using an ORM tool
Reliable DB Transactions: The ACID Test

- **Atomicity** – transaction is indivisible, it either happens or it doesn’t, no possibility of a partial transaction (ex: a DB transaction that updates 2 cells – it either does both or neither)

- **Consistency** – transaction meets all constraint rules (can’t add a DATE to an INT field, can’t have a non-unique PK)

- **Isolation** – RBDMS must be able to sequence simultaneous transactions (ex: 2 transactions to update the same cell. Both must take place, but not at same time, or else you have a write-write failure)

- **Durability** – system must be tolerant to failure (ex: RDBMS has queued 200 transactions in memory, and power fails. How do you know if all 200 transactions took place?)
Normalization

- Techniques of structuring tables to reduce redundancy, dependency between tables
- Consider the “Flat File” example from earlier
  - One of the “Medication” cells has 2 entries
  - This violates a rule known as 1st Normal Form (1NF)
- Goals of Normalization
  - To free the collection of relations from undesirable insertion, update, and deletion dependencies
  - To reduce the need for restructuring the collection of relations as new types of data are introduced, and thus increase the lifespan of application programs
  - To make the relational model more informative to users
  - To make the collection of relations neutral to the query statistics, where these statistics are liable to change as time goes by
First Normal Form

• A DB is said to be in 1NF if it can meet the following conditions:
  – Each cell contains a single value (our “Flat File” example breaks this rule)
  – No duplicate rows (and therefore each row is unique, can be described by a unique key)

<table>
<thead>
<tr>
<th>Patient_ID</th>
<th>Medication</th>
<th>Pharmacy</th>
<th>Formulary</th>
</tr>
</thead>
<tbody>
<tr>
<td>1001</td>
<td>acetaminophen</td>
<td>Glenbrook</td>
<td>yes</td>
</tr>
<tr>
<td>1002</td>
<td>amoxicillin</td>
<td>Medstar</td>
<td>yes</td>
</tr>
<tr>
<td>1002</td>
<td>fluticasone</td>
<td>Medstar</td>
<td>yes</td>
</tr>
<tr>
<td>1003</td>
<td>cetirizine</td>
<td>Brighton</td>
<td>no</td>
</tr>
</tbody>
</table>

• 1NF is susceptible to certain INSERT, DELETE, and UPDATE anomalies:
  – INSERT: A patient can’t have a Pharmacy without a prescription, unless we create a row with NULL values
  – DELETE: If the med “acetaminophen” is deleted, the Pharmacy “Glenbrook” ceases to exist
  – UPDATE: If the “Medstar” pharmacy chain changes their name, we have to edit multiple cells in this table
Second Normal Form

- A DB is said to be in 2NF if it can meet the following conditions:
  - Table meets all criteria for 1NF AND
  - Every non-key attribute is dependent on the Primary Key (In 1NF example, there was no PK)

<table>
<thead>
<tr>
<th>Event_ID (PK)</th>
<th>Patient_ID</th>
<th>Medication_ID</th>
<th>Pharmacy_ID</th>
<th>Formulary</th>
</tr>
</thead>
<tbody>
<tr>
<td>20131</td>
<td>1001</td>
<td>9991212</td>
<td>704</td>
<td>yes</td>
</tr>
<tr>
<td>20132</td>
<td>1002</td>
<td>9984021</td>
<td>216</td>
<td>yes</td>
</tr>
<tr>
<td>20133</td>
<td>1002</td>
<td>9933333</td>
<td>216</td>
<td>yes</td>
</tr>
<tr>
<td>20134</td>
<td>1003</td>
<td>9906761</td>
<td>844</td>
<td>no</td>
</tr>
</tbody>
</table>

- 2NF is susceptible to certain INSERT, DELETE, and UPDATE anomalies:
  - INSERT: We can’t indicate a patient’s pharmacy unless there is a medication prescribed
  - DELETE: If you delete the last row that contains med “9906761”, you no longer know if it’s on formulary
  - UPDATE: to update the formulary status for a Medication_ID may require updating multiple rows
Third Normal Form

- A DB is said to be in 3NF if it can meet the following conditions:
  - Table meets all criteria for 1NF AND 2NF AND
  - No non-key column determines another non-key column (this is a very simplified definition)

<table>
<thead>
<tr>
<th>Event_ID</th>
<th>Patient_ID</th>
<th>Medication_ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>20131</td>
<td>1001</td>
<td>9991212</td>
</tr>
<tr>
<td>20132</td>
<td>1002</td>
<td>9984021</td>
</tr>
<tr>
<td>20133</td>
<td>1002</td>
<td>9933333</td>
</tr>
<tr>
<td>20134</td>
<td>1003</td>
<td>9906761</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient_ID</th>
<th>Pharmacy_ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>1001</td>
<td>704</td>
</tr>
<tr>
<td>1002</td>
<td>216</td>
</tr>
<tr>
<td>1003</td>
<td>844</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication_ID</th>
<th>Formulary</th>
</tr>
</thead>
<tbody>
<tr>
<td>9991212</td>
<td>yes</td>
</tr>
<tr>
<td>9984021</td>
<td>yes</td>
</tr>
<tr>
<td>9933333</td>
<td>yes</td>
</tr>
<tr>
<td>9906761</td>
<td>no</td>
</tr>
</tbody>
</table>

- Even 3NF is susceptible to certain INSERT, DELETE, and UPDATE anomalies!
- Example: What if there was a registration error and patient 1001 and patient 1003 are actually the same patient? How can you avoid changing multiple cells in the first table?
Normalization & Denormalization

- There are higher forms of normalization beyond 3NF, like “Boyce-Codd Normal Form” (abbreviated “BCNF”)
- In practice, a database that is in 3NF can be called “normalized”
- Normalized DBs are safe against most INSERT, UPDATE, and DELETE anomalies, however, to generate a report, you have to “denormalize” the data – requires lots of PK & FK “JOIN” logic in your query
- For high-performance RDBMS apps, denormalized schema may be preferable to allow single-table lookup functions with an index, to avoid additional JOINs and full-table scans
- Also, you need to denormalize data to aggregate the data into meaningful groups (eg: all meds for patient X)
- That is often the role of reporting tools, analytics, data marts, etc
Data Warehouse & Data Marts

• Extract/Transform/Load (ETL) process gets transactional data into a format that is optimal for reporting / queries

• Real life example: Epic EHR runs on Intersystems Caché Object DB for transactional processing. Has a nightly process to push data into an RBDMS (e.g. Oracle SQL)

• Datamart is a smaller collection of related tables and data derived from the warehouse for a specific purpose, usually for analysis, report generation, spreadsheet, dashboards, etc.

• Example: EHR may have a real-time transactional DB, nightly dump to a SQL data warehouse, and weekly extracts to a datamart to generate an updated enterprise asthma performance dashboard.
Network Topologies

- Ring
- Mesh
- Star
- Fully Connected
- Line
- Tree
- Bus

Image credit: http://upload.wikimedia.org/wikipedia/commons/9/97/NetworkTopologies.svg
Network Topologies

- Patterns of links between elements of a computer network
- Choice of topology determines fault tolerance, redundancy, and scalability
- Phone telephony is an example of a point-to-point connection, so is connection between your CPU and the hard-drive
- Centralized – Star, Tree
- Decentralized – Mesh, Fully Connected
Features of Network Protocols

• “Handshake”

• Acknowledgement

• Payload

• Multiple protocols exist for multiple purposes

• Distinguish the Network Protocol from the Data or Encoding Standard
  - Ex: HL7 v2.x message is a pipe-delimited text file, v3 is an XML file, both can be transmitted via TCP/IP across a network
The TCP/IP Stack

- Network protocol used for internet communications
- TCP = transmission control protocol
- IP = internet protocol
OSI Seven Layer Model

- **Host**
  - **Data** [transmission of message via HTTP, SMPT, FTP]
    - 7. Application (HTTP is an application layer protocol)
    - 6. Presentation (character encoding in ASCII or data encryption are at this level)
    - 5. Session (ex: a web conference may have a persistent session to synch audio and video)
  - **Segments**
    - 4. Transport [transmission of segments via TCP, UDP]

- **Media**
  - **Packet/Datagram**
    - 3. Network [transmission of packets via IP, DNS server, through routers]
  - **Frame**
    - 2. Data Link [transmission of frames via Ethernet or PPP]
  - **Bit**
    - 1. Physical [transmission of binary bits via copper wire, coaxial, or fiber optic cable]
## Examples of Protocols by OSI Layer

<table>
<thead>
<tr>
<th>Layer</th>
<th>Example Protocols</th>
</tr>
</thead>
<tbody>
<tr>
<td>7: Application</td>
<td>POP3/IMAP4 for email, HTTP for web content, FTP for file transfer, SSH and HTTPS for secure browsing</td>
</tr>
<tr>
<td>6: Presentation</td>
<td>none</td>
</tr>
<tr>
<td>5: Session</td>
<td>LDAP “Lightweight Directory Access Protocol” for authenticating users against X.500 directories</td>
</tr>
<tr>
<td>4: Transport</td>
<td>TCP “transmission control protocol” (with acknowledgement), UDP “User Datagram Protocol” (without acknowledgement)</td>
</tr>
<tr>
<td>3: Network</td>
<td>IPv4, IPv6, DHCP “dynamic host control protocol” used to assign IP addresses to hosts, for example, when you connect to a wireless hotspot</td>
</tr>
<tr>
<td>2: Data Link</td>
<td>ARP – “address resolution protocol” used by TCP to communicate with hosts when only neighboring hosts’ addresses are known</td>
</tr>
<tr>
<td>1: Physical</td>
<td>none</td>
</tr>
</tbody>
</table>
OSI Real World Analogy
(adapted from http://som.csudh.edu/cis/lpress/471/hout/netech/postofficelayers.htm)

- **7: Application Layer** – I send a letter to Bob. Bob receives and opens the letter.
- **6: Presentation Layer** – my letter is encoded in roman script using the English language
- **5: Session Layer** – I may include one or more letters per session (envelope) as long as I have appropriate postage
- **4: Transport Layer** – There is a typo in the address. The postal service marks it “recipient unknown” and sends it back. I get details of failure or confirmation of success (ex: registered mail)
- **3: Network Layer** – physical mail is sent by plane between cities. Pilot has no awareness of the final destination of the letter she is carrying
- **2: Data Link Layer** – Postal Service worker drives truck within city to deliver message
- **1: Physical Layer** – my letter is comprised of ink or graphite on a piece of paper, folded and tucked into an envelope
Telecommunications

- Telephony has changed rapidly in past decade
- Popularization of mobile, wifi, and VOIP
- Video conferencing
  - Web conferencing / collaboration via H.264 Scalable Video Coding (SVC)
  - This is the the same codec*, known as MPEG-4, used for distribution of video content on IP, like YouTube

*CODEC = coder / decoder – a compression algorithm used for a digital stream to transmit audio, video, etc. They can be “lossy” or “lossless”. Lower bitrate often means lower fidelity.
Short Range Wireless Standards

- Short Range PAN - Personal Area Network
  - RFID (one way) and NFC (two way)
  - IEEE 802.15 – Wireless Personal Area Network and derivatives
    (Bluetooth & Infrared Data Association or IrDA)
Bluetooth Standard

- Historically maintained by IEEE as 802.15.1, but now maintained by Bluetooth SIG
- Bluetooth 4.0 standard introduced Bluetooth Low Energy (aka Bluetooth Smart or Bluetooth LE)
- Bluetooth LE has recently become very popular in health and fitness
  - Healthcare-specific profiles for blood pressure, thermometer, glucose monitor, continuous glucometry
  - Fitness-specific profiles for weight scale, running/cycling speed, heart rate, etc.
Medium Range Wireless Standards

- Medium Range WLAN – Wireless Local Area Network
  - **802.11b** – Max 11Mbps, interferes with other 2.4Ghz devices like microwaves, Bluetooth, cordless phones. Popularized WiFi
  - **802.11g** – Max 54 Mbps, same band as 802.11b, same interference concern.
  - **802.11n** – uses both 2.4Ghz and 5 Ghz spectrum for max speeds of 54 Mbps and 600 Mbps respectively. Speed enhanced by MIMO (Multiple Input, Multiple Output)
  - **802.11ac** – emerging draft standard for “gigabit wifi” – 1 Gbps
Long Range Wireless Standards

- Alphabet Soup & Confusing Marketing Alert!
  - WiMax
  - CDMA
  - 3G
  - 4G
  - LTE
Wireless Applications

- IP Telephony (“Vocera” devices in healthcare)
- SMS text messaging
- Various “secure” texting solutions (HIPAA compliant)
- RFID/NFC tagging of medical devices, patients
RFID

- RFID = Radio Frequency Identification
  - 3 “flavors”: passive, active, battery-assisted
    passive
  - Passive relies on power from the reader, but reader has to emit 1000x stronger signal
  - Tags are read-only or read-write
  - RFID reader sends a signal to interrogate tag
  - RFID tag/chip responds with ID and other info
  - Like tags, readers can be active or passive
  - Uses: animal tags, “Smart cards”, asset tracking

Implantable veterinary RFID chip
Image courtesy Wikimedia
NFC

• NFC = Near Field Communication
  – Used to establish communication between two electronic devices
  – NFC tags passively store data, some can be written to by an NFC device.
  – Typical uses = phone-enabled payment (credit card information), PIN storage
Healthcare Applicability & Challenges

- Retrofitting older facilities with equipment
- Bandwidth limitations as amount of data increases
  - MRI wrist = 5MB
  - CT 3D reconstruction skull = 120MB
  - CT angiogram = 230MB
  - Human genome = 850MB (I’ve seen stats as high as 1.5GB)
  - Challenges with compression, image quality, and transmission
- Keeping up with demand – more and more “ologies”
- Network security – distinct wireless networks for telephony, hospital applications, guest applications. VPN and Remote access
- Both RFID and NFC pose “skimming” concerns -
- “Bring Your Own Device” – everyone has a personal device they’d like to use at work
- Network maintenance – uptimes become more critical, and downtimes become dangerous
End of Lecture
Suggested Additional Reading


Resources for Self-Directed Learning

Two great resources for learning SQL online, in your browser

- [http://www.w3schools.com/sql/](http://www.w3schools.com/sql/)
- [http://sqlzoo.net/](http://sqlzoo.net/)

Database normalization:

Security

Lecture 3A-3

Thomas H Payne, MD, FACMI
University of Washington
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      1.1.1. The discipline of informatics
      1.1.2. Key informatics concepts, models, and theories
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Core Content Covered

3.1.4 Security

3.1.4.1 The HIPAA Security Rule and other government regulations

3.1.4.2 Firewalls

3.1.4.3 Virtual private networks

3.1.4.4 Encryption
Key topics

• Key elements of the HIPAA Security Rule.
• Policy, and technical measures to protect the security of identified patient health information.
• Three technical measures (firewalls, VPNs, and encryption) and the security context in which they are used.
Definitions, 1

Firewall: A set of hardware components (router, hosts, and combinations) and networks with appropriate software to restrict network traffic to conform to the security policy of the site. [Zwicky 2000]

Virtual private network: A VPN is a virtual network, built on top of existing physical networks, that can provide a secure communications mechanism for data and other information transmitted between networks. Because a VPN can be used over existing networks, such as the Internet, it can facilitate the secure transfer of sensitive data across public networks. [NIST, 2008]
Encryption: A method of converting an original message of regular text into encoded text. The text is encrypted by means of an algorithm (type of formula). If information is encrypted, there would be a low probability that anyone other than the receiving party who has the key to the code or access to another confidential process would be able to decrypt (translate) the text and convert it into plain, comprehensible text.
Encryption algorithms and terms

- **Data Encryption** Standard (DES), Triple DES (3DES), Advanced Encryption Standard (AES)
- **Secure Hash Algorithm** (SHA-1, SHA-2), Message-Digest Algorithm (MD5), Hash Message Authentication Code (HMAC)
- **WiFi**
  - Wired Equivalent Privacy (WEP)
  - Wi-Fi Protected Access (WPA)
  - Wi-Fi Protected Access 2 (WPA2)
- **Public key encryption**
HIPAA Security Rule, 1.
[hh.gov, 2013]

Covered entities must:

1. Ensure the **confidentiality, integrity, and availability** of all e-PHI they create, receive, maintain or transmit;
2. Identify and **protect** against reasonably anticipated threats to the security or integrity of the information;
3. Protect against reasonably anticipated, **impermissible uses or disclosures**; and
4. Ensure compliance by their **workforce**.
The Security Rule defines “confidentiality” to mean that e-PHI is not available or disclosed to unauthorized persons. The Security Rule's confidentiality requirements support the Privacy Rule's prohibitions against improper uses and disclosures of PHI. The Security rule also promotes the two additional goals of maintaining the integrity and availability of e-PHI. Under the Security Rule, “integrity” means that e-PHI is not altered or destroyed in an unauthorized manner. “Availability” means that e-PHI is accessible and usable on demand by an authorized person.
Changes to US HIPAA as part of ARRA

- Requirements Expanded to Business Associates
- Provisions Include Data Restrictions, Disclosure and Reporting Requirements
  - Limited Data Sets
  - Restrictions on Disclosures
  - Marketing
  - Reporting Security Breaches
  - Accounting of Disclosures
  - Charitable Fundraising
  - Sales of Protected Health Information
- Enforcement
Changes as part of ARRA

• Expansion to Business Associates
• Data restrictions
• Disclosure requirements
• Reporting requirements
An encrypted laptop from your organization containing PHI on 250 research study patients was misplaced at an airport. Which of the following is true?

A. Your organization must report this to the Secretary of HHS.
B. Because fewer than 400 patients were affected, you are not required to report this to the Secretary of HHS.
C. No report to the press or to HHS is necessary.
D. Individuals must be notified within 60 days of discovery.
Breach Notification

• A breach is the unauthorized acquisition, access, use or disclosure of unsecured PHI which compromises the privacy, security or integrity of the PHI. Unsecured PHI is defined as PHI not secured through technology or method specified by the Secretary through guidance.
• Must notify individuals within 60 days of discovery
• Must resort to public media notification if > 500 records
• Must notify the Secretary without reasonable delay of breaches > 500 records
• Must provide Secretary annual report of all breaches
Security Risk Assessment, ARRA

“Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process.”
Security and Privacy Changes in Stimulus Bill

- HIPAA Privacy and Security rules now apply to Business Associates
- Civil and criminal penalties also apply
- Business Associate Agreements may need to be updated
- BAA must demonstrate documented policies and procedures
- BA must notify covered entity and Secretary of HHS of breaches
Technical measures

- Audit trails
- Encryption
- VPN
- Software discipline
- System assessment
- Individual (strong) authentication of users
- Firewalls
Authentication

Authentication is any process of verifying the identity of an entity that is the source of a request or response for information in a computing environment. It is the linchpin for making decisions about appropriate access to health care information, just as it is for controlling legal and financial transactions. Generally, authentication is based on one or more of four criteria:

1. Something that you have (e.g., a lock key, a card, or a token of some sort);
2. Something that you know (e.g., your mother’s maiden name, a password, or a personal ID number);
3. Something related to who you are (e.g., your signature, your fingerprint, your retinal or iris pattern, your voiceprint, or your DNA sequence); or
4. Something indicating where you are located (e.g., a terminal connected to a hardwired line, a phone number used in a callback scheme, or a network address).

Authentication = who you are. Authorization = What you can do

For the Record: Protecting Electronic Health Information [National Academy Press 199]
Security – Requirements

• Layers of protection
• Dynamic, moves with changes
• Comprehensive
• Commensurate with asset classification, value-adjusted, cost-effective
• Consistent with institutional mission and operation
• Clear, assigned responsibilities
• Metrics

*Defense in-depth*

Slide courtesy of Soumitra Sengupta
Security – Concepts

• There are **NO perfectly secure** information systems
• We have to identify **risks** specific to an **asset** based upon possible **threats**, and then
• Implement and modify **security controls** to reduce risks, so that
• Residual risks are at an **acceptable** level.
• Threats may become security **incidents**, which lead to **sanctions** and modified security controls

*Acknowledge: security controls and ease of access often work **against** each other*
Security – Threats & Incidents

• Types
  – Malicious, accidental, opportunistic/intentional
  – Internal, external
  – Incidental, significant, debilitating

1. Internet hacker exploits our server to distribute copyrighted media
2. A clerk uses his privilege to identity information of wealthy patients
3. A resident drops coffee on a desktop keyboard at a nursing station used by several users
4. A construction worker cuts a power cable in front of the hospital

Slide courtesy of Soumitra Sengupta
Security – Controls & Vulnerabilities

• Types
  – Administrative, Physical, Technical

• Administrative examples
  – Acceptable Internet Use policy
  – Password management policy
  – Use & protection of SSN in clinical research data
  – Business associate agreement, contracts

• Physical examples
  – Badge based entry into sensitive areas
  – Cameras, RFID based protection in Nursery
  – Dual lock system for access to pathogens, access to animal labs
  – Essential data center and data closet security

Slide courtesy of Soumitra Sengupta
Security – Technical Controls

• Network
  – Firewalls
  – **Intrusion detection and prevention systems** (IDPS)
  – Network access control (NAC)
  – Virtual private networks (VPN)
  – Data leakage protection (DLP)

• Systems, applications
  – Authentication, Authorization, Audit logs (Security Event/Incident Management)
  – Patching, up-to-date rules in Anti virus/spyware
  – Host based Firewalls, IDPS, DLP
  – Encryption, encryption, encryption

Slide courtesy of Soumitra Sengupta
Security Practices Recommended for Immediate Implementation

*Technical Practices and Procedures*

- Individual authentication of users
- Access controls
- Audit trails
- Physical security and database recovery
- Protection of remote access points
- Protection of external electronic communications
- Software discipline
- System assessment

Source: For The Record, Institute of Medicine, 1997
Security Practices Recommended for Immediate Implementation

Organizational Practices

• Security and confidentiality policies
• Security and confidentiality committees
• Information security officers
• Education and training programs
• Sanctions
• Improved authorization forms
• Patient access to audit logs

Source: For The Record, Institute of Medicine, 1997
Which of the following is usually not part of an organizational security program?

A. Offsite backup with testing of ability to restore
B. Timely patching of device operating systems
C. Creation of Corporate Integrity Agreement
D. External assessment of security vulnerabilities
# Security layers

## Examples

<table>
<thead>
<tr>
<th>Physical</th>
<th>Intrusion, fire, power, seismic protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Network</td>
<td>Firewalls, WEP (wired equivalent privacy)</td>
</tr>
<tr>
<td>Social</td>
<td>Phishing, malware, spoofing</td>
</tr>
<tr>
<td>Software</td>
<td>Design, updates, authentication</td>
</tr>
<tr>
<td>Data</td>
<td>Backup, restore, redundancy</td>
</tr>
</tbody>
</table>
Security definitions

- **Malware**
  Malicious software

- **Phishing**
  A deception perpetrated via email where recipients are enticed into following an attacker's instructions. Following the instructions may take the reader to malicious sites crafted to impersonate valid ones and steal credentials.

- **Denial of service**
  Attempts to prevent legitimate users from accessing information or services.

- **Ransomware**
  A type of malware that infects computer systems, restricting users’ access to the infected systems. Users are told that unless a ransom is paid, access will not be restored.

US-CERT.gov
Spoofing is best prevented by:

A. Properly configured firewalls
B. Workforce education
C. Encryption of mobile devices
D. Risk transference programs
Security – Risk assessment

• **Methods**
  – Self-assessment of asset owners
  – Assessed by internal group
    • Security, Risk management, Internal audit
  – Assessed by external group
    • Vulnerability scanners, ethical “white-hat” hackers, external auditors

• **Measurement**
  – Qualitative – High, medium, low
  – Quantitative – a derived numeric score

• **Management**
  – Risk acceptance
  – Risk mitigation
  – Risk transference

Slide courtesy of Soumitra Sengupta
Security – Incident Handling

• Examples
  • *DMCA violation by students and staff*
  • *VVIP access*
  • *Unencrypted PHI on a desktop*
  • *Malicious user prints identity for identity theft*

• Breach notification process

• *Office of Civil Rights (OCR)* Audit preparation
  • Risk management portfolio
  • Awareness education
  • Senior management support

Slide courtesy of Soumitra Sengupta
Security – Rules & Regulations

- JCAHO: Joint Commission on Accreditation of Healthcare Organization – Information Management
- HIPAA: Health Insurance Portability and Accountability Act – Information Security of Electronic Protected Health Information. See also references.
- ARRA/HITECH: American Recovery and Reinvestment Act/Health Information Technology for Economic and Clinical Health – Breach notification, accounting of disclosure, etc.
- Sarbanes-Oxley Act of 2002 – Audit functions for financial data
- 21 CFR Part 11 – (FDA) Data Security, Electronic signatures, etc.
- CDC/NIH/FDA Biological Safety Labs and Bioterrorism, information security
- FERPA: Family Educational Rights and Privacy Act – Medical/Nursing/Dental students’ data
- State Laws on HIV and Mental Health Information
- State Information Security Breach and Notification Act
- State Social Security Number Protection Act
- Payment Card Industry Data Security Standard (PCIDSS)
- DMCA: Digital Millennium Copyright Act of 1998 – Copyright violations among immature users

Slide courtesy of Soumitra Sengupta
Additional suggested readings


• See also reference list.
4E-1: Strategic Planning for Clinical Information Systems

Alexis Carter, MD
Physician Informaticist
Children’s Healthcare of Atlanta
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Core Content Covered

4. 5. Strategic and Financial Planning for Clinical Information Systems

4.5.1 Establishing mission and objectives
4.5.2 Environmental scanning
4.5.3 Strategy formulation
4.5.4 Action planning and strategy implementation
4.5.7 Evaluation of planning process
Key Points

• Strategy for information systems must align with organizational strategy

• Strategic planning models can guide strategy formulation

• Environmental scanning informs long range strategic planning

• Components of sound strategic planning are common between strategic models

• Measuring impact of strategic planning helps secure resources for future planning
Strategic Planning

[Schmidt et al. 2009]

Systematic process of envisioning a desired future

Translating this vision into broadly defined goals or objectives

Developing and performing a sequencing of steps to achieve them

- Works backward from desired future state
- Looks at big picture
- Contrast...

<table>
<thead>
<tr>
<th>Long-term planning</th>
<th>begins with current state and works forward to estimate future needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tactical planning</td>
<td>Focuses on achieving narrowly defined interim objectives with predetermined means</td>
</tr>
</tbody>
</table>
Strategic Plan

• Typical plan spans 3-5 years ahead
  – Resource-intensive
  – Provides adequate detail & contingency plans
• Alternative: small ongoing studies
  – Quick and inexpensive
  – Lack detail and sufficient contingency plans
• Unanticipated events may require revisions to the plan
  – Try to anticipate as much as possible
Strategic Information Systems Plan (SISP)

• a.k.a. Strategic Information Management (SIM) Plan

• Process of identifying a portfolio of computer-based applications that will assist an organization in executing its business plans and realizing its business goals. [Lederer et al. 1996]

• Very labor-intensive process
## History of SISP

**[Mangalaraj 2014]**

<table>
<thead>
<tr>
<th>Era</th>
<th>Period</th>
<th>Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>The pre-strategic ISP era</td>
<td>Early to mid-1970s</td>
<td>Assessment of future computing needs.</td>
</tr>
<tr>
<td>The early strategic ISP era</td>
<td>Late 1970s</td>
<td>Influenced by strategic planning, top management was involved.</td>
</tr>
<tr>
<td>The modern era</td>
<td>Late 1980s</td>
<td>Effectiveness consideration and ISP became part of business planning.</td>
</tr>
<tr>
<td>Alignment era</td>
<td>Late 1990s</td>
<td>ISP is part of the process to align business and IS strategy.</td>
</tr>
<tr>
<td>Uncertainty era</td>
<td>Late 2000s</td>
<td>ISP comprehensiveness under uncertain environmental conditions.</td>
</tr>
</tbody>
</table>
### SISP Research Themes

[Mangalaraj 2014](#)

<table>
<thead>
<tr>
<th>Theme</th>
<th>Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodological view</td>
<td>Method(s) used in the SISP</td>
</tr>
<tr>
<td>Process view</td>
<td>Processes used in the SISP, citing that Methodological is too narrow</td>
</tr>
<tr>
<td>Factors view</td>
<td>Factors that influence successful implementation of SISP</td>
</tr>
<tr>
<td>Organizational Impact View</td>
<td>Successful implementation of SISP has beneficial impacts on organization</td>
</tr>
<tr>
<td>Evaluation view</td>
<td>Producing objective quantitative measures of SISP success</td>
</tr>
</tbody>
</table>
Importance of SISP

• Failure to perform SISP well or at all \cite{Basu et al. 2002}:
  – Missed opportunities
  – Duplicated efforts
  – Incompatible systems
  – Wasted resources
Success of SISP
[Basu et al 2002]

• Based on three organizational factors

Organizational commitment
  – Sufficient resources provided
  – Management intervenes in related conflicts
  – *Too much planning can be detrimental to SISP success*

Senior management involvement
  – Championed by top executives who provide feedback and guidance
  – Independently associated with SISP success (not other factors)
  – Can’t have enough (no tipping point)

Team involvement
  – Plan input comes from plan implementers
  – critically important to success in many research studies
SISP

• This is a project
  – Section 4D (Project Management)
• Requires resources
• Ideally led by CIO and CMIO
• Recruit and involve team and stakeholders
  – Just as you would for any other project
## SISP Process

[Lederer et al. 1996]

<table>
<thead>
<tr>
<th>Core Content</th>
<th>Process step</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.5.1 Establishing Mission and Objectives</td>
<td>1. Scope definition and organization</td>
</tr>
</tbody>
</table>
| 4.5.2 Environmental Scanning | 2. Business and Competitive Assessment  
3. Present Status Assessment (Situation analysis) |
| 4.5.3 Strategy Formulation | 4. Information Technology Opportunities  
5. Information Technology Strategies |
| 4.5.4 Action Planning Strategy Implementation | 6. Organization Plan  
7. Data and Application Plan  
8. Technology Plan  
9. Information Action Plan  
10. Project Definition and Planning |
| 4.5.7 Evaluation Of Planning Process | Post-plan evaluation and monitoring |
SISP Content

[Brigl et al. 2005]

• Summary
• Introduction
• The Hospital
  – Vision, Mission, Objectives
  – Hospital characteristics, Organizational structure, Spatial structure (layout)
• Information management of the hospital
  – Organization of information management
  – Information management principles, goals and standards
• Assessment of current state (information system and organization)
• Desired target (future) state of the information system and organization
• Action Plan
• Contingency and mitigation plan for alternative scenarios
• Planned evaluation and monitoring of progress
Question: Failure to perform a strategic information systems plan would result in all of the following EXCEPT:

A. Duplicated resources
B. Missed opportunities
C. Duplicated efforts
D. Incompatible systems
Answer: Failure to perform a strategic information systems plan would result in all of the following EXCEPT:

A. Duplicated resources
B. Missed opportunities
C. Duplicated efforts
D. Incompatible systems
Strategic Planning Models

• Organizational Pull model
• Technology Push model
• Component Alignment model
Strategic Planning: Organizational Pull model

- Prioritizes the organization’s business objectives as fully driving the IT requirements

- Overall organization “pulls” IT organization
  - set organizational business objectives, then
  - call on IM or IS to develop an IT plan to meet requirements from the business plan
Strategic Planning Models
Organizational Pull

• Organization drives the strategy
• Pulls information technology along with it
• Strategic planning for information technology follows that of the organization
Strategic Planning Models
Technology Push

• Concept that evolving information technology will enable organization to expand business scope

• Information technology pushes the organization into new areas of business or service delivery
Strategic Planning Models
Component Alignment

- [Martin 2001]
- Seven multi-aligned components
- Promotes success in rapidly changing complex environment
Strategic Planning Models
Component Alignment

The 7 Components of Component Alignment Model:

1. External environment (external forces affecting healthcare delivery)
2. Emerging IT (can influence mode of service delivery)
3. Organizational Mission
4. Organizational Infrastructure and Processes
5. IT infrastructure and processes
6. Organizational Business Strategy
7. IT strategy (rationale used in IT procurement and propagation)
Other Strategic Planning Techniques

**[Pollack 2010]**

<table>
<thead>
<tr>
<th>Stages of growth</th>
<th>Look at early successes, contagion, control and integration stages to determine where an organization is on the learning curve</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical Success Factors</td>
<td>Key areas (&lt;10) that must go right for an organization to flourish</td>
</tr>
</tbody>
</table>
| Competitive Forces Model | Five competitive forces in strategic use of information systems  
1. New entrants  
2. Bargaining power of buyers and suppliers  
3. Threat of substitute products  
4. Rivalry among competitors |
| Three emerging forces | Consider  
1. Growth of digitalization  
2. Globalization of commerce  
3. Deregulation of trade |
### Other Strategic Planning Techniques

[Pollack 2010]

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Value chain analysis**      | Five activities must get attention to get product or service created  
1. Logistics  
2. Operations  
3. Outbound logistics  
4. Marketing  
5. Sales and service |
| **E-Business value matrix**   | Portfolio management approach - four categories of projects  
1. New fundamentals  
2. Operational excellence  
3. Rational experimentation  
4. Breakthrough strategy |
| **Linkage analysis planning** | Examination of inter-organizational electronic links and identification of power relationships with suppliers, buyers and strategic partners |
| **Scenario planning**         | Plan what to do in the event of certain scenarios |
ESTABLISHING MISSION AND OBJECTIVES
SISP Vision and Mission

• Critical to align SISP with organization’s enterprise strategy
  – i.e., mission, vision and objectives must align with organization to…
    • Support/enhance quality healthcare delivery
    • Enable/amplify financial health and strategy
    • Foundation for integration of service delivery
VMOSA

[Community Tool Box 2016]

<table>
<thead>
<tr>
<th><strong>Vision</strong></th>
<th>The dream</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mission</strong></td>
<td>The what and why</td>
</tr>
<tr>
<td><strong>Objectives</strong></td>
<td>How much of what will be accomplished and when</td>
</tr>
<tr>
<td><strong>Strategies</strong></td>
<td>The how</td>
</tr>
<tr>
<td><strong>Action Plan</strong></td>
<td>Action items, their assignees &amp; deadlines</td>
</tr>
</tbody>
</table>
Vision

• Defines the entity’s purpose in context of its values
• Should inspire others
• Should convey sense of higher purpose
• Success of communicating vision with positive response → competency of leader
  – Section 4A: Leadership
Mission

• Defines entity’s purpose and primary objectives (business goals)
• Action-oriented
• Describes
  – Main function
  – Reason for existence
  – Customers (beneficiaries)
Objectives (Goals)

• Tangible desired accomplishments
• Describes how the vision and mission will be fulfilled
  – how it will be operationalized
• SMART
  – Specific, Measurable, Attainable, Realistic, Time-limited
ENVIRONMENTAL SCANNING
Environmental Scan

• Collection of data about external and internal influences that could affect desired future state

• Internal
  – human resources, financial resources, facilities, organizational culture, other resources

• External
  – collaborators and affiliates, regulators, vendors, contractors, competitors, professional organizations, current industry standards, etc.
### Environmental Scan - Internal

This information helps to define technical requirements later:

<table>
<thead>
<tr>
<th>Category</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Organizational</strong></td>
<td>Size, # of beds, departments, clinics, outpatient/inpatient, etc.</td>
</tr>
<tr>
<td><strong>Services</strong></td>
<td># outpatient visits, # inpatients, average length of stay, bed occupancy rate, # radiology &amp; imaging exams, # of procedures, etc.</td>
</tr>
<tr>
<td><strong>Business Management</strong></td>
<td>Expenditures (total organizational, material, capital expenditures, IT capital), number of employees, personnel costs, etc.</td>
</tr>
<tr>
<td><strong>Research &amp; Education</strong></td>
<td># of students &amp; trainees, third party funds (grants, etc.), total research expenditure, total education costs</td>
</tr>
</tbody>
</table>

Environmental Scan - External

- Survey external influences that will affect mission, vision, goals and strategies for future of your organization’s CIS
- Survey other entities similar to yours in size and current mission or future mission (Benchmarking)
- Current and anticipated Industry Standards & Regulations (Healthcare & Health IT)
# Environmental Scan - Methods

## PESTLE Analysis

<table>
<thead>
<tr>
<th>P</th>
<th>Political</th>
<th>existing and potential effect of political influences</th>
</tr>
</thead>
<tbody>
<tr>
<td>E</td>
<td>Economical</td>
<td>effect and influence of local, national and global economy</td>
</tr>
<tr>
<td>S</td>
<td>Social</td>
<td>projection of social changes inside the organization, cultural influences are also part of it (local, national, regional, global)</td>
</tr>
<tr>
<td>T</td>
<td>Technological</td>
<td>effects of existing, new and advanced technologies</td>
</tr>
<tr>
<td>L</td>
<td>Legal</td>
<td>effects of national, European and international legislation</td>
</tr>
<tr>
<td>E</td>
<td>Ecological</td>
<td>local, national and global environmental issues and questions of its solution</td>
</tr>
</tbody>
</table>
Environmental Scan - Methods

• **PESTLE Analysis** [PESTLE 2016]

• Other versions
  – PEST
    • P - Political – existing/potential effect of political influences
    • E - Economical - effect and influence of economy
    • S - Social - projection of social changes
    • T - Technological - effects of existing & new technologies
  – STEEPLED
    • Same as PESTLE except adds Ethical and Demographic factors
  – PESTELI, STEER, SLEPT and STEP also
Question: All of the following represent environmental scan methods EXCEPT:

A. PEST
B. SNOP
C. PESTLE
D. SWOT
E. Benchmarking
Answer: All of the following represent environmental scan methods EXCEPT:

A. PEST
B. SNOP
C. PESTLE
D. SWOT
E. Benchmarking
STRATEGY FORMULATION
Strategic Formulation

• Define desired future (target) state
  – Where should the organization be in 3-5 years?
  – Should align with Vision, Mission, Objectives
  – Should respond to the SWOT analysis by
    • Preserving Strengths
    • Resolving Weaknesses
    • Maximizing Opportunities
    • Mitigating Threats
Strategic Formulation

• Define desired future (target) state
  – Get input/consensus from appropriate stakeholders
  – Get approvals and signatures
Strategic Formulation

• Set the strategy
  – Determine strategies needed to take organization from current state to future state
  – Impossible to achieve all of future state at once
  – Define incremental steps which will keep you towards the goal
    • And NOT take you backwards!
Strategic Formulation

- When Murphy’s law strikes…
  - Expect the unexpected
    - New regulations
    - Budget cutbacks
    - Events which escalate problems to the top
  - Include a well-thought out contingency and mitigation plan
  - Outline a change control process for the SISP
ACTION PLANNING
STRATEGY IMPLEMENTATION
Action Planning & Strategy Implementation

• Create portfolio of projects for your strategy
  – Each project should bring the organization closer to future state
  – High-level estimates of time, people and money included in SISP
  – Define portfolio governance in the SISP
  – Follow all the same rules as for good project (and portfolio) management
Action Planning & Strategy Implementation

• Alignment to organizational strategic plan will reduce deviations
• Employ all other tools in section 4 of core content
EVALUATION OF PLANNING PROCESS
Evaluation of SISP Implementation

• “Monitor and Control” Process Groups of your implementation
  – For same reasons
• Goals and metrics of evaluation
• Control processes to be used
• Mechanisms for these should be included in the SISP
End of Lecture
Answer: Failure to perform a strategic information systems plan would result in all of the following EXCEPT:

A. Duplicated resources
B. Missed opportunities
C. Duplicated efforts
D. Incompatible systems

• Failure to perform a strategic information systems plan (SISP) well or at all could result in missed opportunities, duplicated efforts, incompatible systems and wasted resources. However, it would not typically result in duplicated resources.
Answer: All of the following represent environmental scan methods EXCEPT:

A. PEST
B. SNOP
C. PESTLE
D. SWOT
E. Benchmarking

• SNOP stands for systematized nomenclature of pathology, which is a predecessor to SNOMED-CT. PEST, PESTLE, SWOT and Benchmarking are all methods that can be used to perform an environmental scan during the strategic planning process.
4E-1 REF-Strategic Planning

References

Free online resources

Other resources (not free)
3D1-3: Clinical Data Standards

William Hersh, MD
Oregon Health & Science University
# Core Content Covered in this Lecture

## 1. Fundamentals

1. Clinical Informatics
   1.1. The discipline of informatics
   1.1.2. Key informatics concepts, models, and theories
   1.1.3. Clinical informatics literature
   1.1.4. International clinical informatics practices
   1.1.5. Ethics and professionalism
   1.1.6. Legal and regulatory issues
2. The Health System
   1.2.1. Determinants of individual and population health
   1.2.2. Primary domains, organizational structures, cultures, and processes
   1.2.3. The flow of data, information, and knowledge within the health system
   1.2.4. Policy & regulatory framework
   1.2.5. Health economics and financing
   1.2.6. Forces shaping health care delivery
   1.2.7. Institute of Medicine quality components

## 2. Clinical Decision Making and Care Process Improvement

2.1. Clinical Decision Support
   2.1.1. The nature and cognitive aspects of human decision making
   2.1.2. Decision science
   2.1.3. Application of clinical decision support
   2.1.4. Transformation of knowledge into clinical decision support tools
   2.1.5. Legal, ethical, and regulatory issues
   2.1.6. Quality and safety issues
   2.1.7. Supporting decisions for populations of patients
2.2. Evidence-based Patient Care
   2.2.1. Evidence sources
   2.2.2. Evidence grading
   2.2.3. Clinical guidelines
   2.2.4. Implementation of guidelines as clinical algorithms
   2.2.5. Information retrieval and analysis
2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
   2.3.1. Methods of workflow analysis
   2.3.2. Principles of workflow re-engineering
   2.3.3. Quality improvement principles and practices

## 3. Health Information Systems

3.1. Information Technology Systems
   3.1.1. Computer Systems
   3.1.2. Architecture
   3.1.3. Networks
   3.1.4. Security
   3.1.5. Data
   3.1.6. Technical approaches that enable sharing data
   3.2. Human Factors Engineering
   3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
   3.2.2. HCI Evaluation, usability testing, study design and methods
   3.2.3. Interface design standards and design principles
   3.2.4. Usability engineering
   3.2.5. Health Information Systems and Applications
   3.3.1. Types of functions offered by systems
   3.3.2. Types of settings where systems are used
   3.3.3. Electronic health/medical records systems as the foundational tool
   3.3.4. Telemedicine
   3.4. Clinical Data Standards
   3.4.1. Standards development history and current process
   3.4.2. Data standards and data sharing
   3.4.3. Transaction standards
   3.4.4. Messaging standards
   3.4.5. Nomenclatures, vocabularies, and terminologies
   3.4.6. Ontologies and taxonomies
   3.4.7. Interoperability standards
3.5. Information System Lifecycle
   3.5.1. Institutional governance of clinical information systems
   3.5.2. Clinical information needs analysis and system selection
   3.5.3. Clinical information system implementation
   3.5.4. Clinical information system testing, before, during and after implementation
   3.5.5. Clinical information system maintenance
   3.5.6. Clinical information system evaluation

## 4. Leading and Managing Change

4.1. Leadership Models, Processes, and Practices
   4.1.1. Dimensions of effective leadership
   4.1.2. Governance
   4.1.3. Negotiation
   4.1.4. Conflict management
   4.1.5. Collaboration
   4.1.6. Motivation
   4.1.7. Decision making
4.2. Effective Interdisciplinary Teams
   4.2.1. Human resources management
   4.2.2. Team productivity and effectiveness
   4.2.3. Group management processes
   4.2.4. Managing meetings
   4.2.5. Managing group deliberations
4.3. Effective Communications
   4.3.1. Effective presentations to groups
   4.3.2. Effective one-on-one communication
   4.3.3. Writing effectively for various audiences and goals
   4.3.4. Developing effective communications program to support system implementation
4.4. Project Management
   4.4.1. Basic principles
   4.4.2. Identifying resources
   4.4.3. Resource allocation
   4.4.4. Project management tools (non-software specific)
   4.4.5. Informatics project challenges
4.5. Strategic and Financial Planning for Clinical Information Systems
   4.5.1. Establishing mission and objectives
   4.5.2. Environmental scanning
   4.5.3. Strategy formulation
   4.5.4. Action planning and strategy implementation
   4.5.5. Capital and operating budgeting
   4.5.6. Principles of managerial accounting
   4.5.7. Evaluation of planning process
4.6. Change Management
   4.6.1. Assessment of organizational culture and behavior
   4.6.2. Change theories
   4.6.3. Change management strategies
   4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core content covered

3.4 Clinical Data Standards
  3.4.1 Standards development history and current process
  3.4.2 Data standards and data sharing
  3.4.3 Transaction standards
  3.4.4 Messaging standards
  3.4.5 Nomenclatures, vocabularies, and terminologies
  3.4.6 Ontologies and taxonomies
  3.4.7 Interoperability standards
Key topics

• Importance and limitations of standards in clinical information systems
• Major types of standards and their roles in clinical information systems
• Identifier standards
• Transaction standards
• Messaging standards
• Terminology standards
3D1-3: Clinical Data Standards

- Standards and Interoperability: Basic Concepts
- Identifier Standards
- Transaction Standards
- Message Exchange Standards
- Terminology Standards
Why are standards important in clinical informatics?

• Promote consistent naming of individuals, events, diagnoses, treatments, etc.

• Allow better use of data for patient care as well as secondary uses, such as quality assurance, research, public health, etc.

• Enhance ability to transfer data among applications, allowing better system integration

• Facilitate interoperability among information systems and users
What is a standard?

• There’s a standard for that!
• From ISO, 2004 (cited by Benson, 2016)
  – A standard document established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the optimum degree of order in a given context
Standards facilitate interoperability

• IEEE original definition, widely cited (1990)
  – “The ability of two or more systems or components to exchange information and to use the information that has been exchanged.”

• Extended for healthcare in 2005 by NAHIT (2005) and endorsed by 40 other healthcare organizations
  – “The ability of different information technology systems and software applications to communicate; to exchange data accurately, effectively, and consistently; and to use the information that has been exchanged.”

• Current IEEE definition
  – “Ability of a system or a product to work with other systems or products without special effort on the part of the customer. Interoperability is made possible by the implementation of standards”
Levels of interoperability for healthcare (*Walker, 2005*)

- **Level 1** – no interoperability
  - e.g., mail, fax, phone, etc.
- **Level 2** – machine-transportable (structural)
  - Information cannot be manipulated
  - e.g., scanned document, image, PDF
- **Level 3** – machine-organizable (syntactic)
  - Sender and receiver must understand vocabulary
  - e.g., email, files in proprietary format
- **Level 4** – machine-interpretable (semantic)
  - Structured messages with standardized and coded data
  - e.g., coded results from structured notes, lab, problem list, etc.
Value of standards throughout history

- Roman chariots
- Railroad tracks
- Telephones
- ASCII text in computers
- Wi-Fi to connect computers, smartphones, tablets, etc. wirelessly to the Internet
- Global financial transactions
- Other examples?
Benefits and limitations of standards

• Benefits
  – Interoperability
  – May allow innovation based on common foundation

• Limitations
  – Dominance by one segment of industry
  – May stifle innovation

• May be a mixed bag
  – Microsoft “standards,” e.g., Windows, Office, etc.
  – Ever hear of Esperanto? Why did English prevail? (Patterson, 1999)
  – “The nice thing about standards is that there are so many of them to choose from.” (Tanenbaum, 2010 – disputed)
The standards development process – four approaches (Hammond, 2014)

- **Ad hoc** – groups agree to informal specifications
- **De facto** – single vendor controls industry
- **Government mandate** – government agency creates standard and mandates its use
- **Consensus** – interested parties work in open process
Standards development

- Recently published comprehensive overview (Benson, 2016)
- Health IT Standards 101 – another overview (Boone)
- Stages of development (Hammond, 2014)
  - Identification
  - Conceptualization
  - Discussion
  - Specification
  - Early implementation
  - Conformance
  - Certification

(Benson, 2016)
Some US standards bodies (private, non-profit)

- American National Standards Institute (ANSI, www.ansi.org) that accredits standards development organizations (SDOs), including in healthcare
  - Accredited Standards Committee (ASC) X12
  - Health Level 7 (HL7)
  - American Society for Testing and Materials (ASTM, www.astm.org), which has a Committee E31 on Healthcare Informatics
International standards bodies

• International Organization for Standardization (ISO, www.iso.org)
  – Technical Committee 215 (TC 215) focuses on health informatics standards

• European Committee for Standardization (CEN, www.cen.eu)
  – CEN/TC 251 is health informatics standards body for Europe

• International Telecommunication Union (ITU, www.itu.int) - UN agency focused on telecommunications standards (general, not medical)
US government health information standards leadership efforts

• A number of approaches over the years
  – Consolidated Health Informatics (CHI) initiative – effort to adopt ready standards by health-related US government agencies
  – Healthcare Information Technology Standards Panel (HITSP) of the Office of the National Coordinator for Health IT (ONC) – effort to identify ready standards and gaps needing to be filled
  – National Institute for Standards and Technology (NIST) – focused on efforts supporting ONC (http://healthcare.nist.gov)
  – National Library of Medicine (NLM) – efforts mostly around insuring terminology standards support messaging standards efforts (e.g., HL7)
• All standards work now being led by ONC Health IT Standards Committee
Health IT Standards Committee

- http://www.healthit.gov/policy-researchers-implementers/health-it-standards-committee
- Charged with making recommendations to ONC on “standards, implementation specifications, and certification criteria for electronic exchange and use of health information”
- Timeline of recent activities
  - JASON report calls for move to more “modern” API-based approaches to interoperability (MITRE, 2014)
  - ONC establishes JASON Task Force to respond to recommendations and develops evolving plans and documents
    - Interoperability Vision (2014) – vision and framework
    - Interoperability Roadmap (2015) – how to get there
    - Argonaut Project (2014) – implementing details
    - Standards Advisory (2016) – standards ready for use, updated annually
Integrating the Health Enterprise (IHE, www.ihe.net; Samarth, 2013)

• Non-federal effort that identifies and demonstrates solutions to real-world interoperability problems
  – Organizes interoperability showcases to demonstrate solutions
    • www.interoperabilityshowcase.org

• Organized across various clinical and operational domains
  – Each domain produces own set of Technical Framework documents in coordination with other domains
  – Committees in each domain review and republish these documents annually, often expanding with supplements that expand existing or define new profiles
  – Profiles eventually republished for trial implementation; if criteria for successful testing achieved, profile is published in final form
    • http://www.ihe.net/Profiles/
Example IHE profiles from domain: Patient Care Coordination

http://wiki.ihe.net/index.php?title=Patient_Care_Coordination

- [MS] Medical Summaries describes the content and format of Discharge Summaries and Referral Notes
- [XPHR] Exchange of Personal Health Record describes the content and format of summary information extracted from a PHR system for import into an EHR system, and visa versa
- [FSA] Functional Status Assessments describes the content and format of Functional Status Assessments that appear within summary documents
- [QED] Query for Existing Data queries data repositories for clinical information on vital signs, problems, medications, immunizations, and diagnostic results
- [IC] Immunization Content exchanges immunization data
- [CM] Care Management exchanges information between HIT systems and applications used to manage care for specific conditions
- [PPOC] Patient Plan of Care exchanges data related to creating and managing individualized patient care between and among HIT systems
- [RCG] Request for Clinical Guidance obtains decision support when ordering medications, determining appropriate immunizations, diagnostic tests, etc.
- [EDR] Emergency Department Referral communicates medical summary data from an EHR System to an EDIS System
No discussion of standards is complete without mentioning HIPAA

• Health information standards were a key focus of the Health Insurance Portability and Accountability Act of 1996 (HIPAA; aka, the Kennedy-Kassebaum Bill)

• Main focus of legislation, however, was health insurance issues
  – Reducing denial based on pre-existing conditions
  – Improving portability across jobs

• But now HIPAA is best known for its addressing of
  – Standards for financial transactions and code sets
  – Unique identifiers for patients, healthcare providers, and employers
  – Development of privacy and security standards for transmission of electronic health data

• HIPAA privacy and security regulations expanded in HITECH
Clinical informatics standards

- Identifiers
- Transactions
- Message exchange
- Terminology
Identifiers

• Various approaches exist (or have been proposed) for
  – Patients
  – Providers
  – Employers
  – Health Plans
Patient identifiers

• Benefits
  – Easy linkage of records
  – Facilitate health information exchange
  – Reduce errors and costs arising from duplicate records

• Risks
  – Easy linkage of records
  – Potentially compromise privacy and confidentiality
Challenges of duplicate and overlaid records

- Identifier errors compromise quality of care and can be costly (Fernandes, 2001)
  - $4,500 to correct duplicate patient records in operating room
  - 325 minutes of work to correct duplicate records in hospital
  - Cost increases with length of time error not identified

- Duplicate records more likely to be associated with missed abnormal test results (Joffe, 2009)

- Study of five large academic centers found (McCoy, 2013)
  - Occurrence of matching first and last name was 16.5-40.7%, reduced to 0.2-15.5% when date of birth added
  - Highly variable policies for preventing, detecting, and removing duplicate records, and for mitigating errors
Patient identifiers – key attributes (Connecting for Health, 2005)

- Unique – only one person has a particular identifier
- Non-disclosing – discloses no personal information
- Permanent – will never be re-used
- Ubiquitous – everyone has one
- Canonical – each person has only one
- Invariable – will not change over time
One solution is government-issued patient identifiers

• Most industrialized countries have them, e.g.,
  – Iceland Health Sector Database (Arnason, 2002)
    • Have also created national genetic database (Gulcher, 2000)
  – Singapore issues National Registration Identity Card (NRIC) to all citizens and Foreign Identification Number (FIN) to all long-term visitors, which are used as identifiers in healthcare
  – Most Western European countries also use them without controversy
Government-issued patient identifiers in the US?

- HIPAA mandated creation of patient identifiers but public pressure forced postponement
  - Approach and issues described in (HHS, 1998)
- Could/should we use the social security number as a national health identifier?
  - Technical problems: many duplicates, numbers reused, no check digit for checksum validation (Winkler, 2009)
  - Other problems: used for too many other purposes, including re-identification from public data sources (Acquisti, 2009)
- Some advocate voluntary identifiers
  - Those agreeing to have would sign consent form outlining benefits and risks (Hieb, 2006; Hieb, 2008; http://gpii.info/)
Others argue it is unnecessary and politically infeasible in US

- **Connecting for Health, 2005**
  - “Not worth the fight” (Ferris, 2005; Ferris, 2005)
  - Probably politically impossible to deploy in US
  - There may be other ways to achieve goals for national identifiers
  - Expenses up front; benefits accrue later

- **Counterpoint:** Unique patient identifier would reduce errors and improve system interoperability in US (Hillestad, 2008; Detmer, 2010; Aranow, 2013)
  - Costs would be substantial ($3.9-9.2 billion) but be offset by other improvements in healthcare system
  - Would not significantly increase risk for security breaches over other options
Alternatives to a national identifier

• Use of probabilistic matching algorithms to link patient records based on various attributes, e.g., name, address, date of birth, phone, etc.

• Many methods show relatively high level of accuracy (Grannis, 2003; Grannis, 2004; Tromp, 2008; Tromp, 2011; Li, 2013; Sayers, 2016)
  – Methods use widely in health information exchange (Kho, 2015; McFarlane, 2016)

• Research still required for problems with non-standardized (“dirty”) data (Randall, 2013) and missing data (Ong, 2014)
Current state of patient record-matching *(Morris, 2014)*

- From recently commissioned report by ONC
- Imperative as a patient safety, care coordination, and data quality issue (among others)
- Current state-of-art works well, but would benefit from standardizing patient-identifying attributes in record, such as
  - First/given, middle/second given, and last/family names
  - Suffix – e.g., Jr./Sr., II/III/etc., MD/RN/PhD, Esq., etc.
  - Date of birth – YYYYMMDD, with HHMMSS if available
  - Current and historical addresses – in some international format
  - Phone number – all known
  - Gender – from HL7 value set; M, F, UN
- Also need process for handling changes across healthcare system
- Advocates further research to evaluate algorithms and additional attributes as well as dissemination of best practices
Provider identifiers

- Universal Physician Identifier Number (UPIN) was maintained by the US government for physicians who treated Medicare patients
- National Provider Identifier (NPI) now assigned to all US physicians
  - Issued by the National Provider System (NPS), overseen by the Department of HHS
  - 10-digit number with last digit serving as check digit
  - CMS no longer processes claims without NPI
Employer and health plan identifier standards

• Employers – National Standard Employer Identifier (EIN)

• Health plans – new Health Plan Identifier (HPID) and Other Entity Identifier (OEID) mandated in Affordable Care Act (ACA)
Transactions

• ASC X12N standards are designed to encourage electronic commerce for health claims, simplifying current situation of 400+ different formats
  – HIPAA mandated use of these standards for healthcare business electronic data exchange
    • “Administrative simplification”
  – Original version of HIPAA ASC X12 standards was called version 4010 and was superseded by Version 5010, which had deadline for compliance of January 1, 2012 (Moynihan, 2010)
    • http://ama-assn.org/go/5010
ASC X12N transactions – Version 5010

- Health claims and equivalent encounter information (837)
- Enrollment and disenrollment in a health plan (834)
- Eligibility for a health plan (request 270/response 271)
- Health care payment and remittance advice (835)
- Health plan premium payments (820)
- Health claim status (request 276/response 277)
- Referral certification and authorization (278)
- Coordination of benefits (837)
You don’t believe these are important?

- Ask President Obama!
- Part of the reason for the early failure of the Healthcare.gov (www.healthcare.gov) Web site was due to health plans not properly having implemented the 834 standard for enrollment and disenrollment in health plans
  - News media: “Obamacare’s most important number: 834” (Kliff, 2013)
  - More technical description (Laszewski, 2013)
  - Many other informatics lessons learned as well (Blumenthal, 2013)
Message exchange standards

- Health Level 7 (HL7)
- Fast Health Interoperability Resources (FHIR)
- Images: Digital Imaging and Communications (DICOM)
- Devices: IEEE 1073 / ISO 11073 and others
- ePrescribing: NCPDP and SCRIPT
- Laboratory: ELINCS
- Patient summaries: CCR, CCD, and ABBI
- Platforms: Substitutable Medical Apps, reusable technologies (SMArt)
Health Level 7 International (HL7, www.hl7.org)

- Major messaging standards for healthcare as well as the standards development organization that supports the standard
- Name based on OSI seven-layer model of network communications
- Two substantially different versions
  - Version 2 widely used and syntactic-oriented
  - Version 3 still being adopted and aims for semantic interoperability
- Documentation less than ideal but
  - Standards documents on Web site with voluminous detail
  - Overview book (Benson, 2016) and another with detailed discussion (Trotter, 2011)
HL7, version 2

- (Henderson, 2003; Benson, 2016)
- Current versions (2.X) supported by most vendors for interchange of data
- Is mostly a syntax, where sender and receiver must understand meaning of messages, but subsequent versions adding more semantics (meaning)
- Implemented by bar-delimited ASCII files
- Each message has segments consisting of three-character identifier and values, e.g.,
  - MSH – message header
  - EVN – event type
  - PID – patient identifier
  - OBR – results header
  - OBX – result details
HL7 version 2.5 example (Benson, 2016)

MSH|^~\&||^123457^Labs||20080814 1530||ORU^R01|123456789|P|2.4
PID||123456^^^SMH^PI||MOUSE^MICKEY||19620114|M||14 Disney Rd^Disneyland^^^MM1 9DLPV1|||5N||||G123456^DR SMITH
OBR||54321|666777^CULTURE^LN|||20080802||||||SW^^^FO
OT^RT|C987654
OBX||CE|0^ORG|01|STAU|||F
OBX||CE|500152^AMP|01|||R|||F
OBX||CE|500155^SXT|01|||S|||F
OBX||CE|500162^CIP|01|||S|||F

Report from Lab123457, 15:30 14-Aug-2008, Ref 123456789
Patient: MICKEY MOUSE, DoB: 14-Jan-1962, M
Address: 14 Disney Rd, Disneyland, MM1 9DL
Specimen: Swab, FOOT, Right, Requested By: C987654,
Location: 5N
Patients GP: Dr Smith (G123456)
Organism: STAU
Susceptibility:
AMP R
SXT S
CIP S
Another HL7 version 2.5 example
(Hammond, 2014)

MSH|^~&\DHIS|OR|TMR|SICU|199212071425|password|ADT|166035
29|P|2.1<c>
EVN|A02|199212071425||<cr>
PID||Z99999^5^M11||GUNCH^MODINE^SUE|RILEY|19430704
|F||C|RT. 1, BOX 97^ZIRCONIA^NC^27401 |HEND|(704)982-1234|(704)983-1822||S|C||245-33-9999<cr>
PV1|1||N22^2204|||OR^03|0940^DOCTOR^HOSPITAL^A|||SUR|<<<|A3<cr>
OBR|7|||93000^EKG
REPORT|R|199401111000|199401111330||RMT|||1994011111330|?|P030|'|||199401120930|'|||88-126666|A111|VIRANYI^ANDREW<cr>
OBX|1|ST|93000.1^VENTRICULAR RATE(EKG)||91|/MIN|60-100<cr>
OBX|2|ST|93000.2^ATRIAL RATE(EKG)||150|/MIN|60-100<cr>
...
OBX|8|ST|93000&IMP^EKG DIAGNOSIS|1|^ATRIAL
FIBRILATION<cr>
Releases of HL7 V2

http://www.hl7argentina.org.ar/

- V2.1 (1990): First implemented version - very basic, but still used
- V2.2 (1994): Basic enhancements
- V2.3 (1997): Scheduling and Finance messages added
- V2.3.1 (1999): Pathology, Allergies, Referral as Scheduling
- V2.4 (2000): Clinical Focus - Referrals and Discharge Summaries
- V2.5 (2003): Data field lengths standardized
- V2.5.1 (2007): Four data items added due to US regulatory requirements
- V2.6 (2007): Data type changes
  - Coded Element (CE) → Coded With (No) Exceptions (CNE/CWE)
  - Time Stamp (TS) → Date/Time (DTM)
- V2.7 (2011): Collaborative Care Message
- V2.7.1 (2012): Lab Orders/Results features added for US “Meaningful Use”
- V2.8 (2014): Authorization and Ordering information added
HL7 version 3 (Hinchley, 2005)

• Attempts to introduce semantics (meaning, also termed computable semantic interoperability) beyond syntax of version 2
  – Differences demonstrated in (Ringholm, 2007)
• Based on Reference Information Model (RIM), an object model of entities that pass messages (Mead, 2005)
  – Implemented in eXtensible Mark-Up Language (XML)
• Thought by many to be complicated, by some overly so
  – Some aspects have been called “incoherent” (Smith, 2006)
Overview of the RIM (Mead, 2005; Benson, 2016)

• RIM uses object-oriented approach to define healthcare interactions based on five abstract classes
  – Entity – things in world, e.g., people, organizations, other living subjects, drugs, devices
  – Role – capability or capacity, e.g., patient, practitioner
  – Participation – role in context of an act, e.g., performer, target
  – Act – clinical or administrative definitions, e.g., observation, diagnosis, procedure
  – Act relationship – links between acts, e.g., diagnosis act

• All clinical, administrative, financial, etc. activities of healthcare can be expressed in “constraints” to model
HL7 version 3 instance of pulse measured at physician office visit

Observations modeled as Entity-Attribute-Value (EAV) and ideally are based on standard terminology, e.g., pulse (palpated at wrist) – rate 50 beats/minute
Backward and forward: Fast Health Interoperability Resources (FHIR)

- Response to complexity of HL7 V3, but maintaining compatibility with other HL7 standards, e.g., Clinical Document Architecture (CDA) (Boone, 2012)
- Uses “modern” application programming interface (API) approach but less detailed semantics than HL7 V3
- Substantial backing, including via Argonaut Project
- Key component is Resource, which defines and represents data elements, building them from data types that define common reusable patterns of elements
Readable resource: FHIR for Clinical Users


- API like accessing a file cabinet
  - Search – search through folders for ones that meet set of search criteria
  - Read – get copy of one of specific folders in drawer
  - Create – add new folder to the appropriate drawer (with a new number)
  - Update – alter contents of specific folder
  - Delete – remove a folder from the cabinet
  - History – get history for one of the folders, or an entire drawer, or entire system
  - Transaction – give server a bunch of folders all at once to update
## Growing development of Resources

### Clinical General:
- AllergyIntolerance
- Condition (Problem)
- Procedure
- ClinicalImpression
- FamilyMemberHistory
- RiskAssessment
- DetectedIssue

### Care Provision:
- CarePlan
- Goal
- ReferralRequest
- ProcedureRequest
- NutritionOrder
- VisionPrescription

### Medication & Immunization:
- Medication
- MedicationOrder
- MedicationAdministration
- MedicationDispense
- MedicationStatement
- Immunization
- ImmunizationRecommendation

### Diagnostics:
- Observation
- DiagnosticReport
- DiagnosticOrder
- Specimen
- BodySite
- ImagingStudy
- ImagingObjectSelection

### Identification
#### Individuals:
- Patient
- Practitioner
- RelatedPerson

#### Groups:
- Organization
- HealthcareService
- Group

### Entities:
- Location
- Substance
- Person
- Contract

### Devices:
- Device
- DeviceComponent
- DeviceMetric

### Workflow
#### Patient Management:
- Encounter
- EpisodeOfCare
- Communication
- Flag

#### Scheduling:
- Appointment
- AppointmentResponse
- Schedule
- Slot

#### Workflow #1:
- Order
- OrderResponse
- CommunicationRequest
- DeviceUseRequest
- DeviceUseStatement

#### Workflow #2:
- ProcessRequest
- ProcessResponse
- SupplyRequest
- SupplyDelivery

### Infrastructure
#### Information Tracking:
- Questionnaire
- QuestionnaireResponse
- Provenance
- AuditEvent

#### Documents & Lists:
- Composition
- DocumentManifest
- DocumentReference
- List

#### Structure:
- Media
- Binary
- Bundle
- Basic

#### Exchange:
- MessageHeader
- OperationOutcome
- Parameters
- Subscription

### Conformance
#### Terminology:
- ValueSet
- ConceptMap
- NamingSystem

#### Content:
- StructureDefinition
- DataElement

#### Operations Control:
- Conformance
- OperationDefinition
- SearchParameter

### Financial Support:
- Coverage
- EligibilityRequest
- EligibilityResponse
- EnrollmentRequest
- EnrollmentResponse

### Billing:
- Claim
- ClaimResponse

### Payment:
- PaymentNotice
- PaymentReconciliation

### Other:
- ExplanationOfBenefit
Example resources: patient and medication
Some additional activities of HL7

• Clinical Context Object Workgroup
• Clinical Decision Support Workgroup
• Clinical Document Architecture

• (many more)
Clinical Context Object Workgroup (CCOW)

- [http://www.hl7.org/special/committees/visual/index.cfm](http://www.hl7.org/special/committees/visual/index.cfm)
- Manages context of caregivers who may need to access different computer applications in process of care
- Oft-stated goal is “single sign-on” across applications, network, data, etc.
- Defines protocol that enables applications to link context of patient, provider(s), encounter, etc.
- Not widely used, but an implementation described in (Berger, 2009)
Clinical Decision Support Workgroup

- Aiming to reconcile competing approaches to clinical decision support (CDS) and clinical guidelines

- Workgroup projects
  - Virtual Medical Record (VMR) – data model for representing input and output to CDS systems
  - Terminology management model – Clinical Terminology Services 2 (CTS2)
  - Formalism for data manipulation in CDS – GELLO
  - Formal method for describing process and work flow
  - Taxonomy of services or actions evoked by guidelines
Clinical Document Architecture (CDA; Dolin, 2006; Boone, 2011)

• Much healthcare information is in “documents” required for human reading, but still want computable structure.
• CDA defines XML-based standard structure and metadata for clinical documents
  – Templates are reusable, computable components of CDA documents
  – “Unstructured” documents can be “wrapped” in CDA framework
  – Current release is version 2 (Dolin, 2006; Boone, 2011)
• Three “levels” of CDA
  – Level 1 – general document specification
  – Level 2 – adds document types with allowable structures
  – Level 3 – adds mark-up expressible in RIM
Health Story – structuring CDA where cost-effective

(www.healthstory.com)
Toward Consolidated CDA

• A series of “reusable templates” consisting of
  – Document templates – from Health Story Project, guides for specific types of common clinical notes, which are based on
  – Section templates – describe basic elements of notes, which are based on
  – Entry templates – contain the actual data
CCDA document and section templates (ONC, 2012)

Document Templates: 9
- Continuity of Care Document (CCD)
- Consultation Note
- Diagnostic Imaging Report (DIR)
- Discharge Summary
- History and Physical (H&P)
- Operative Note
- Procedure Note
- Progress Note
- Unstructured Document

Section Templates: 60
Entry Templates: 82

Section templates in YELLOW demonstrate CDA's interoperability and reusability.
Digital Imaging and Communications (DICOM)

- (Rorden, 2007; Pianykh, 2010)
- Developed by American College of Radiology (ACR) and National Electrical Manufacturers Association (NEMA)
  - http://medical.nema.org
- Defines how images and associated data are moved between electronic devices, including information systems
- Used in most radiology picture and archiving systems (PACS)
- Growing transfer of radiology images digitally leads to viewing problems when DICOM not used (Kalia, 2011)
DICOM format files (Rorden, 2007)

Overall

Header

First 128 bytes: unused by DICOM format
Followed by the characters ‘D’, ‘I’, ‘C’, ‘M’
This preamble is followed by extra information e.g.:

0002,0000,File Meta Elements Group Len: 132
0002,0001,File Meta Info Version: 256
0002,0010,Transfer Syntax UID: 1.2.840.10008.1.2.1.
0008,0000,Identifying Group Length: 152
0008,0060,Modality: MR
0008,0070,Manufacturer: MRIcon
0018,0000,Acquisition Group Length: 28
0018,0050,Slice Thickness: 2.00
0018,1020,Software Version: 46\64\37
0028,0000,Image Presentation Group Length: 148
0028,0002,Samples Per Pixel: 1
0028,0004,Photometric Interpretation: MONOCHROME2.
0028,0008,Number of Frames: 2
0028,0010,Rows: 109
0028,0011,Columns: 91
0028,0030,Pixel Spacing: 2.00\2.00
0028,0100,Bits Allocated: 8
0028,0101,Bits Stored: 8
0028,0102,High Bit: 7
0028,0103,Pixel Representation: 0
0028,1052,Rescale Intercept: 0.00
0028,1053,Rescale Slope: 0.00392157
7FE0,0000,Pixel Data Group Length: 19850
7FE0,0010,Pixel Data: 19838

Transfer Syntax UID reports structure and compression of image, e.g., JPEG and amount of compression.
Medical device standards (HIMSS Analytics, 2010; Day, 2011)

• What is a medical device? From US Food, Drug, and Cosmetic Act, section 201(h)
  – An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory that is:
    • Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
    • Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes
Medical information bus (MIB)

- **Kennelly, 1997; Kennelly, 1998**
- Aims to develop standards for control and linkage of information from medical devices
- Most implementations just transfer data, but there is capability to issue commands, e.g., change settings of an intravenous fluid (IV) pump
- Emerged as IEEE 1073 and now ISO 11073, but never widely adopted
Related medical device standards

• Open-Source Integrated Clinical Environment (OpenICE, www.openice.info) – prototype clinical ecosystem connecting medical devices and clinical applications
  – Provides framework for integration of devices and apps
  – Includes Medical Device “Plug-and-Play” Interoperability Program (www.mdpnp.org) – focus on interoperability of network-based medical devices (Whitehead, 2008; CIMIT, 2012)

• Continua Health Alliance (www.continuaalliance.org) – consortium of companies and organizations devoted to interoperability of personal telehealth devices (Cnossen, 2010)
Continua “personal health eco-system”
NCPDP and SCRIPT

• National Council for Prescription Drug Programs (NCPDP, www.ncpdp.org) has developed family of standards for pharmacy claims benefits

• SCRIPT is NCPDP standard for electronic communications between prescriber and pharmacy

• HITECH meaningful use criteria require NCPDP and SCRIPT standards for e-prescribing
EHR-Laboratory Interoperability and Connectivity Standard (ELINCS)

- (Sujansky, 2009)
- Goal to standardize laboratory ordering from and reporting to EHRs
- Constrains ORU field of HL7 version 2 to defined set of allowable elements
- Maintained by HL7
Continuity of Care Record and Document (CCR, CCD)

• CCR was a “set of basic patient information consisting of the most relevant and timely facts about a patient’s condition”
• Goal was for use when patient was referred, transferred, or discharged among healthcare providers and/or facilities, containing basic information for providing continuity of care
• Original CCR was not compatible with existing standards, so HL7 and vendors created CCD, which was based on HL7 V3 and CDA (EHRVA, 2007)
• CCD has resulted in more standard use (D’Amore, 2012) but errors and allowable variation from standard has limited semantic interoperability (D’Amore, 2014)
CDA templates in CCD – Meaningful Use (MU) Stage 2 required data set

- Header
- Purpose
- Problems
- Procedures
- Family history
- Social history
- Payers
- Advance directives
- Alerts
- Medications
- Immunizations
- Medical equipment
- Vital signs
- Functional statistics
- Results
- Encounters
- Plan of care
Blue Button Initiative

• “Public-private partnership to empower consumers with easy and secure access to their health records from a variety of sources in a format they can use”

• Started with Blue Button Initiative of VA that allowed patients to download an electronic summary of their medical data
  – http://www.va.gov/bluebutton/

• Led to ONC launching Blue Button Toolkit to facilitate development
  – http://bluebutton toolkit.healthit.gov
Platforms

- Much criticism that current EHRs are monolithic systems ("traps") and not platforms (Mandl, 2012)
- Substitutable Medical Apps, reusable technologies (SMART, www.smartplatforms.org) – one of ONC SHARP projects
  - Based on platform for "app" development accessing store of information (Mandl, 2012)
  - "SMART on FHIR" uses FHIR as API (Mandel, 2016) – http://smarthealthit.org/smart-on-fhir/
  - Has been implemented for genomics (Alterovitz, 2015) and precision medicine applications (Warner, 2016)
Vendor efforts to develop platforms

- Surescripts – e-prescribing platform expanded to
- Allscripts “open architecture platform”
  - [http://www.allscripts.com/company/partners/allscripts-developer-program-registration](http://www.allscripts.com/company/partners/allscripts-developer-program-registration)
- Epic open API for accessing data and services using FHIR and is developing an “app store” (Newman, 2015)
  - [http://open.epic.com](http://open.epic.com)
  - [https://open.epic.com/Interface/FHIR](https://open.epic.com/Interface/FHIR)
Class interaction

• What is/are the best messaging standard(s) for the following situations?
  – Patient summary for transfer from hospital to skilled nursing facility
  – Transfer of laboratory data from a hospital to an emergency department in health information exchange
  – Identification of a patient in a remote hospital
  – Transfer of a previously performed imaging study in a free-standing radiology center
Terminology standards

• Another important area of standards
• Benefits of computerization of clinical data depend upon its “normalization”
• Clinical language is inherently vague, which is at odds with the precision of computers
• The words cancer and carcinoma are no more similar to a computer than apple and zebra
• Medicine should have “fewer words, more meaning” like air traffic control and military (Voytovich, 1999)
The terminology of terminologies

• Terminology – “terms,” but not so simple
• Concept – thing or idea, expressed in one or more terms
• Synonym – different term for same concept
• Polysem – term that means more than one concept
• Dictionary – concepts plus meaning
• Thesaurus – synonyms grouped by concept
• Vocabulary – concepts and terms in a domain
• Ontology – structured concepts and relationships between them
Use cases for standardized terminology (Chute, 2005)

• Information capture – documenting findings, conditions, and outcomes
• Communication – transferring information
• Knowledge organization – classification of diseases, treatments, etc.
• Information retrieval – accessing knowledge-based information
• Decision support – implementing decision support rules
Harder for computers than humans: synonymy and polysemy

- How many different ways can you say *common cold*?
- Synonyms include
  - Cold
  - Upper respiratory infection
  - URI
  - Pharyngitis, bronchitis, rhinitis, etc.
  - Viral syndrome
  - ...

- How many different ways is *lead* used in medicine?
- Polysems include
  - Hypertension leads to heart disease
  - An EKG lead
  - Lead poisoning
  - ...

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Standardized medical vocabularies

• Usually have hierarchical structure and some sort of coding scheme
• Ultimately want to represent concepts as codes
• Cimino (1998) has elucidated “desiderata”
• Various approaches to codes include
  – Numerical – sequentially or random
  – Mnemonic – abbreviation
  – Hierarchical – indicate level in hierarchy
  – Juxtaposition – composite codes
  – Combination – composite using ordering
• Should avoid “semantic” codes that put meaning in codes
A few issues about terminologies and coding

- **Rosenbloom (2006)** distinguishes categories and uses of terminology
  - Interface – support data entry (**Rosenbloom, 2008**)
  - Processing – optimize natural language processing
  - Reference – enable storage, analysis, retrieval

- Coding is a major activity of health information management (HIM) profession (**Scott, 2008**)
  - With growth of uses and technology, field is changing (**Calhoun, 2012**)
  - Computer-assisted coding is use of computer programs to assist human coders (**Tully, 2012**)

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Terminology standards (Giannangelo, 2015)

- **Diagnoses**
  - ICD-9, ICD-10, ICD-11
  - Diagnosis-related groups (DRG)

- **Drugs**
  - National Drug Code (NDC)
  - National Drug File Reference Terminology (NDF-RT)
  - RxNorm/RxTerms

- **Laboratory**
  - LOINC

- **Procedures and diagnostic studies**
  - CPT-4, HCPCS, CDT

- **Nursing**
  - NANDA, NIC/NOC, Omaha, etc.

- **Literature**
  - Medical Subject Headings (MeSH)

- **Devices**
  - Universal Medical Device (UMD) Nomenclature

- **Comprehensive**
  - SNOMED Clinical Terms (CT)
  - Unified Medical Language System (UMLS)

- **Others**
  - DSM, ICF, ICPC, commercial, etc.
International Classification of Diseases (ICD)

• Originated in 1893 as International List of Causes of Death
  – Initial primary purpose was to compile mortality statistics
  – Eventually taken over by World Health Organization (WHO)

• Now called International Classification of Diseases (ICD)
  – Has evolved as means to code diseases for more than just cause of death
ICD-9 and its variants

• ICD-9 approved by WHO in 1975
  – Organized hierarchically with one digit for each level of hierarchy
  – ICD-9 has four-digit codes

• ICD-9-CM (clinical modifications) is U.S. variant with more detail and five-digit codes

• Also has additional set of letter codes
  – V – for encounters related to prevention and screening
  – G – document provision of specific services, such as quality measures

• Use in US discontinued with transition to ICD-10-CM in October, 2015, although much data still coded in ICD-9-CM
Example of ICD-9-CM

481 Pneumococcal pneumonia
482 Other bacterial pneumonia
  482.0 Pneumonia due to Klebsiella pneumoniae
  482.1 Pneumonia due to Pseudomonas
  482.2 Pneumonia due to Hemophilus influenzae
  482.3 Pneumonia due to Streptococcus
    482.30 Pneumonia due to Streptococcus, unspecified *
    482.31 Pneumonia due to Group A Streptococcus *
    482.32 Pneumonia due to Group B Streptococcus *
    482.39 Other streptococcal pneumonia *
  482.4 Pneumonia due to Staphylococcus
    482.40 Pneumonia due to Staphylococcus, unspecified *
    482.41 Pneumonia due to Staphylococcus aureus *
    482.49 Other Staphylococcus pneumonia *
  482.8 Pneumonia due to other specified bacteria
    482.81 Pneumonia due to anaerobes *
    482.82 Pneumonia due to Escherichia coli *
    482.83 Pneumonia due to other Gram-negative bacteria *
    482.84 Legionnaires’ disease *
    482.89 Pneumonia due to other specified bacteria *
  482.9 Bacterial pneumonia, unspecified
  483 Pneumonia due to other specified organism
    483.0 Mycoplasma pneumoniae *
  484 Pneumonia in infectious diseases classified elsewhere *
    484.3 Pneumonia in whooping cough *
    484.5 Pneumonia in anthrax *
Some limitations of ICD-9 (Chute, 1998)

- “Not otherwise specified” (NOS) codes indicate “other” category that may be ambiguous, e.g.,
  - 482.30 Pneumonia due to Streptococcus, unspecified
  - Changes with new diseases, such as from Non-A, Non-B Hepatitis to C, D, etc.
- “Not elsewhere classified” (NEC) codes indicate no separate specific code available to represent condition documented
  - 311 Depressive disorder, not elsewhere classified
  - Used for “non-major” depression
Limitations of ICD-9 (cont.)

- Use of digits in codes can be problematic
  - When there are more than 10 items at a level
- Granularity often inadequate
  - Only one code for most cancers in a given location
  - e.g., 162.4 Malignant neoplasm of middle lobe, bronchus or lung
- Not extensible
  - Cannot add modifiers for location, severity
  - Cannot indicate causal relationships
ICD-10

- http://www.who.int/classifications/icd/en/
- Adopted by WHO in 1990 – significant changes in structure from ICD-9
- Implemented as ICD-10-CM in US after numerous delays in October, 2015 (Outland, 2015)
- Also in US, added inpatient procedure codes as ICD-10-PCS
  - CPT-4 still used for outpatient procedures
- Adaptation of ICD-10 for US included (Barta, 2008)
  - ICD-10-CM for diagnosis codes – 3-7 levels
  - ICD-10-PCS for procedure codes – 7 levels
  - General Equivalence Mappings (GEM) for translation from ICD-9-CM
Differences between ICD-9-CM and ICD-10-CM

ICD-9-CM
- 13,000+ codes
- 3-5 characters
  - First character numeric or V/G/E
  - Characters 1-3 – category
  - Characters 4-5 – etiology, anatomic site, or other clinical detail

ICD-10-CM
- 69,000+ codes
- 3-7 characters
  - First character alpha
  - Character 2-3 numeric
  - Character 4-7 alphanumeric
  - Character 7 – extension
  - Characters 1-3 – category
  - Characters 4-6 – etiology, anatomical site, or other clinical detail
  - Character 7 – extension
Major difference is increased granularity... on a massive scale

995.29 Unspecified adverse effect of other drug, medicinal and biological substance

- T360X5A Adverse effect of penicillin's, initial encounter
- T361X5A Adverse effect of cephalosporins and other beta-lactam antibiotics, initial encounter
- T362X5A Adverse effect of chloramphenicol group, initial encounter
- T363X5A Adverse effect of macrolides, initial encounter
- T364X5A Adverse effect of tetracyclines, initial encounter
- T365X5A Adverse effect of aminoglycosides, initial encounter
- T366X5A Adverse effect of rifampicins, initial encounter
- T367X5A Adverse effect of antifungal antibiotics, systemically used, initial encounter
- T368X5A Adverse effect of other systemic antibiotics, initial encounter
- Plus 170 additional codes
ICD-10-PCS increases from 3,838 to 71,957 codes

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Body System</th>
<th>Root Operation</th>
<th>Body Part</th>
<th>Approach</th>
<th>Device</th>
<th>Qualifier</th>
</tr>
</thead>
</table>

Example: **0SRD0JZ**
Right knee joint replacement:

0 Medical and Surgical Section
S Lower Joints
R Replacement
D Knee
0 Open
J Synthetic Substitute
Z No Qualifier
Granularity also an issue for ICD-10-PCS

<table>
<thead>
<tr>
<th>37.31 Pericardiectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>025N0ZZZ Destruction of Pericardium, Open Approach</td>
</tr>
<tr>
<td>025N3ZZZ Destruction of Pericardium, Percutaneous Approach</td>
</tr>
<tr>
<td>025N4ZZZ Destruction of Pericardium, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>02BN0ZZZ Excision of Pericardium, Open Approach</td>
</tr>
<tr>
<td>02BN3ZZZ Excision of Pericardium, Percutaneous Approach</td>
</tr>
<tr>
<td>02BN4ZZZ Excision of Pericardium, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>02TN0ZZZ Resection of Pericardium, Open Approach</td>
</tr>
<tr>
<td>02TN3ZZZ Resection of Pericardium, Percutaneous Approach</td>
</tr>
<tr>
<td>02TN4ZZZ Resection of Pericardium, Percutaneous Endoscopic Approach</td>
</tr>
</tbody>
</table>
Some excess granularity reaching absurdity (Mathews, 2011)?

- Struck by falling object on board a watercraft
  - V93.40 – Merchant ship
  - V93.41 – Passenger ship
  - V93.42 – Fishing boat
  - V93.43 – Powered watercraft
  - V93.44 – Sailboat
  - V93.48 – Unpowered watercraft
  - V93.49 – Unspecified
Detailed codes invite artistry
(www.icd10illustrated.com)

**V97.33xD**
Sucked into jet engine, subsequent encounter

**V32.1xxS**
Passenger in three-wheeled motor vehicle injured in collision with two-or three-wheeled motor vehicle in nontraffic accident, sequela
More about ICD-10

- 50% of all codes are related to musculoskeletal system, primarily injuries
- 25% of all codes are related to fractures
- 36% of all codes distinguish laterality, i.e., left vs. right
- Most impacted are Orthopedics, Obstetrics/Gynecology, and Behavioral Health
- Primary care has medium level of impact
- Medical specialties have low level of impact
- Informatics concerns over excess granularity of ICD-10 and whether transition to a more extensible terminology system, such as SNOMED or even ICD-11, might be a better approach (Chute, 2012)
ICD-10 in the US

• ICD-10-CM and ICD-10-PCS were successively delayed until October, 2015
  – ICD-10 Illustrated author noted ICD-9 code: 738.42 – Delayed Milestones

• Implementation deemed successful by CMS (Slavitt, 2016)
  – New codes to be added yearly, starting with 3600+ diagnosis and 1900+ procedure codes in 2016 (Slabodkin, 2016)

• Help for physicians: http://www.roadto10.org
Informatics concerns about ICD-10-CM

- Excess granularity of ICD-10-CM
  - Would transition to a more compositional terminology system, such as SNOMED or even ICD-11 (to be derived from SNOMED), be a better approach (Chute, 2012)?
  - Although ICD-11 not slated for completion until 2017
- 36% of all mappings between ICD-9-CM and ICD-10-CM are convoluted, ranging by specialty from 5% (hematology) to 60% (obstetrics and injuries) (Boyd, 2013)
- Majority of physicians see little value for ICD-10-CM (as opposed to coders) (Butz, 2016)
Diagnosis-related groups (DRG)

- Original intent was to aggregate ICD-9 codes into groups for health services research.
- Set of several hundred codes that “lump” hospital illnesses.
- Adopted by HCFA (now CMS) in 1980s for prospective payment for hospitalization in Medicare.
- DRG categories will stay same initially for ICD-10-CM but may change later (Mills, 2015).
DRG examples for respiratory diseases

Respiratory disease w/ major chest operating room procedure, no major complication or comorbidity 75
Respiratory disease w/ major chest operating room procedure, minor complication or comorbidity 76
Respiratory disease w/ other respiratory system operating procedure, no complication or comorbidity 77
Respiratory infection w/ minor complication, age greater than 17 79
Respiratory infection w/ no minor complication, age greater than 17 80
Simple Pneumonia w/ minor complication, age greater than 17 89
Simple Pneumonia w/ no minor complication, age greater than 17 90
Respiratory disease w/ ventilator support 475
Respiratory disease w/ major chest operating room procedure and major complication or comorbidity 538
Respiratory disease, other respiratory system operating procedure and major complication 539

• Classification of procedures performed by physicians
• Usually required for reimbursement by government and private insurance companies in U.S.
• Evaluation/management (E/M) portion documents clinical encounters
• Developed, maintained, and copyrighted by American Medical Association (AMA)
HCFA Common Procedure Coding System (HCPCS)

- [http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/](http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/)
- HCPCS Level One is CPT-4
- HCPCS Level Two adds items and supplies and non-physician services
- HCPCS Level Three added local codes
  - Abolished in 2003 under HIPAA rules
- With adoption of ICD-10, professional fees and outpatient procedures will be billed using CPT-4/HCPCS and inpatient procedures will be billed using ICD-10-PCS
  - ICD-10-CM diagnosis codes will be required for all
Drug terminology

- A number of different code sets, mostly led by US government
- FedMed is interagency collaboration on agreed set of standard, comprehensive, and freely accessible Federal Medication Terminologies (FMT)
- Includes
  - National Drug Codes (NDC)
  - Unique Ingredient Identifier (UNII)
  - National Drug File Reference Terminology (NDF-RT)
  - NCI Thesaurus (NCIt) Structured Product Labeling (SPL)
  - RxNorm, RxTerms
National Drug Codes (NDC)

- [http://www.fda.gov/cder/ndc/](http://www.fda.gov/cder/ndc/)
- There is an 11-digit code for each and every pharmaceutical preparation
  - First 5 digits for manufacturer, assigned by Food & Drug Administration (FDA), e.g., Merck, Pfizer, etc.
  - Next 4 digits for product name, strength, dose form
    - One code for all variants of these
    - Problem: Not unique for same drug from different manufacturer
  - Final 2 digits are code for packaging
    - e.g., number of tablets in bottle
- Map into other terminology systems in FedMed
Other drug terminology standards

• Unique Ingredient Identifier (UNII) specifies ingredients in drugs and other compounds

• National Drug File Reference Terminology (NDF-RT, produced by VA) maintains mechanism of action, physiological effect, and structural class

• NCIt SPL maintains pharmaceutical dosage form, route of administration, and potency

• RxNorm provides semantic structure for formulations and their components (NLM, 2012)
  – RxTerms provides interface terminology to RxNorm (Fung, 2008)
  – RxNorm/RxTerms emerging as standard into which other drug terminologies must map
Relationships in RxNorm (Bodenreider, 2004)
Relationship of federal drug terminologies

http://www.ncvhs.hhs.gov/040730p1.pdf
Logical observations, identifiers, and numerical codes (LOINC)

- [www.loinc.org](http://www.loinc.org)
- For each observation, specify
  - Component (analyte) – substance or entity measured or observed
  - Property – e.g., mass concentration, numeric fraction
  - Time – point in time
  - Specimen (system) – e.g., blood, cerebrospinal fluid
  - Scale – e.g., qualitative, quantitative, ordinal, nominal
  - Method – optional, procedure used to make observation
- Being extended beyond original laboratory tests and into other languages beyond English ([Vreeman, 2012](http://www.loinc.org))
LOINC Examples

• Blood glucose GLUCOSE:MCNC:PT:BLD:QN:
• Serum glucose GLUCOSE:MCNC:PT:SER:QN:
• Urine glucose concentration GLUCOSE:MCNC:PT:UR:QN:
• Urine glucose by dip stick GLUCOSE:MCNC:PT:UR:SQ:TEST STRIP
• Ionized whole blood calcium CALCIUM.FREE:SCNC:PT:BLD:QN:
• 24 hour calcium excretion CALCIUM.TOTAL:MRAT:24H:UR:QN:
• Automated hematocrit HEMATOCRIT:NFR:PT:BLD:QN:AUTOMATED COUNT
• Erythrocyte MCV ERYTHROCYTE MEAN CORPUSCULAR VOLUME:ENTVOL:PT:RBC:QN:AUTOMATED COUNT
• ESR by Westergren method ERYTHROCYTE SEDIMENTATION RATE:VEL:PT:BLD:QN:WESTERGREN
SNOMED Clinical Terms (SNOMED CT)

• Systematized Nomenclature of Medicine (SNOMED)
• Originally developed by College of American Pathologists (CAP, www.snomed.org)
  – Originally a classification for pathologists (SNOP) but extended to all of medicine as SNOMED in 1980s (Cote, 1993)
  – Merged with English Clinical Terms Project to form SNOMED CT in 2000 (Spackman, 2000)
• In 2007, ownership transferred to International Health Terminology Standards Development Organisation (IHTSDO, www.ihtsdo.org)
• Multilingual – currently available in US English, UK English, Spanish, Danish and Swedish; being translated to others
SNOMED CT license

• In 2003, CAP and NLM negotiated five-year license for all of US
  – Continued with transfer to IHTSDO
• Can be freely used by all public and private entities within US (or other countries that license) for any healthcare, public health, research, educational, or statistical use
• Can encode patient level data sets and redistribute them as long as users do not extract significant portions
SNOMED CT

• Starter Guide and other documentation
  – http://ihtsdo.org/fileadmin/user_upload/doc/

• Richest vocabulary for describing clinical observations and findings
  – Coverage is extensive (Wasserman, 2003; Elkin, 2006)
  – Key feature is “multi-axial” or compositional approach
    • Allows terms to be combined, e.g., lung + inflammation
    • Allows modifiers to be added, e.g., severe, worsening

• Contains
  – > 300,000 concepts
  – > 1M “descriptions” (terms) expressing concepts
  – > 1M relationships between concepts
SNOMED CT design

SNOMED CT HIERARCHIES
- Concepts are organized into top-level hierarchies
  - Body structure
  - Clinical finding
  - Environment or geographical location
  - Event
  - Linkage concept
  - Observable entity
  - Organism
  - Pharmaceutical / biologic product
  - Physical force
  - Physical object
  - Procedure
  - Qualifier value
  - Record artifact
  - Situation with explicit context
  - Social context
  - Special concept
  - Specimen
  - Staging and scales
  - Substance

SNOMED CT DESIGN
- Concepts
- Hierarchies
- Attributes
- Identifiers
- Descriptions
- Relationships

RELATIONSHIPS
- Is a relationships connect concepts in a hierarchy
  - Arthropathy
  - Joint finding
- Attribute relationships connect concepts in different hierarchies
  - Appendicitis
  - Associated morphology
  - Inflammation

Heart failure (disorder)
- Weak heart
- Cardiac failure
- HF - Heart failure
- Myocardial failure

84114007
SNOMED CT expressions – some are pre-coordinated

<table>
<thead>
<tr>
<th>Precoordinated expression representing fracture of tibia</th>
<th>Identifier only</th>
<th>With display term</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>31978002</td>
<td>31978002</td>
</tr>
</tbody>
</table>
Nursing vocabularies

• Many of same issues impeding of other clinical terminologies
  – Irreconcilable information models
  – Terms not always the way clinicians express themselves
  – Tedious to use in patient documentation
  – Question of whether data is transferable across settings
Nursing vocabularies – a variety to choose from

<table>
<thead>
<tr>
<th>Nomenclatures</th>
<th>Diagnoses</th>
<th>Interventions</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Nursing Diagnosis Association (NANDA)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nursing Interventions Classification (NIC)</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Nursing Outcomes Classification (NOC)</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Omaha System</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Clinical Care Classification</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>International Classification for Nursing Practice</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

All are approved by the ANA; included in the UMLS Metathesaurus
Efforts at reconciliation of vocabularies

- The Unified Medical Language System (UMLS) Project of the NLM is an attempt at reconciliation (Humphreys, 1998)
- Consists of three components
  - Metathesaurus
  - Semantic network – generic relationships between semantic types of concepts, e.g., diseases and treatment
  - Specialist lexicon – based on Metathesaurus words and terms, designed to assist in natural language processing applications
UMLS Metathesaurus

• From documentation
  – The Metathesaurus is “a database of information on concepts that appear in one or more of a number of different controlled vocabularies and classifications used in biomedicine”
• Is a “meta”-thesaurus among terms across the major vocabularies
  – Synonymous terms from different vocabularies are given same concept identifier
  – Each distinct term can have different lexical variants, aka strings
Structure of UMLS Metathesaurus

- All terms from all vocabularies representing same notion are grouped as a concept
  - Linked by Concept Unique Identifier (CUI)
- All source terms of similar form (i.e., differing only in lexical variation) are grouped as terms
  - Linked by Term Unique Identifier (LUI)
- Within each term, lexical variants are strings
  - Linked by String Unique Identifier (SUI)
- Each string is an atom from its source
  - Linked by Atomic Unique Identifier (AUI)
Example Metathesaurus concept: Atrial Fibrillation

- **Atrial Fibrillation**
- **Auricular Fibrillation**
- **AF - Atrial Fibrillation**
- **afib**
- **a fib**
- **af**

**Concepts**
- Atrial Fibrillation
- Auricular Fibrillation
- AF - Atrial Fibrillation

**Terms**
- Atrial Fibrillation
- Fibrillation, Atrial
- Auricular Fibrillation
- Fibrillation, Auricular
- Atrial Fibrillations
- Auricular Fibrillations

**Strings**
- Atrial Fibrillation
- Fibrillation, Atrial
- Auricular Fibrillation
- Fibrillation, Auricular
- Atrial Fibrillations
- Auricular Fibrillations
Limitations and use of UMLS Metathesaurus

• Limitations
  – Only one-to-one relationships are mapped
  – Only terms from source vocabularies present; no new terms added
  – No unifying hierarchy is present, only those that exist in source vocabularies
  – Not extensible (i.e., in the SNOMED sense)

• Use
  – Modest at this point
  – More of a “repository” for vocabularies
Some other healthcare vocabularies

- Common Dental Terminology (CDT)
- Medical Subject Headings (MeSH) (discussed in information retrieval)
- Universal Medical Device Nomenclature (UMD)
- Diagnostic and Statistical Manual of Mental Disorders (DSM) – has its controversies (Kupfer, 2013)
- International Classification of Functioning, Disability, and Health (ICF)
- International Classification of Primary Care (ICPC)
Other terminology activities

• Development by NIH of common data elements (CDEs) for research studies – http://www.nlm.nih.gov/cde/, e.g.,
  – Patient Reported Outcome Measurement System (PROMIS, www.nihpromis.org)
  – National Institute of Neurological Disorders and Stroke Common Data Elements Project (www.commondataelements.ninds.nih.gov/)
  – Global Rare Diseases Registry (GRDR, www.grdr.info)
  – Consensus Measures for Phenotypes and Exposures (PhenX, www.phenx.org)
Clinical element model (CEM)

- “Stack of coded items” can be ambiguous, need model for clinical elements (Coyle, 2008)
- Clinical Information Modeling Initiative (CIMI) aims to create CEMs for clinical data
  - [http://informatics.mayo.edu/CIMI/index.php/Main_Page](http://informatics.mayo.edu/CIMI/index.php/Main_Page)
- Used in ONC SHARPn Project for secondary uses of clinical data (Tao, 2013)
- Most experience at Intermountain Healthcare (Oniki, 2014)
Some commercial terminology efforts

- Intelligent Medical Objects (IMO, [www.e-imo.com](http://www.e-imo.com)) – provides mapping, updates, and access to terminologies
- Medcin (Medicomp, [www.medicomp.com](http://www.medicomp.com)) – focused on documentation at point of care in EHR
- HDD Access ([www.hddaccess.com](http://www.hddaccess.com)) – terminology system developed by 3M, moved to open-source model
Class interaction

• What is/are the best terminology standard(s) for the following situations?
  – Patient diagnosis for possible recruitment into a research study
  – Normalization of names of laboratory studies in a health system
  – Transfer of medication details for a patient from one hospital to another
  – Structured representation of history and physical exam for a new patient
Bringing it all together

- Toward semantic interoperability – “computer utterance” in one system has same effect in any other (Dolin, 2011)
- Likely direction? From ONC Interoperability Roadmap, JASON Task Force Report, Argonaut Project Charter, etc.
  - RESTful architecture
  - FHIR-based API
  - OAuth2/OpenID security and authentication
  - Types of data
    - Documents – IHE specifications, CCDA
    - Discrete – Meaningful Use Common Data Set, SNOMED CT and other terminologies
Suggested additional readings

• Key articles

• General references


Implementation & Operation of Clinical Information Systems

Lecture 3E1-2

Thomas H Payne, MD, FACMI
University of Washington
Clinical Informatics Board Review Course

Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
   1.1.1. The discipline of informatics
   1.1.2. Key informatics concepts, models, and theories
   1.1.3. Clinical informatics literature
   1.1.4. International clinical informatics practices
   1.1.5. Ethics and professionalism
   1.1.6. Legal and regulatory issues
   1.2. The Health System
   1.2.1. Determinants of individual and population health
   1.2.2. Primary domains, organizational structures, cultures, and processes
   1.2.3. The flow of data, information, and knowledge within the health system
   1.2.4. Policy & regulatory framework
   1.2.5. Health economics and financing
   1.2.6. Forces shaping health care delivery
   1.2.7. Institute of Medicine quality components

2. Clinical Decision Making and Care Process Improvement
   2.1. Clinical Decision Support
   2.1.1. The nature and cognitive aspects of human decision making
   2.1.2. Decision science
   2.1.3. Application of clinical decision support
   2.1.4. Transformation of knowledge into clinical decision support tools
   2.1.5. Legal, ethical, and regulatory issues
   2.1.6. Quality and safety issues
   2.1.7. Supporting decisions for populations of patients
   2.2. Evidence-based Patient Care
   2.2.1. Evidence sources
   2.2.2. Evidence grading
   2.2.3. Clinical guidelines
   2.2.4. Implementation of guidelines as clinical algorithms
   2.2.5. Information retrieval and analysis
   2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
   2.3.1. Methods of workflow analysis
   2.3.2. Principles of workflow re-engineering
   2.3.3. Quality improvement principles and practices

3. Health Information Systems
   3.1. Information Technology Systems
   3.1.1. Computer Systems
   3.1.2. Architecture
   3.1.3. Networks
   3.1.4. Security
   3.1.5. Data
   3.1.6. Technical approaches that enable sharing data
   3.2. Human Factors Engineering
   3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
   3.2.2. HCI Evaluation, usability testing, study design and methods
   3.2.3. Interface design standards and design principles
   3.2.4. Usability engineering
   3.3. Health Information Systems and Applications
   3.3.1. Types of functions offered by systems
   3.3.2. Types of settings where systems are used
   3.3.3. Electronic health/medical records systems as the foundational tool
   3.3.4. Telemedicine
   3.4. Clinical Data Standards
   3.4.1. Standards development history and current process
   3.4.2. Data standards and data sharing
   3.4.3. Transaction standards
   3.4.4. Messaging standards
   3.4.5. Nomenclatures, vocabularies, and terminologies
   3.4.6. Ontologies and taxonomies
   3.4.7. Interoperability standards
   3.5. Information System Lifecycle
   3.5.1. Institutional governance of clinical information systems
   3.5.2. Clinical information needs analysis and system selection
   3.5.3. Clinical information system implementation
   3.5.4. Clinical information system testing, before, during and after implementation
   3.5.5. Clinical information system maintenance
   3.5.6. Clinical information system evaluation

4. Leading and Managing Change
   4.1. Leadership Models, Processes, and Practices
   4.1.1. Dimensions of effective leadership
   4.1.2. Governance
   4.1.3. Negotiation
   4.1.4. Conflict management
   4.1.5. Collaboration
   4.1.6. Motivation
   4.1.7. Decision making
   4.2. Effective Interdisciplinary Teams
   4.2.1. Human resources management
   4.2.2. Team productivity and effectiveness
   4.2.3. Group management processes
   4.2.4. Managing meetings
   4.2.5. Managing group deliberations
   4.3. Effective Communications
   4.3.1. Effective presentations to groups
   4.3.2. Effective one-on-one communication
   4.3.3. Writing effectively for various audiences and goals
   4.3.4. Developing effective communications program to support system implementation
   4.4. Project Management
   4.4.1. Basic principles
   4.4.2. Identifying resources
   4.4.3. Resource allocation
   4.4.4. Project management tools (non-software specific)
   4.4.5. Informatics project challenges
   4.5. Strategic and Financial Planning for Clinical Information Systems
   4.5.1. Establishing mission and objectives
   4.5.2. Environmental scanning
   4.5.3. Strategy formulation
   4.5.4. Action planning and strategy implementation
   4.5.5. Capital and operating budgeting
   4.5.6. Principles of managerial accounting
   4.5.7. Evaluation of planning process
   4.6. Change Management
   4.6.1. Assessment of organizational culture and behavior
   4.6.2. Change theories
   4.6.3. Change management strategies
   4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core Content Covered

3.5 Information System Lifecycle
3.5.1 Institutional governance of clinical information systems
3.5.2 Clinical information systems needs analysis and system selection
3.5.3 Clinical information system implementation
3.5.4 Clinical information system testing
3.5.5 Clinical information system maintenance
Key topics

• Institutional governance models for clinical information systems
• Formal and informal methods to define and specify system requirements, and solicit vendor proposals
• System conversion strategies and their relative merits
• Elements of a system implementation plan
• Key elements of clinical system operations and maintenance program
Core Content Covered

3.5 Information System Lifecycle

3.5.1 Institutional governance of clinical information systems

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3.5.3 Clinical information system implementation

3.5.4 Clinical information system testing

3.5.5 Clinical information system maintenance
Institutional governance of clinical information systems, 1.

- Integrate into existing governance (or build new)
- Information system projects are best viewed as \textit{clinical} rather than IT
- Leadership best derived from opinion leaders versus technophilic users
Institutional governance of clinical information systems, 2.

• Where does clinical computing fit into the organizational chart, and where would it ideally be placed? Consider:
  – CMOs and CNOs
  – CXIOs (CCIO, CMIO, CNIO)
  – IT and CIOs
The relationship between clinical computing and operational leadership

In general, health IT leadership has migrated up the org chart
Medical Center bylaws and medical records

• Bylaws typically cover:
  – Content of medical record
  – Who is permitted to add to and view it
  – Responsibility of physicians for entering into the medical record for their patients
  – Standards for timely completion

• Oversight of medical records often vested in Medical Record or Health Information Management Committee

Consider also: The Joint Commission, state, federal law
Regarding legal agreements in health IT:

A. BAAs, DUAs, and SLAs are all required by HIPAA.
B. BAAs are used when a business associate has access to PHI.
C. BAAs, DUAs, and SLAs are usually formal legal agreements rather than contractual.
D. DUAs are required before sharing of data between healthcare organizations.
Legal agreements

- **BAA** – Business Associates Agreement
  - Required by HIPAA
  - Associate has access to PHI
- **DUA** – Data Use Agreement
  - Conditions for use and sharing of data between organizations
- **DSA** – Data Storage Agreement
  - Similar to above, but parties store data for another
- **SLA** – Service Level Agreement
  - Typically contractual rather than legal agreements for performance

Slide courtesy of Dave Chou
EMR policies developed by Medical Record Committees

- Who can enter into medical record
- Use of alerts
- Retention of records
- Medical record completion
- Co-signature requirements
- Typically charged with preparation for Information Management section of Joint Commission review
Core Content Covered

<table>
<thead>
<tr>
<th>3.5</th>
<th>Information System Lifecycle</th>
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<tr>
<td>3.5.1</td>
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</tbody>
</table>
Methods for identifying clinical information system needs

- Create project team
- Define requirements
- Identify viable candidates
- System selection…

Observation
Mapping
Interviews
Focus groups
Expert interviews
Clinical information system selection

| I   | Understand what you want, and how to get it  
|     | Informal investigation |
| II  | Formal investigation: Request for Proposals (RFP), Request for Information (RFI) (or neither) |
| III | Demonstrations  
|     | Site visits  
|     | Reference calls  
|     | Business investigation |
| IV  | Selection |
| V   | Negotiation  
|     | Contract |

- Software and Hardware costs
- Implementation services scope and costs
- What constitutes acceptance of the system
- Performance clauses and Failure to Perform
- A key protection for successful systems
Assessment of clinical processes that will be required

• Need clinically-savvy people
• List tasks: orders, notes, results, messaging
• May use formal workflow analysis tools and methodology or less formal diagrams
• Consider off-site work done by clinicians
Information needs of office practice

[Covell and Manning 1985]

- 2 questions arose for every 3 patients
- Only 30% were answered during visit

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<thead>
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<th>Information Sources</th>
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<th>Observed Use of Information Sources (n = 80)</th>
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<td>Pharmaceutical textbooks</td>
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<td>6.7</td>
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<td>Drug company information</td>
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<td>1.3</td>
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<tr>
<td>Generalist</td>
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<td>Office partner</td>
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<td>4</td>
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<tr>
<td>Pharmacist</td>
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<td>2.7</td>
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<tr>
<td>Nurse</td>
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<td><strong>Other sources</strong></td>
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<td>Laboratory data, patient response</td>
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<td>13.3</td>
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<tr>
<td><strong>Total</strong></td>
<td>7.0</td>
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</tbody>
</table>
Clinical information needs analysis and system selection

RFP  Request for proposal. A document that an organization posts to elicit bids from potential vendors for a product or service. A weighted point assignment method of evaluation may be used if considered appropriate.

RFI  Request for information. Request made typically during the project planning phase where a buyer cannot clearly identify product requirements, specifications, and purchase options. RFIs clearly indicate that award of a contract will not automatically follow.

RFQ  Request for quotation. Used when requirements are clear-cut

“You are buying what they are selling.”
Contents of the RFP
[Kelly 1999]

• Describe your organization
• Describe your needs—functional, technical, business requirements
• Timing and implementation requirements
• Financial issues
• Lay out the vendor selection process, timeline, and selection criteria
• Conform to organizational requirements
Vendor investigations—due diligence

- Demonstrations for small or large groups
  - Useful for group investigation, ↑ buy-in
  - Require vendor to specify what is future functionality

- Site visits
  - Critically important part of vendor selection
  - Visit sites like your own

- Conference calls
  - Cheaper and faster than site visits
  - Expand your reach
Business investigation

- Will the vendor remain in business or not?
- How long have they been in business?
- Are they privately or publicly held?
- Are they likely to be acquired?
- What does their balance sheet tell you about their likely future?
- Involve your business office/CFOs.
Contract negotiations

• Basis for long-term financial and professional relationship
• For large contracts, strongly consider hiring legal counsel. Vendor will have it.
• Vendor proposal should be submitted in form to be included in contract.
• Contract controls project, functionality, payments
• Allow sufficient time to do this properly
Do you need outside help to acquire a system?

• Can consultants help?
  – Yes, for a price.
  – They are no panacea.
  – You can do it yourself if you have enough time and expertise.

• Do you have sufficient internal expertise?
  – Existing staff with current expertise or time to learn
  – Alternative is recruiting new staff with expertise

• How high are the stakes?
  – Large, complicated, expensive projects are riskier.
  – Remember that over long term, most money is in support payments, which are governed by the contract—strongly consider legal counsel in contract negotiations.
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3.5  Information System Lifecycle
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3.5.4  Clinical information system testing
3.5.5  Clinical information system system maintenance
Implementation overview

- Assess current state
- Process Design--future state
- Software design
- Configuration—building the system
- Test, Test, Test…

- Train
- Convert/Go-Live
- Post Conversion Assessment
- Move into Ongoing Support Model
Elements of a system implementation plan. 1

- Project management (PMP=Project Management Professional)
- Budgeting
- External audit
- Testing
- Training
- Support
Elements of a system implementation plan. 2
[Grisim, Longhurst 2011]

• Transition planning ("go-live," "activation", "conversion")
  – Big bang (or modified), versus pilot, or phased (staggered, sequential)
  – By medical service or location
  – Consider risks, budget for support, costs of transition

• When choosing transition approach, consider:
  – Functionality
  – Geography
Testing. 1

- **Unit.** Directed at menus, templates, and other modules and subunits of the system, without regard to other system components internal or external to a given application.
- **Application.** All modules and subunits of the application work in connection with each other.
- **Integration.** Conformation that information flow between the EMR and external systems occurs as expected.
- **Performance.** With production loads and users, system functions within expected boundaries.
- **Post-production.** After conversion, all aspects of system operate as required.
Regarding testing, which statement is the most accurate?

A. Contingency testing is usually not needed if other testing has occurred prior to go-live.
B. Integration testing assures all functional modules within an EHR system work together.
C. Unit testing is usually the final step in testing the entire EHR before go-live.
D. Regression testing determines if other components of a system operate after a change is introduced.
Testing. 2

Other testing terms you may hear

- **System.** Tests all aspects of a given system or application, e.g. - how well the software satisfies the stakeholders’ functionality, security, performance, load, reliability, compatibility, availability, etc. requirements.

- **Regression.** Tests to make certain that, with the exception of the change currently being requested, all components of the software’s functionality / behavior are unchanged.

- **Backout or contingency.** Tests the ability to back out the changes being made to a system or, if changes cannot be backed out, tests the contingency plan if modifications cause problems once implemented.
Testing. 3

- **Test environment.** Domain (or instance) of system with configuration and data similar to production in which testing occurs.
- **Scripts.** Structured simulations of workflow and system use that can reproducibly be used for testing versions of proposed production version.

Testing is tiring, monotonous, critically important, and shortened at great risk.
Clinical information system testing
Before, during and after implementation

- Before implementation—as above
- Real-world active surveillance
- Upgrade testing
- Capturing user feedback
- Safety reporting systems
- Simulation of production use
- Robot monitoring of user experience
Conversion. 1
(aka activation, go-live) [Ash 2003]

• Command Center
  – On-site presence
  – All teams: technical, application, interface, user liaisons
  – Planning duration and logistics should begin early

• User support team
  – Goal is overwhelming support, “at the elbow”
  – Project and non-project team
  – Roamers

• Communication methods and plan
  – Pagers, cell phones, scheduled status calls, shift reports
Conversion. 2

• Issue management
  – Capture and triage
  – Documentation
  – Communication and closing the loop
• Review downtime procedures
• Have back-out or remediation plan
User support models

• During conversion and ongoing
• Determine model:
  – Who provides it?
  – Role of Help Desk
  – Onsite vs remote
  – Escalation procedures
  – Remove viewing of user experience vs. in-person
    Super User or IT team member
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Operating Clinical Computing Systems

• Operations entails the day-to-day
  – running,
  – maintenance,
  – enhancement, and
  – safeguarding
of the system to meet the
  – availability and
  – reliability requirements

Slide courtesy of Soumitra Sengupta.
CIS transitions and decommissioning of systems

- Data transfer risk/benefit
- Keep old system for review?
- Drivers
  - External—E.g. certification, Y2K, ICD10
  - Internal
    - Best of breed vs integration
    - Better system now available
    - What is cycle time between systems?
Models of user training and support processes that can meet clinician needs

- Classroom, web-based or blended
- Concierge
- In-person—tailor to specialty
- Strengths and weaknesses of SuperUser
- Be on wards/clinics—"at elbow"
Operations – Premises with downtime

- All systems will be down sometime
- Must prepare ahead of time
- Communication between interested parties is critical
- Parties must know \textit{a priori} what to do
- Business must continue
- Reducing the time a system is down is a key metric

Slide courtesy of Soumitra Sengupta.
Operations – Trends

• The primary mission of most healthcare organizations care rather than information technology
• Outsourcing specific applications such as EHR
• Managed services with internal systems
• Cloud computing
  – the provision of dynamically scalable and often virtualized resources as a service over the Internet on a utility basis (wikipedia)
  – Infrastructure/Platform/Software as a Service (IaaS/PaaS/SaaS)
  – Makes good economic sense due to scales of operations
  – Unclear understanding with Privacy issues
• Models of operational consolidation

Slide courtesy of Soumitra Sengupta.
The best phrase to describe change control:

A. A process for pacing functionality change experienced by users when implementing an EHR
B. Permits assessment of testing of technical features before introduced into production systems.
C. Most consider it a useful but optional step.
D. Is a formal process used to ensure that changes to a system are introduced in a controlled manner.
Change control

• Change control requires that updates or changes to software, hardware, or other parts of the infrastructure or application go through testing and analysis of its expected and potential impacts. Those making the change are expected to test changes, understand impacts, notify users, and minimize unexpected side effects. (Chou, Sengupta).

• Change control is a formal process used to ensure that changes to a product or system are introduced in a controlled and coordinated manner. (Wikipedia)
### UW Medicine IT Systems Change Request Criteria Checklist

#### General Info
1. USD Number for the Change Request
2. Affected stakeholders have been identified and sign-off on the implementation date has been obtained by the appropriate authorizing party (e.g., Application Owner, Manager, etc.).

See definitions at the following network path: [UW path](#).
3. List potential impact(s) on real-time patient/business critical systems due to this change (e.g., Security, Operations, Ongoing system management & support).
4. List the name of the person or group that has reviewed and approved the technical soundness of the change.

#### Documentation
5. End User documentation has been created (or modified) and distributed to the appropriate parties.
6. Production support documentation has been created (or modified) and distributed to the appropriate parties.
7. System/application configuration documentation has been created (or modified) and distributed to the appropriate parties.
8. Implementation instructions (including implementation monitoring steps) for the group that will implement the changes have been developed, documented, communicated, and accepted.
9. Back out or other contingency plan has been developed, documented, communicated, and accepted.
10. Post-implementation validation plan that will involve operations, application support, and customers has been developed, documented, communicated, and accepted.
11. If the change will affect batch job schedules, database maintenance schedules, remote support capabilities, monitoring, alarming, security, data retention requirements, etc., detailed operational support instructions have been developed, documented, communicated, and accepted.

#### Testing
- If changes CAN be tested before implementation
  12. Test results summary has been provided at the end of this document.

- If changes CANNOT be fully tested before implementation
  13. Code review or implementation procedure walkthrough has been completed with successful results.
  14. Post-implementation validation and signoff has been provided as an attachment to the change request.
  15. Back out or other contingency planning has been reviewed with successful results.

#### Communication
16. All affected customers, interface groups, and downstream systems required to make corresponding changes have been notified.
17. If the change requires downtime, downtime notification procedures are followed.
18. If the change requires downtime, it is scheduled during approved maintenance window. If no, then why?

#### Operations/Maintenance
19. Software version control standard has been followed.
20. Security review has been completed (if applicable).

### Example of Change Control Checklist

#### Test Results Summary
(Fill out this section if your changes can be tested before implementation)

- **Test Performed By:**
- **Test Results Validated By:**
- **Test Start Date:**
- **Test Completion Date:**

The following are some common types of testing and the objective of each testing type. This is not an exhaustive list. The required testing types will depend on the nature and complexity of the change. Please check the boxes (double click) to indicate which testing has been completed with successful results:

- **Unit Testing** - Tests the basic functionality of the smallest piece of software, without regard to other system components, external or external to a given application.
- **Integration Testing** - Tests how all system components (e.g., modules, programs, sub-systems, interface, etc.) interact with each other and with data.
- **System Testing** - Tests all aspects of a given system or application, e.g., how well the software satisfies the stakeholders’ functionality, security, performance, load, reliability, compatibility, availability, etc. requirements.
- **Backout or Contingency** - Tests the ability to back out the changes being made to a system, or, if changes cannot be backed out, tests the contingency plan if modifications cause problems once implemented.
- **Regression Testing** - Tests to make certain that, with the exception of the change currently being requested, all components of the software's functionality/behavior are unchanged.
- **Workflow** - Generally conducted by functional (non-IT) representatives, workflow testing tests whether or not system modifications work well within functional workflow.
- **Other** - (Specify)

Please Review functions that worked as expected and functions that did not work below:

- Functions tested that worked:
- Functions tested that did not work:
- Functions not tested and why:

How did differences between test and production environments, if any, affect testing?
Downtime

• Definition
  – Systems not available to significant group
  – Significant functions not available
  – Performance has degraded below usable threshold

• Planning is essential

• Divided between planned and unplanned
Scheduled downtime

- Develop and train **downtime procedures** including workflow, data access, preparation and backloading from paper
- Select **optimal time** based on
  - Schedule of clinical activity and key business
  - Availability of internal and external technical resources
- **Stratify** plans by length of planned downtime
- **Notify** user community in advance
True or false?

The most common causes of downtime are human error and insufficient system testing of changes.
Unscheduled downtime

- **Causes:**
  - Human error
  - Changes in system insufficiently tested
  - Software fault
  - Hardware or connectivity failure
  - Reaching capacity
  - Disaster
  - Malicious activity

- Have and follow plan that includes structured incident command, triage, communication, post-mortem review
Disaster recovery

- Unanticipated large-scale loss of clinical computing functionality and/or data
- Recovery of business operations requires ability to rapidly restore both data and functionality.
- Off-site storage, remote hosting, HVAC and local power generation and communications may be part of this plan.
- Planning, rehearsal, and updating increase risk of success
Operations – Actions when down

• Communicate
  – Conference calls, emails, personal calls to Sr. Mgmt.
  – Right frequency, right timing, with right, relevant details
  – If big problem, then have separate technical solution group and User communication group
    • Shield solution group from communication group (no lynching rule – it wastes time)
    • Comm. group triggers business continuity plans, unless it is triggered automatically
  – Each affected work area manager and each affected service follows their business continuity plan
Operations – Actions when down

- Solution group
  - Needs a General: solution group must be led
  - The solution group must have time to propose, vet and try alternatives
  - The General and the group focus on alternatives to minimize downtime, *not necessarily* solve the problem
  - Pay attention to when to let members of solution group to be fed and relieved
  - Involve vendor early, show urgency, demand speed, call their bosses
  - Conduct detailed post mortem for root cause analysis later, if not found as yet
Issues when the system is back up

- Are data on paper back-loaded? When, and by whom?
- Are results generated by departmental systems loaded retrospectively?
- Plan transition of orders and medication administration from paper to EMR.
- Pay attention to staff fatigue.
How can we reduce risk?

- **Code Updates**
  - Avoid the “bleeding edge”, let others go first
  - Limit changes to those that are absolutely necessary
- **Downtime Windows**
  - Allow resources to adjust their body clock
  - Ensure backup plans for key resources, check-in in advance and keep in contact throughout the downtime
- **Vendor Availability**
  - Get on the vendor’s activity calendar – Make sure they know what you’re doing ahead of time and that they can support it
- **Planning, testing, and post-implementation validation**
  - Sufficient test environments, testing tools, and standardized / reusable test scripts
  - Post-Implementation validation should be done by people on the front-lines
Operations – ITIL

- **Information Technology Infrastructure Library** is a framework for “IT service management.”
- Developed in the UK by the CCTA (Central Computer and Telecoms Agency) in the 1980’s, initially to cut costs
- Gained recognition in the 1990’s when Microsoft used ITIL as the basis for its Microsoft Operations Framework (MOF)
- Defines the organizational structure and skill requirements of an IT area and documents a set of operational management procedures to foster more effective management of an IT operation and infrastructure
- Portfolio → services → processes → procedures
Operations – Service View

• Information Technology Service Portfolio
  – A collection of high level, grounded, objectives
  – Manage performance, Secure assets, Manage identities, Plan strategically

• Each folio is a set of Services
  – Offered to a user, peer, institution with Service Level Agreements
  – Minimize expected downtime, Manage a reported performance problem, Protect perimeter

• Each service is a collection of processes
  – Processes are collection of procedures using a set of tools by a collection of custodians
  – Who does what using what?

• Each procedure is measured for resource and efficiency, and these collections generate operational metrics
Disaster recover and downtime

- Off-site storage needed
- Test restore processes
- Corruption risks—stagger versions
- Rehearse downtime, day and night
- To/from Daylight Savings Time
Processes and mechanism that obtain and respond to clinician feedback

[Ozdas and Miller, 2007]

- Embedded in clinical world—Rounding, using systems give insights
- Monitoring remotely
- “Feedback button,” “Pizza budget,” meals coupled with feedback sessions are valuable.
- Regular communication at meetings, via pages, using ad hoc hallway and clinical setting conversations
Organizational Strategies Necessary to EHR safety
[Walker 2008]

• Care-process transformation
• Patient safety
• Human-factors engineering
• Software safety
• Project management
• Continuous improvement
Clinical information system maintenance

- Patches, upgrades from vendor
- Coding system updates (ICDX, DDI databases, etc)
- Interfaces with other systems
- Delivery
  - End user devices
  - Citrix
EMR Optimization

• Post-implementation focus on features and functionality that have been incompletely or sub-optimally adopted.
• Review of workflow and tailored education
• Use of EMR to assist in meeting organizational quality, safety and financial goals.
Clinical computing systems and compliance

• Documentation, orders, results review and other tasks and audit trails scrutinized by compliance are increasingly accomplished using computing systems
  – Compliance officers charged with protecting the organization may not have full understanding of clinical computing system functionality and workflow

• Compliance and DOJ focus on cloning, upcoding, copy/paste
Clinical computing systems and the law

- The importance of authentication and authorization
- Concept of non-repudiation
- Audit trails, document version history
- Close cooperation with compliance and general counsel
Additional suggested readings


4A: Leadership Models, Processes and Practices

Alexis B. Carter, MD
Children’s Healthcare of Atlanta
Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
   1.1.1. The discipline of informatics
   1.1.2. Key informatics concepts, models, theories
   1.1.3. Clinical informatics literature
   1.1.4. International clinical informatics practices
   1.1.5. Ethics and professionalism
   1.1.6. Legal and regulatory issues
   1.2. The Health System
   1.2.1. Determinants of individual and population health
   1.2.2. Primary domains, organizational structures, cultures, and processes
   1.2.3. The flow of data, information, and knowledge within the health system
   1.2.4. Policy & regulatory framework
   1.2.5. Health economics and financing
   1.2.6. Forces shaping health care delivery
   1.2.7. Institute of Medicine quality components

2. Clinical Decision Making and Care Process Improvement
   2.1. Clinical Decision Support
   2.1.1. The nature and cognitive aspects of human decision making
   2.1.2. Decision science
   2.1.3. Application of clinical decision support
   2.1.4. Transformation of knowledge into clinical decision support tools
   2.1.5. Legal, ethical, and regulatory issues
   2.1.6. Quality and safety issues
   2.1.7. Supporting decisions for populations of patients
   2.2. Evidence-based Patient Care
   2.2.1. Evidence sources
   2.2.2. Evidence grading
   2.2.3. Clinical guidelines
   2.2.4. Implementation of guidelines as clinical algorithms
   2.2.5. Information retrieval and analysis
   2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
   2.3.1. Methods of workflow analysis
   2.3.2. Principles of workflow re-engineering
   2.3.3. Quality improvement principles and practices

3. Health Information Systems
   3.1. Information Technology Systems
   3.1.1. Computer Systems
   3.1.2. Architecture
   3.1.3. Networks
   3.1.4. Security
   3.1.5. Data
   3.1.6. Technical approaches that enable sharing data
   3.2. Human Factors Engineering
   3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
   3.2.2. HCI Evaluation, usability testing, study design and methods
   3.2.3. Interface design standards and design principles
   3.2.4. Usability engineering
   3.3. Health Information Systems and Applications
   3.3.1. Types of functions offered by systems
   3.3.2. Types of settings where systems are used
   3.3.3. Electronic health/medical records systems as the foundational tool
   3.3.4. Telemedicine
   3.4. Clinical Data Standards
   3.4.1. Standards development history and current process
   3.4.2. Data standards and data sharing
   3.4.3. Transaction standards
   3.4.4. Messaging standards
   3.4.5. Nomenclatures, vocabularies, and terminologies
   3.4.6. Ontologies and taxonomies
   3.4.7. Interoperability standards
   3.5. Information System Lifecycle
   3.5.1. Institutional governance of clinical information systems
   3.5.2. Clinical information needs analysis and system selection
   3.5.3. Clinical information system implementation
   3.5.4. Clinical information system testing, before, during and after implementation
   3.5.5. Clinical information system maintenance
   3.5.6. Clinical information system evaluation

4. Leading and Managing Change
   4.1. Leadership Models, Processes, and Practices
   4.1.1. Dimensions of effective leadership
   4.1.2. Governance
   4.1.3. Negotiation
   4.1.4. Conflict management
   4.1.5. Collaboration
   4.1.6. Motivation
   4.1.7. Decision making
   4.2. Effective Interdisciplinary Teams
   4.2.1. Human resources management
   4.2.2. Team productivity and effectiveness
   4.2.3. Group management processes
   4.2.4. Managing meetings
   4.2.5. Managing group deliberations
   4.3. Effective Communications
   4.3.1. Effective presentations to groups
   4.3.2. Effective one-on-one communication
   4.3.3. Writing effectively for various audiences and goals
   4.3.4. Developing effective communications program to support system implementation
   4.4. Project Management
   4.4.1. Basic principles
   4.4.2. Identifying resources
   4.4.3. Resource allocation
   4.4.4. Project management tools (non-software specific)
   4.4.5. Informatics project challenges
   4.5. Strategic and Financial Planning for Clinical Information Systems
   4.5.1. Establishing mission and objectives
   4.5.2. Environmental scanning
   4.5.3. Strategy formulation
   4.5.4. Action planning and strategy implementation
   4.5.5. Capital and operating budgeting
   4.5.6. Principles of managerial accounting
   4.5.7. Evaluation of planning process
   4.6. Change Management
   4.6.1. Assessment of organizational culture and behavior
   4.6.2. Change theories
   4.6.3. Change management strategies
   4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core content covered

**Leading and Managing Change:** The knowledge and skills that enable clinical informaticians to lead and manage changes associated with implementing clinical information systems and promoting adoption by health professionals.

**4.1. Leadership Models, Processes, and Practices**

4.1.1. Dimensions of effective leadership
4.1.2. Governance (e.g., processes; responsibility versus authority)
4.1.3. Negotiation
4.1.4. Conflict management
4.1.5. Collaboration
4.1.6. Motivation
4.1.7. Decision making
Key topics

• Enable and support effective technology adoption in healthcare through:
  – Dimensions of effective leadership
  – Organizational governance
  – Effective techniques in Negotiation, Conflict Management, Collaboration, Motivation, and Decision Making
DIMENSIONS OF EFFECTIVE LEADERSHIP
Definition of Leadership

- The power or ability to lead other people
- The capacity to lead
- The act or instance of leading

Source: http://www.merriam-webster.com/dictionary/leadership
Definition of Leadership for Healthcare Organizations

• Behavior of an individual…
  when directing the activities of a group
towards a shared goal
Leadership Skills for the Clinical Informaticist

- Foundation in clinical informatics
- All skills in section 4 of core content:
  - Negotiation, Conflict Management, Collaboration, Motivation, Decision-making (section 4A)
  - Building effective interdisciplinary teams across divides (section 4B)
  - Communication, communication, communication (section 4C)
  - Project management (section 4D)
  - Strategic and financial planning for clinical information systems (section 4E)
  - Change management (section 4F)
People, Process and Technology

\[
\text{Value} = \frac{\text{Quality}}{\text{Cost}}
\]

LEADERSHIP MODELS
Leadership Theories

• Most were developed for business, not healthcare
  – **Great Man Theory** (pre 1940)
    • Leadership is inherent, not learned
  – Behavioral theories
    • **Authoritarian**: My way or the highway
    • **Democratic**: Let’s have a vote
    • **Laissez-faire**: Let the people lead themselves
Leadership Theories

• Situational and contingency theories
  – Focus on worker, task and situation/environment

• List of sites for leadership:
Interactional Theories

- **Action-Centered Leadership Model**
  - John Adair, “Action Centered Leadership” (1973)
  - [http://www.johnadair.co.uk/](http://www.johnadair.co.uk/)
  - **Functional leadership model:**
    - Leadership is a set of behaviors that help a group of people perform their task/goal
    - Leadership meets needs in three areas --Task, Team, Individual

Transactional Theories

• **Functional Results-Oriented Healthcare Leadership Model (FROHLM)**
  
  – Leadership model developed for healthcare
  
  – Most common model for healthcare leadership
  
  – Leaders facilitate effective healthcare provision by meeting needs for
    
    • Task + Team + Individual ==> Results
  
  – Leaders are responsible for measurable outcomes
  
  – Reinforcement for outcome goals achieved
  
  – In some cases, punishment for not achieving desired outcome goals


Transformational Leadership

- Group needs to have a shared sense of mission to perform beyond expectations
- **Leader** must effectively communicate the vision
  - Meaningful and exciting message
  - Creates unity and collective purpose
- Leader must positively influence attitudes towards mission
- Four factors

<table>
<thead>
<tr>
<th>Idealized influence</th>
<th>Leader must make followers believe that leader is passionate for cause and worthy of attention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspirational motivation</td>
<td>Leader must persuade and inspire others to join the mission</td>
</tr>
<tr>
<td>Intellectual stimulation</td>
<td>Leader gets followers to embrace new mission and develop creative solutions to effectively carry out mission</td>
</tr>
<tr>
<td>Individual consideration</td>
<td>Leader addresses each follower's doubts with the new mission</td>
</tr>
</tbody>
</table>
Collaborative Leadership

• Pros
  – Leaders communicate information to the group
    • Allows group to make their own informed decisions
  – Encourage dialog → share knowledge → reduce complexity
  – Facilitate interdependency among stakeholders

• Cons
  – Fosters collaboration but not technical solutions, which may be needed
  – Requires a lot of time for collaboration, which may not be available

• Best use: low-key clinical, research and healthcare policy settings
Collaborative Leadership

• Collaborative Healthcare Leadership
  – Center for Creative Leadership (www.ccl.org)
  – Six-part model
    • Collaborative patient care teams
    • Resource stewardship
    • Talent transformation
    • Boundary spanning
    • Capacity for complexity, innovation and change
    • Engagement and well-being
Shared Leadership

• Team-level management/leadership
• Empowers staff within decision-making processes
  – e.g., Lean technology (Toyota Production System)
• Individual staff adopt:
  – Leadership behavior
  – Greater autonomy
  – Improved patient care outcomes
• Reasons for popularity in healthcare
  – Many healthcare workers are VERY autonomous
    (e.g., physicians)
  – Do not respond well to authoritarianism
Distributed Leadership

• Individuals in a team complement each other's strengths and offset their weaknesses
  – Workers offset leader’s weaknesses and vice versa

• Four key characteristics for a leader in this approach

<table>
<thead>
<tr>
<th>Sense-making</th>
<th>Ability to understand constantly changing environment; interpret impacts of changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relating</td>
<td>Ability to build trusting relationships and support</td>
</tr>
<tr>
<td>Visioning</td>
<td>Create credible and compelling image of desired future</td>
</tr>
<tr>
<td>Inventing</td>
<td>Create new ways of approaching tasks/problems</td>
</tr>
</tbody>
</table>
Ethical Leadership

• Leader must have intentions, values and behaviors that...
  – Intend no harm
  – Respect rights of all parties
Servant Leadership

• Greenleaf (1977)
• Focuses on leader's development through self-awareness and self-knowledge
• Leads to development of **moral core** to serve others, particularly those least privileged
• Fits well with healthcare because many providers "called to serve" their patients

• Cons
  – May lack speed needed for urgent issues
  – May not be the best to address certain types of conflict
  – Can result in lack of clarity with certain leaders
LEADERSHIP DEVELOPMENT MODEL
Healthcare Quality Professional Leadership Development Model

Fostering of Positive Change
Organizational Awareness
Performance Improvement
Communication
Self-Development & Self-Management
Professionalism & Professional Values

National Association for Healthcare Quality.
http://www.nahq.org/membership/leadership/devmodel.html
ASSESSING LEADERSHIP COMPETENCY
Health Leadership Competency Model

- National Center for Healthcare Leadership (NCHL)
  - Defines competencies required for outstanding healthcare leadership
  - Leadership is at the hub of all three activities
- Section L12. Information Technology management

ACHE 2016 Competencies Assessment Tool

• American College of Healthcare Executives (ACHE)

• Five domains:
  – Leadership (center)
  – Communication and Relationship Management
  – Professionalism
  – Business skills and knowledge
    • Includes information management competencies (page 17-18)
  – Knowledge of the Healthcare Environment

• References
Definitions

- Leadership = a **person** leading a group
- Governance = a **group** leading a group(s)
Governance in Health IT Projects

• Definition
  – infrastructure, strategies and approaches to support physicians [clinicians] in the definition of clinical content, refinement of the care processes and the adoption of new technologies before, during and after implementation

## Corporate Governance Theories

<table>
<thead>
<tr>
<th>Theory</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Agency**         | - Emphasis on conformance of the subordinate groups  
                      - Emphasis on the monitoring nature of the governing board  
                      - Diminishes board's role in setting strategy, mission and objectives  |
| **Stewardship**    | - Managers and owners share common agenda and work side by side  
                      - Board's role is to develop strategy but not to monitor or enforce  
                      - Can lead to failure, strategic drift or inertia  |
| **Resource Dependency** | - Board's role is to minimize uncertainty caused by external factors by creating dependencies on internal resources  
                      - Board provides advice, access to information, preferential access to resources and legitimacy  
                      - Too overtly focused on external issues  |
| **Stakeholder**    | - Governance occurs through inclusion of range of stakeholders  
                      - Ensures group representation, balances competing priorities and avoids dominance of one group over another  
                      - Can be risk averse, bland and lowest common denominator for decision making  |
# Governance Responsibilities

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Conformance</td>
<td>Fiduciary</td>
<td>Policy making</td>
</tr>
<tr>
<td>External accountability</td>
<td>Strategic</td>
<td>Decision making</td>
</tr>
<tr>
<td>Supervision of management</td>
<td>Generative</td>
<td>Oversight</td>
</tr>
<tr>
<td>Performance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Policy formulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strategic thinking</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Governance Authority

- Individual board members do **not** have authority
- Only the governing body has authority to carry out its responsibilities
  - Governance bodies may require a quorum of voting members for this
Effective Governance

- **Arnwine DL (2002)**

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Functioning in accordance with the board's roles and responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structure</td>
<td>Structure of operations (agendas, procedures, minutes)</td>
</tr>
<tr>
<td>Expectations</td>
<td>Board members' knowledge of what is expected of them and what they can expect from others</td>
</tr>
</tbody>
</table>
Question: Governance for health information technology systems address all of the following needs, EXCEPT:

A. Managing change
B. Communication
C. Vendor system design
D. Medical Staff Bylaws
Answer: Governance for health information technology systems address all of the following needs, EXCEPT:

A. Managing change
B. Communication
C. Vendor system design
D. Medical Staff Bylaws
Question: All of the following are corporate governance theories EXCEPT:

A. Goal-directed
B. Stewardship
C. Resource dependency
D. Stakeholder
Answer: All of the following are corporate governance theories EXCEPT:

A. Goal-directed
B. Stewardship
C. Resource dependency
D. Stakeholder
NEGOTIATION AND CONFLICT MANAGEMENT
Negotiation

• Definition
  – Process by which two or more parties with different interests or perspectives attempt to reach agreement
Negotiation

- Many styles which can be leveraged according to the situation
- Fail to prepare = prepare to fail
Negotiation Process

• Focus on interests, not positions
  – Positions = What people want
  – Interests = Why people want it

• Frame the discussion
  – how you say it is just as important as what you say

• Negotiation space
  – Keep an eye on all parties, not just ones at table

Negotiation

• Negotiation styles and strategies are very similar to (and sometimes the same as) those used for conflict management
  – Healthy debate (good) → Negotiation
  – Conflict (bad) → Conflict Management
# Negotiation vs. Conflict Management

<table>
<thead>
<tr>
<th>Healthy Debate (needs Negotiation)</th>
<th>Conflict (needs Conflict Management)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open to hearing others’ ideas</td>
<td>People assume they’re right</td>
</tr>
<tr>
<td>Listen and respond to ideas</td>
<td>People state their ideas without</td>
</tr>
<tr>
<td>(even if they don’t agree with them)</td>
<td>responding to others’ ideas</td>
</tr>
<tr>
<td>Try to understand the views of others</td>
<td>No interest in other points of view</td>
</tr>
<tr>
<td>Stay objective</td>
<td>Personal attacks</td>
</tr>
<tr>
<td>Focus on the facts</td>
<td>Blaming</td>
</tr>
<tr>
<td><strong>Systematic approach</strong> to situation and solutions</td>
<td>Hot topics get thrashed out in an <strong>unstructured</strong> way</td>
</tr>
</tbody>
</table>

Conflict Management

• Common sources of conflict
  – Individualistic behavior within organization
  – Poor communication
  – Organizational structures
  – Inter-individual conflicts
  – Inter-group conflicts
Conflict Management

• Conflict-Handling Modes
  – Thomas-Kilmann Conflict Mode Instrument
  – Five modes
  – Natural conflict mode can be flexed to another mode depending on the situation

<table>
<thead>
<tr>
<th>Competing (Forcing)</th>
<th>Individual pursues own concerns at the expense of others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collaborating (Problem-Solving)</td>
<td>Individual attempts to get &quot;win-win&quot;</td>
</tr>
<tr>
<td>Compromising</td>
<td>Individual looks for compromises where both parties partially get what they want, typically in order to achieve resolution to conflict quickly</td>
</tr>
<tr>
<td>Avoiding (Withdrawing)</td>
<td>Individual does not address the conflict.</td>
</tr>
<tr>
<td>Accommodating</td>
<td>Individual neglects own concerns to satisfy the concerns of another person. Element of self-sacrifice.</td>
</tr>
</tbody>
</table>

Conflict Management

• Facilitative Conflict Management Process
  1. **Clarify** the issue
  2. Have **rules** for appropriate norms in place (e.g., good behavior)
  3. Set **time frame** for the discussion
  4. Explain the **process** to be used
  5. Analyze the **facts** of the situation
  6. Generate a **range of possible solutions**
  7. **Evaluate** the solutions
  8. Plan to **implement** the highest-ranked solution

COLLABORATION
Collaboration

- Collaboration as a leadership tool considers and attempts to meet the needs of all parties involved in a process.
- Based on a premise of cooperation to achieve effective outcome.
- Particularly helpful when you need to consider a variety of viewpoints to arrive at an effective solution, when there have been previous conflicts in a group or organization, or when multiple stakeholders in a process or project also have responsibility or requirements to meet the needs of their own sub-groups.
- Discussed further under leadership theories, conflict management in this section (4A) and change management (4F).
MOTIVATION
Motivation

• Definition
  – The desire of an **individual** to behave in certain ways
    OR
  – for **organizations**, a behavioral, affective and cognitive process that influences the willingness of workers to perform their duties in order to achieve personal and organizational goals, influencing the extent and level of their effectiveness at work

• [Okello, 2015.](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4384237/)
Motivation

• **Extrinsic motivation**
  – Generated when an action or task is performed to receive external rewards or outcomes
    • e.g., monetary rewards, incentives, promotion

• **Intrinsic motivation**
  – Generated when actions or tasks are performed for internal fulfilment or enjoyment of the activity itself
    • e.g., self-esteem and a feeling of belonging
Motivation

• Cannot only focus interventions on extrinsic motivation
  – Leads to low trust
  – Undermines intrinsic motivation

• Intrinsic motivation is linked to…
  – positive health worker behaviors
  – enjoyment of the work
  – quality of work performed
  – retention of health workers in current jobs
Motivation Theories

• Cognitive theories
• Social-cognition theories
• Humanistic theories
• Behavioral theories
• Psychoanalytical theories
• Social learning theories

We will go through only some of these

• https://motivation-project.wikispaces.com/Theories+of+Motivation+-+Overview
Humanistic Theories of Motivation

• **Self-determination theory**
  – Self-determination achieved by intrinsic motivation
  – Intrinsic motivation achieved through autonomy, competence and relatedness
  – Example: Getting patients to change their behavior

<table>
<thead>
<tr>
<th>Autonomy</th>
<th>Level of intrinsic motivation for change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competence</td>
<td>Patient's confidence and ability to change</td>
</tr>
<tr>
<td>Relatedness</td>
<td>Patient's perception of being respected, understood, cared for</td>
</tr>
</tbody>
</table>
Humanistic Theories of Motivation

• Herzberg’s theory
  – Focus on motivating employees
  – Motivator-hygiene theory (a.k.a. two-factor theory)
    • Motivator factors: Duties or position itself \(\rightarrow\) increased satisfaction
    • Hygiene factors: corporate aspects \(\rightarrow\) decreased satisfaction

<table>
<thead>
<tr>
<th>Motivator factors</th>
<th>Hygiene factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achievement</td>
<td>Pay and Benefits</td>
</tr>
<tr>
<td>Recognition</td>
<td>Company policy and administration</td>
</tr>
<tr>
<td>Work itself</td>
<td>Relationships with co-workers</td>
</tr>
<tr>
<td>Responsibility</td>
<td>Supervision</td>
</tr>
<tr>
<td>Promotion</td>
<td>Status</td>
</tr>
<tr>
<td>Growth</td>
<td>Job security</td>
</tr>
<tr>
<td></td>
<td>Working conditions</td>
</tr>
<tr>
<td></td>
<td>Personal life</td>
</tr>
</tbody>
</table>
Humanistic Theories of Motivation

- **Maslow’s theory**
  - Basic needs must be met before higher level needs

![Maslow's Hierarchy of Needs](image)
## Socio-cognitive Theories of Motivation

<table>
<thead>
<tr>
<th>Theory</th>
<th>Description</th>
<th>Image</th>
</tr>
</thead>
</table>
| **Social Cognitive** | Individual’s learning directly related to:  
  - Individual observation  
  - Learning through imitation  
  - Influences of own thoughts  
  - Influences of learning environment | ![Image of Social Cognitive Theory](image) |
| **Self-Efficacy**   | Person’s perception of their ability to perform appropriately or reach a goal  
  - Cycles can be positive or negative  
  - Success drives positive cycle (more confidence, more motivation, etc.)  
  - Lack of success drives negative cycle (lower confidence, lower motivation, etc.) | ![Image of Self-Efficacy Theory](image) |
# Socio-cognitive Theories of Motivation

<table>
<thead>
<tr>
<th>Theory</th>
<th>Description</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal Theory</td>
<td>• Edwin Locke</td>
<td><a href="#">The relationship between goal difficulty and performance</a></td>
</tr>
<tr>
<td></td>
<td>• To motivate, goals must have:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Clarity</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Challenge</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Commitment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Feedback</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Task complexity</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>SMART goals</strong> – Specific, Measurable, Attainable, Relevant, Time-Bound</td>
<td><a href="#">https://wikispaces.psu.edu/display/PSYCH484/6.+Goal+Setting+Theory</a></td>
</tr>
<tr>
<td></td>
<td>• Generally accepted as most valid in organizational psychology</td>
<td></td>
</tr>
</tbody>
</table>
Cognitive Theories of Motivation

• **Attribution Theory**
  – Assumes that people try to determine what they do (what attributed to their actions?)

• **Expectancy-Value Theory**
  – must occur in sequence for motivation to occur

  - **Expectancy**
    • Will my effort lead to high performance?

  - **Instrumentality**
    • Will performance lead to outcomes?

  - **Valence**
    • Rewards
    • Do I find the outcomes desirable?

Question: **When considering how best to increase the motivation of an employee to engage in changing to a new EHR using Herzberg’s theory of motivation, which of the following factors would be most important to include:**

A. Increase the employee’s pay and benefits

B. Give the employee increased responsibility for the conversion

C. Ensure that the employee’s work is covered by company policy

D. Reassure the employee that his/her job is secure
Answer: When considering how best to increase the motivation of an employee to engage in changing to a new EHR using Herzberg’s theory of motivation, which of the following factors would be most important to include:

A. Increase the employee’s pay and benefits

B. Give the employee increased responsibility for the conversion

C. Ensure that the employee’s work is covered by company policy

D. Reassure the employee that his/her job is secure
DECISION MAKING
## Decision Making

- **Process/skill which leads to a decision (outcome)**

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
</table>
  | **Unilateral decisions** | • Fast  
  |                       | • Little effort                                                      | • May not satisfy needs of all parties  
  |                       | • May have unanticipated consequences not previously considered      |                                   |
  | **Shared decision-making** | • Higher likelihood of resulting in long-term success | • Can be very slow  
  |                       |                                                           | • Takes more effort |

**Clinical Informatics Board Review Course**
Decision Making

• Traits of effective decision making
  – Everyone clear about purpose of decision-making conversation
  – People with power to make decision are present
  – People understand and follow decision making approach
  – All ideas viewed as equally important
  – No domination by a single party
  – Deadlocks are examined and resolved
  – Discussion ends with clear action plan

Decision Making

• Levels of empowerment
  I. Management decides then informs staff
  II. Management gets staff input before deciding
  III. Employees decide and recommend
  IV. Employees decide and act
Decision Making Options

<table>
<thead>
<tr>
<th></th>
<th>Pros</th>
<th>Cons</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Consensus Building</strong></td>
<td>Collaborative</td>
<td>Slow</td>
<td>Important issues</td>
</tr>
<tr>
<td></td>
<td>Systematic</td>
<td>Requires data</td>
<td>When total buy-in needed for success</td>
</tr>
<tr>
<td></td>
<td>Encourages commitment</td>
<td>Requires skills</td>
<td></td>
</tr>
<tr>
<td><strong>Multi-voting</strong></td>
<td>Systematic</td>
<td>Limits dialogue</td>
<td>When there are many solutions to choose from</td>
</tr>
<tr>
<td>(rank ordering options based on a set of criteria)</td>
<td>Objective</td>
<td>Real priorities may not surface</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Participative</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Feels like a win</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Compromise</strong></td>
<td>Discussion</td>
<td>Win-lose</td>
<td>When positions polarized; consensus improbable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adversarial</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Divides group</td>
<td></td>
</tr>
<tr>
<td><strong>Majority voting</strong></td>
<td>Fast</td>
<td>Too fast?</td>
<td>Trivial matters</td>
</tr>
<tr>
<td></td>
<td>May have dialogue</td>
<td>Winners / losers</td>
<td>Clear options</td>
</tr>
<tr>
<td></td>
<td>Clear outcome</td>
<td>No dialogue</td>
<td></td>
</tr>
<tr>
<td><strong>One person decides (unilateral decision)</strong></td>
<td>Fast</td>
<td>Lack of input, buy-in</td>
<td>One person is expert</td>
</tr>
<tr>
<td></td>
<td>Clear accountability</td>
<td>No synergy</td>
<td>and accountable</td>
</tr>
</tbody>
</table>
Decision Making Theories

• There are a lot
  – http://changingminds.org/explanations/theories/a_decision.htm

• Decision analysis and influence diagrams
  – http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4818954/
Additional suggested readings

• Organizations
  – American College of Physician Leadership (www.physicianleaders.org)
    • Formerly American College of Physician Executives (ACPE)
  – American College of Healthcare Executives (www.ache.org)
  – National Center for Healthcare Leadership (www.nchl.org)
  – Center for Creative Leadership (www.ccl.org)
Answer: Governance for health information technology systems address all of the following needs, EXCEPT:

A. Managing change  
B. Communication  
C. Vendor system design  
D. Medical Staff Bylaws

HIT Governance strategies address the following needs: Managing change, Clinician-focused benefits, Clinical knowledge-based content, Care process by physicians/clinicians, Communication, Training and support, and Vendor system design. By contrast, Medical Staff Bylaws may need to be reviewed in light of changes introduced by HIT governance activities; however, HIT Governance does not have authority over the specific content of Medical Staff Bylaws.
Answer: All of the following are corporate governance theories EXCEPT:

A. Goal-directed  
B. Stewardship  
C. Resource dependency  
D. Stakeholder

While corporate governance bodies may be goal-directed, this is not a specific governance theory.
Answer: When considering how best to increase the motivation of an employee to engage in changing to a new EHR using Herzberg’s theory of motivation, which of the following factors would be most important to include:

A. Increase the employee’s pay and benefits
B. Give the employee increased responsibility for the conversion
C. Ensure that the employee’s work is covered by company policy
D. Reassure the employee that his/her job is secure

Herzberg’s theory focuses on motivating employees through motivator factors which include achievement, recognition, the work itself, responsibility, promotion and growth. Hygiene factors result in decreased satisfaction and include Pay and Benefits, Company policy and administration, Relationships with co-workers, Supervision, Status, Job security, Working conditions and Personal life.
4A - Leadership

References

Free online resources

Leadership

Governance

Negotiation

Shortliffe's Biomedical Informatics Textbook - Pages
Government: 432, 458, 513
Data Driven Reasoning: 126,671
Decision making and analysis: 90ff, 658, 39, 644, 656ff, 803,804
Decision science: 30, 67ff
Collaboration: 517-8, 129
3A-4: Healthcare Data Reuse: Challenges and Strategies

William Hersh, MD, FACP, FACMI
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Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
   1.1.1. The discipline of informatics
   1.1.2. Key informatics concepts, models, and theories
   1.1.3. Clinical informatics literature
   1.1.4. International clinical informatics practices
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   2.3.2. Principles of workflow re-engineering
   2.3.3. Quality improvement principles and practices

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   3.1.1. Computer Systems
   3.1.2. Architecture
   3.1.3. Networks
   3.1.4. Security
   3.1.5. Data
   3.1.6. Technical approaches that enable sharing data
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   3.2.2. HCI Evaluation, usability testing, study design and methods
   3.2.3. Interface design standards and design principles
   3.2.4. Usability engineering
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   3.3.1. Types of functions offered by systems
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   3.5.6. Clinical information system evaluation

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   4.6.1. Assessment of organizational culture and behavior
   4.6.2. Change theories
   4.6.3. Change management strategies
   4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core content covered

3.1.5. Data
   3.1.5.1 Integrity
   3.1.5.2 Mapping
   3.1.5.3 Manipulation (e.g., querying, SQL, reporting)
   3.1.5.4 Representation and types
   3.1.5.5 Warehousing
   3.1.5.6 Data mining and knowledge discovery

3.1.6. Technical approaches that enable sharing data
   3.1.6.1 Integration versus interfacing
   3.1.6.2 Dealing with multiple identifiers
   3.1.6.3 Anonymization of data
Key topics

• Use and limitations of clinical data for patient care and other purposes
• Flow of data in clinical systems from collection to storage to analysis
• Use and challenges for identification and anonymization of patient data
3A-4: Healthcare Data Reuse: Challenges and Strategies

- Use and limitations of clinical data
- Flow and analysis of clinical data
- Identifiers and anonymization for clinical data
Data integrity

- Data integrity can refer to many things, such as:
  - Data provenance – where does your data come from?
  - Data completeness and correctness – must insure for re-use

(Hersh, 2013)
Data mapping and manipulation

• Mapping – to and from controlled terminologies, as discussed in 3D1-3
• Manipulation – retrieval from databases, as discussed in 3A1-2
  – Querying
  – SQL
  – Reporting
Representation and types of clinical data

- Narrative – recording by clinician
- Numerical measurements – blood pressure, temperature, lab values
- Coded data – selection from a controlled terminology system
- Textual data – other results reported as text
- Recorded signals – EKG, EEG
- Pictures – radiographs, photographs, and other images
- Metadata – information about the data, that give context and detail, e.g., electronic header information in notes
Coding of clinical data

- Historically performed by a Clinical Coding Specialist (CCS)
  - Major purpose has historically been for reimbursement (Scott, 2008)
- A core issue in biomedical informatics has been how to generate and use coded data for other purposes
- Trade-offs
  - Standardization of language vs. freedom of expression
  - Time to narrate vs. code
- Other difficulties
  - Creating and maintaining coding systems
  - Structuring coding systems to capture meaning
A big challenge for paper or electronic records: data entry

• General categories of data entry
  – Free-form entry by historical methods
    • Writing
    • Dictation
    • Typing
  – Structured (menu-driven) data entry by mouse, typing, or (in past) pen
  – Speech recognition for either of above
  – “Scribes” – people who enter data for physicians (Baugh, 2012)
Structured or menu-driven data entry

- Many attempts from old (Greens, 1970; Cimino, 1987; Bell, 1994) to new (Oceania; OpenSDE – Los, 2005)
- Can be done via mouse or pen, with typing
- Benefits
  - Data codified for easier retrieval and analysis
  - Reduces ambiguity if language used consistently
- Drawbacks
  - In general, more time-consuming
  - Requires exhaustive vocabulary
  - Requires dedication to use by clinicians
Speech recognition for data entry

• Most common use is for narration
  – e.g., computer dictation of clinical notes
• Continuous speech recognition now commercial reality
• Many established systems on the market that operate on front end (used by clinician) or back end (process dictations) (Brown, 2008)
  – An advantage to front-end systems is instant availability of dictated content
  – Problem with back-end systems is editing task transferred from professional transcriptionist to clinician-author
Benefits and limitations of speech recognition

• Modern speech recognition systems are improved but still have challenges
  – Systems have output lag behind user input, which can be distracting
  – Require area with minimum of background noise and where patient privacy can be protected

• Most common types of errors systems make include (Zafar, 2004)
  – Enunciation errors from mispronunciation
  – Dictionary errors from missing terms
  – Suffix errors from misrecognition of appropriate tenses of a word
  – Added or deleted words
  – Homonym errors from substitution of phonetically identical words

• Recent systematic review of research studies (Johnson, 2014) found
  – Productivity – report turnaround time faster
  – Quality – human transcription slightly more accurate, varies by setting and system
  – System design – macros and templates improve turnaround time, accuracy, and completeness
Other challenges for electronic data entry

• Copy and paste ([Hersh, 2007](#))
  – Current systems make it easy; occurs in up to 10-20% of charts ([Weir, 2003](#); [Embi, 2004](#); [Thielke, 2007](#))
  – Maybe need to re-think documentation in electronic era, e.g., annotation of data instead of copying ([Cimino, 2013](#))?
  – Best practices ([ECRI, 2016](#))

• EHRs also make it easier for fraud?
  – Ongoing debate ([Simborg, 2013](#); [AMIA Board of Directors, 2013](#))
Warehousing and data flow

- Departmental system
- Departmental system
- Departmental system

Additional financial and administrative data

Data Warehouse

EHR

Regional and national systems (Health information exchange)
Registries

• More limited form of EHR
  – Can be separate from EHR or extract of data from it (Dreyer, 2009; Hersh, 2011)

• Typically oriented to one or small number of diseases, most often chronic diseases

• Usual functions
  – Patient reports – status of monitored conditions
  – Exception reports – outliers, overdue for care
  – Aggregate reports – how is care team delivering recommended care
Data mining and knowledge discovery

- Data mining (also called Knowledge Discovery in Databases, or KDD) is process of discovering patterns (or knowledge) in large databases (Bellazzi, 2008)

- Related (and now more commonly used) term is analytics (Hersh, 2014)
  - Defined as “the extensive use of data, statistical and quantitative analysis, explanatory and predictive models, and fact-based management to drive decisions and actions” (Davenport, 2007)
Levels of analytics and business intelligence (Adams, 2011)

<table>
<thead>
<tr>
<th>Degree of Competitive Advantage and Complexity</th>
<th>BI Type</th>
<th>Example Uses</th>
<th>Questions Answered</th>
<th>BI Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimization</td>
<td></td>
<td>Diagnostic and therapeutic approaches</td>
<td>How can we achieve the best outcome?</td>
<td>Prescriptive</td>
</tr>
<tr>
<td>Predictive modeling</td>
<td></td>
<td>Identify high-risk patients</td>
<td>What will happen next if...?</td>
<td>Predictive</td>
</tr>
<tr>
<td>Forecasting</td>
<td></td>
<td>Public health issues</td>
<td>What if these trends continue?</td>
<td></td>
</tr>
<tr>
<td>Simulation</td>
<td></td>
<td>Business processes</td>
<td>What could happen if...?</td>
<td></td>
</tr>
<tr>
<td>Alerts</td>
<td></td>
<td>Infection outbreaks</td>
<td>When are actions needed?</td>
<td>Descriptive</td>
</tr>
<tr>
<td>Query/drill-down</td>
<td></td>
<td>“Slice and dice”</td>
<td>What exactly is the problem?</td>
<td></td>
</tr>
<tr>
<td>Ad hoc reporting</td>
<td></td>
<td>Out-of-range metrics</td>
<td>How many, how often, where?</td>
<td></td>
</tr>
<tr>
<td>Standard reporting</td>
<td></td>
<td>Key metrics</td>
<td>What happened?</td>
<td></td>
</tr>
</tbody>
</table>
Data mining – related terms

- Big data – 4 “V”s (Zikopolous, 2011; O’Reilly, 2015)
  - Volume
  - Velocity
  - Variety
  - Veracity
- Machine learning – area of computer science focused on systems and algorithms that learn from data (Flach, 2012; Crown, 2015)
- Text mining – applying data mining to unstructured textual data (Aggarwal, 2012)
- Data provenance – origin and trustworthiness (Buneman, 2010)
- Business intelligence – use of data to obtain timely, valuable insights into business and clinical data (Adams, 2011)
- Precision medicine (IOM, 2011; Collins, 2015; Ashley, 2015) – “prevention and treatment strategies that take individual variability into account” (Collins, 2015)
Challenges for analytics in healthcare

- Data quality and accuracy is not a top priority for busy clinicians (de Lusignan, 2005)
- Average pediatric ICU patient generates 1348 information items per 24 hours (Manor-Shulman, 2008)
- Patients get care at different places (Bourgeois, 2010; Finnell, 2011)
- Much data is “locked” in text (Hripcsak, 2012)
- Electronic records of patients at academic medical centers not easy to combine for aggregation (Broberg, 2015)
Technical issues of sharing data

• Integration versus interfacing
  – Data integration is merging of data from different sources into a single integrated whole
  – Data interfacing is how data must be transformed to allow real or virtual integration

• Dealing with multiple identifiers – discussed in 3D1-3

• Anonymization of data
Anonymization of data

- 87% of US population uniquely identified by five-digit zip code, gender, and date of birth (Sweeney, 2002)
- One analysis identified Governor William Weld of Massachusetts in health insurance database for state employees by purchasing voter registration for Cambridge, MA for $20 and linking zip code, gender, and date of birth to “de-identified” medical database (Sweeney, 1997)
- Genomic data can aid re-identification in clinical research studies (Malin, 2005; Lumley, 2010)
- Social security numbers can be predicted from public data (Acquisti, 2009)
- Dates and results in lab data facilitate re-identification (Cimino, 2012)
How Governor Weld was re-identified

Ethnicity
Visit date
Diagnosis
Procedure
Medication
Charge

Zip
Date of birth
Gender

Name
Address
Date registered
Party affiliation
Date last voted
Suggested additional readings


3B: Human Computer Interaction

Bimal R. Desai, MD, MBI, FAAP
The Children’s Hospital of Philadelphia
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INFORMATICS PROFESSIONALS. LEADING THE WAY.

Clinical Informatics Board Review Course
Core Content Covered

3.2 Human Factors Engineering

3.2.1 Models, theories, and practices of human-computer (machine) interaction (HCI)

3.2.2 HCI Evaluation, usability testing, study design and methods

3.2.3 Interface design standards and design principles

3.2.4 Usability engineering
Key Topics

- Examples of clinical errors that can be prevented through the application of human factors engineering principles.
- Contrast usability inspection, usability testing and usability inquiry
- The three components of discount usability engineering: prototypes, simplified think-aloud exercise, and heuristic evaluation
- Commonly accepted standards of good interface design
3B: Human Computer Interaction

- HCI Definition
- Applicability to healthcare
- Errors attributable to HCI issues and EHR Usability
- Models of HCI – predictive and descriptive
- Usability Evaluation – testing, inspection, inquiry
- Discount Usability Engineering
- Design Standards
- NIST recommendations for 3-step testing of EHR Usability
Human Computer Interaction

• Definition of the Discipline
  – Study of people and computers
  – Discipline combines computer science, behavioral science, psychology, design, human factors analysis, and more

• Applicability to Healthcare
  – Increasing awareness that HCI limitations responsible for medical errors
  – Cognitive overload, “alert fatigue”
  – One of the “grand challenges” facing Clinical Decision Support
Increasingly Important to Informatics

Figure 3. A model for analysis and understanding of use-related risks of EHR systems.

HCI / Usability-related Errors

- **Wrong Patient** – user has 2 charts open, enters orders on the wrong one
- **Wrong Mode for Action** – user tries to enter 100mg (direct dose) but accidentally enters 100mg/kg (weight-based dose)
- **Inaccurate Data Display** – lab value is truncated in a report, causing user to come to incorrect conclusion
- **Incomplete Data Display** – summary view of vital signs only shows last value per shift, user overlooks the max value within that shift
HCI / Usability-Related Errors (cont.)

- **Non-standard measurement, convention, or term** – weight based medications calculated using metric units, but order entry screen shows weight in English units.

- **Reliance on user recall** – vaccine administration documentation screen requires a lot number. Lot number is visible on previous screen, but not on this one. Users mis-type info or type in nonsense data as a result.
HCI / Usability-Related Errors (cont.)

- **Inadequate feedback** – User attempts to order med requiring 0.1cc precision and submits incorrect dose because system silently rounds dose to nearest 0.5cc, calculation not transparent to user.

- **Corrupted Data Storage** – User enters orders in discharge workflow then clicks “next”, but orders are not submitted because user did not click “sign” before proceeding to next step.
Predictive Models of HCI

- **Hick-Hyman Law**
  - expresses user response time as a function of number of possible responses ($n$)
  - predicts user response to hierarchical menus, response to finding correct option among an unfamiliar list (like a non-QWERTY keyboard)
  - Law predicts: $RT = a + b \log_2(n)$

- **Keystroke-Level Model (KLM)**
  - time to task completion is the sum of the time spent key-stroking, pointing, homing, drawing, mental operator (thinking), system response operator (waiting).
  - Used to anticipate which functions are most amenable to shortcuts and “hotkeys”.
Descriptive Models of HCI

Buxton’s Three-State Model of Graphical Input

- Exhaustive description of the states and transitions involved in using a mouse.
- Three states: out of range, tracking, and dragging. To transition from “out of range” to “tracking” you lift or put down the mouse. To transition from “tracking” to “dragging”, you depress or release the button.

Image credit: Buxton, 1990
Guiard’s Model of Bimanual Skill

- Hands are not used equally. Each hand, because of single hand dominance, has distinct roles.
- The model describes – for example - why left handed users are ill-served by modern 101-key keyboards.
- Some keys are unilateral and only available on the left side, like CTRL, ESC, TAB, FN; putting those who use the mouse on the left side at a disadvantage.
- Similarly, most “acknowledge” buttons on modal dialogues are on the bottom right – more mouse travel and possible error for lefties.
Usability Evaluation

Three major categories of evaluation

1. Testing
   - Coaching
   - Thinking-aloud
   - Eye-tracking / Click tracking
   - Performance

2. Inspection
   - Cognitive walkthrough
   - Heuristic evaluation

3. Inquiry
   - Field Observation
   - Focus groups / Interviews
   - Surveys
   - Usage Logs
Usability Testing

- **Coaching method** – user asked to perform a task, allowed to ask any questions they want to an expert coach. Coach keeps track of questions – useful in determining training and documentation needs.

- **Thinking-aloud** – user attempts to complete a task and speaks aloud each step he/she is doing, along with articulating difficulties, confusion, realizations.
Usability Testing

- **Eye-tracking / Click-tracking** – electronic or manual measurement of use, can generate “heat map” of an interface

- **Performance measurement** – Ideally, 5-8 users attempt to complete a specified set of tasks. Evaluator measures performance such as:
  - Task completion time and rate
  - Recovery rate (user makes a misstep but recovers)
  - Failure rate (user unable to complete task)
  - Frequently and never used features
  - For tasks with multiple ways of accomplishing the same thing, measuring which way users choose to do it.
Usability Inspection

- **Cognitive walkthrough** – using low-fidelity paper models or wireframes
  - Will the users try to achieve the right effect? Ex: system requires a weight before entering medication order. Will the user know to enter the weight?
  - Will the user notice that the correct action is available? Ex: Button to submit/sign order is in an inconspicuous location. Will user see it?
  - Will the user associate the correct action with the effect to be achieved? Ex: are the labels intuitive and easy to follow?
  - If the correct action is performed, will the user see that progress is being made toward solution of the task? Ex: does system give feedback that a step in task was completed.
Usability Inspection

• **Heuristic Evaluation** – design principle or “rule of thumb” used to critique interface.
  
  – Example heuristic for web design: Jakob Nielsen’s Heuristic List
  
Nielsen’s 10 Usability Heuristics

Principles of User Interface Design

1. The system status should be visible.
2. There should be a match between the terminology and concepts used by the system and those in common use in the “real world”.
3. The system should give users control and freedom, with a clear way to undo, redo, or exit a task.
4. The system should be consistent and use standards where possible.
5. Built-in error prevention is better than a clever error message.
6. A user’s recognition of icons and pathways is stronger than their recall. By showing options that facilitate user action, one can avoid forcing users to memorize sequences of menus or keystrokes.
7. The system should support novice and expert users, with shortcuts and “accelerators”.
8. Dialogues should be sparingly written; design should be minimalist.
9. The system should help users to recognize, diagnose, and recover from errors.
10. The system should provide succinct and context-sensitive help and documentation.
Usability Inquiry

- Field observation
- Focus groups / Interviews
- Surveys
- Review of usage logs
Discount Usability Engineering

• Method of HCI Evaluation that does not require large number of personnel or budget, described by Jakob Nielsen.

• Minimum 5 testers perform a modified version of testing and inspection
  – modified think-aloud, focus on qualitative aspects of interface
  – heuristic evaluation
  – low-fidelity prototypes to test one process at a time, rapid iterations
Wireframes / Low Fidelity Prototyping

• Technique to design and gather feedback about an interface without actually having to code it
• As in SDLC, identifying errors early is less costly
• Can be paper based, designed as “wireframe” designs, or can even mimic full applications using drag-and-drop software (e.g. Balsamiq, Proto.io, atomic.io)
• But there are advantages to keeping it “lo fi”
Low-Fi vs. Hi-Fi

• Low-fidelity prototypes
  – Cheap (can be made on paper)
  – Theoretically quicker
  – Quickly visualize alternative design solutions
  – Some evidence that users feel more comfortable suggesting changes when prototypes feel less “final”

• High-fidelity prototypes
  – Can look almost as good as finished user interface, complete with interactivity
  – Allows more accurate testing of things like task completion
Examples of low-fidelity prototypes

Wireframes

• One form of prototype used to suggest basic structure of a user interface and relationship between pages
• Serves as blueprint for design – precedes any design work, with focus on layout
• Can be easily created in design, presentation, or word processing software packages
Digital Tools for Low-Fidelity Prototyping

- Often intentionally look “hand drawn”, again to emphasize the design is not final and to encourage feedback
- Some tools have built in rendering options to switch between wireframe, “sketch” mode, and “hi fi” mode
- Often allow interactivity (in example on the right, clicking the blue button takes user to next virtual screen of the application)
Importance of Design Standards

• Widely accepted standards for interface design and HCI do not exist in Healthcare, but are an active area of innovation and research.

• Challenge with commercial EHRs that much of design / usability is set by vendor
NIST 2012 Recommendations

Standard for testing, validation of EHR usability. Three-step approach that includes many of the evaluation techniques described above.

- **Step 1 – EHR application analysis**
  - Who are users?
  - What is their work environment? (lighting, noise, hardware)
  - What do they do?
  - What does the interface look like?
  - What mistakes might they make?
  - What evaluation has been done to mitigate mistake and improve usability?

- **Step 2 – EHR User Interface Expert Review**
  - Two-person **heuristic** review
  - Clinical subject matter expert review for potential errors

- **Step 3 - User Interface Validation Test**
  - Performance measurement (**task completion** and associated metrics)
  - Post-testing interview
Cognitive Informatics

• Emerging field within health informatics
• Study of human processing mechanisms: how and why people make decisions
• National Center for Cognitive Informatics & Decision Making in Healthcare
  – Located at UT Health Science Center at Houston, 9 partners
  – Site of a Strategic Health IT Advanced Research Project (SHARPC)
  – Led by Dr. Jiajie Zhang
Five Projects under SHARPC

1. Project 1: Work-centered Design of Care Process Improvements in HIT
   A. EHR Usability
   B. EHR Workflow

2. Project 2
   B. Modeling of Setting-Specific Factors to Enhance CDS Adaptation

3. Project 3: Automated Model-based Clinical Summarization of Key Patient Data

4. Cognitive Information Design and Visualization: Enhancing Accessibility and Understanding of Patient Data
Better EHR

- Free PDF or iBook from NCCD
- Describes TURF EHR Usability Framework
  - Task, User, Representation, Function
  - Main dimensions of usability
  - Useful: supports the work domain
  - Usable: easy to learn, use, adapt
  - Satisfying: good subjective experience

https://sbmi.uth.edu/nccd/better-ehr/
TURF Usability Software

- Software for user testing
- Users create products for heuristic evaluation
  - Capture screenshots of EHR, upload into TURF software
  - Markup image to capture design violation, using problem descriptions
- Also capture usability surveys
Safety Enhanced Design Briefs

- Design guidelines for a variety of EHR use cases
  - Effective use of color
  - Table design
  - Reducing wrong patient selection errors
  - Result management
  - Drug-drug and drug-allergy checking
  - Medication and Allergy lists
  - CDS
  - ePrescribing
  - Medication and Problem Reconciliation
  - CPOE

- Each is a high impact, actionable, evidence-based recommendation for enhancing safety
- Each is a downloadable, illustrated PDF file
Example Design Brief: Using Color

Safety Enhanced Design Brief
Making Effective Use of Color

Carefully used colors can dramatically improve the efficiency and safety of health information systems by drawing attention to important items and making it easier to perceive differences and trends.

Incorrectly used colors can make a display hard to use, hard to interpret and misleading.

1. To maximize the communication benefits of color, design
   - Use gray scale, then add color sparingly
   - Colors emphasize only title and high (orange) / low (blue) values

2. To group items into different categories
   - Use no more than 7 colors (4 recommended)

3. To show sequential ranges of quantitative values
   - Use 1 color (for sequential) and 2 colors (for diverging) values
   - Vary color intensity from pale (low values) to darker (extreme values)

Endocrine Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Value</th>
<th>Date</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP</td>
<td>170/80</td>
<td>03/02/09</td>
<td>12/09/09</td>
</tr>
<tr>
<td>Wt</td>
<td>85,300</td>
<td>02/09/09</td>
<td>02/09/09</td>
</tr>
<tr>
<td>BMI</td>
<td>0</td>
<td>02/09/09</td>
<td>02/09/09</td>
</tr>
<tr>
<td>Smoking Hx</td>
<td>Non Smoker</td>
<td>03/02/09</td>
<td>12/09/09</td>
</tr>
<tr>
<td>HGB</td>
<td>14.3 g/dL</td>
<td>03/02/09</td>
<td>12/09/09</td>
</tr>
<tr>
<td>K+</td>
<td>3.8 mEq/L</td>
<td>03/02/09</td>
<td>12/09/09</td>
</tr>
<tr>
<td>Cr</td>
<td>0.84 mg/dL</td>
<td>03/02/09</td>
<td>12/09/09</td>
</tr>
<tr>
<td>MicroAlb/Cr</td>
<td>18.3 mg/dL</td>
<td>10/05/09</td>
<td>11/04/08</td>
</tr>
<tr>
<td>GFR (AA)</td>
<td>112.22 mL/min</td>
<td>03/02/09</td>
<td>10/05/09</td>
</tr>
<tr>
<td>GFR (non AA)</td>
<td>92.59 mL/min</td>
<td>03/02/09</td>
<td>12/09/09</td>
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<tr>
<td>Glu</td>
<td>105 mg/dL</td>
<td>03/02/09</td>
<td>12/09/09</td>
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<tr>
<td>HBA1c</td>
<td>5.7%</td>
<td>03/02/09</td>
<td>03/09/09</td>
</tr>
<tr>
<td>Total Chol</td>
<td>205 mg/dL</td>
<td>10/05/09</td>
<td>09/09/09</td>
</tr>
<tr>
<td>HDL</td>
<td>1.26 mg/dL</td>
<td>10/05/09</td>
<td>09/09/09</td>
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<tr>
<td>Chol/HDL</td>
<td>7.9</td>
<td>10/05/09</td>
<td>09/09/09</td>
</tr>
</tbody>
</table>

Compliance Heatmap

Month, Year of Date of Discharge

|-------------|------------|--------------|-----------------|---------------|----------------|----------------|--------------|---------------|-------------|

Compliance Rate

- Potential Quality
- Clarified
- No Action
- Hospice/ED

2-color heatmap of varying intensity visualizes sequential ranges
Example: Reducing Wrong Patient Errors

Safety Enhanced Design Brief
Reducing Wrong Patient Selection Errors

Wrong patient errors are a major issue for patient safety as patients may be harmed from not receiving the test or treatment they need, or from receiving a medication or treatment intended for someone else.

Careful design of the user interface can mitigate the problem by helping providers recall their patients' identity, accurately select their name, and realize that an error has occurred before the order is submitted.

1. To help remember patients' identity, and locate them in lists
   - Never truncate patients' full names
   - In addition to the name include photos and/or other patient information (e.g., date of birth, main complaint or diagnosis, etc.)
   - Facilitate narrowing list by diagnosis or location e.g., ICU (could use floor plan)
   - Provide sorting and search (especially for long lists)
   - Notify clinicians if similar names exist

2. To help select a patient in a list
   - Maximize font size and contrast to increase readability
   - Provide access to short lists (e.g., the user's own patients, the patients of other providers the user is covering)
Example: CDS

Safety Enhanced Design Brief
Clinical Decision Support

Clinical decision support (CDS) systems bring relevant information to the clinician at the point of decision making.

Implementing CDS systems presents many challenges such as:

- Complex system constraints
- Complex nature of information to be displayed
- Challenging human-computer interaction design
- Organizational and change management to ensure system adoption

CDS is one of the most complex subsystems available in EHR systems. This document reviews guidelines to design useful and usable CDS interventions.

1. To create useful, consistent and reliable communication of support material to the user
   - Ensure your CDS system is capable of identifying preventable errors and informing the user of potential clinical hazards
   - Adapt CDS interventions to the clinical workflow and not the opposite
   - Create a system that supports human decision making rather than corrects it (e.g., give feedback on entered data as opposed to changing it automatically)
   - Clearly differentiate alerts and interventions according to their type
   - Show decision support elements near corresponding data entry fields or buttons
   - Classify decision support elements (e.g., rules and alerts) by severity levels
   - Incorporate insurance coverage information into the CDS scope
   - Match the intrusiveness of the CDS intervention to the severity level of the problem

2. To prevent alert fatigue, provide support beyond alerting
   - Use indicators to signal potential conflicts before triggering an alert
   - Provide reduced lists of options based on context (e.g., a short list of clinically appropriate painkillers is presented when pain is entered as the chief complaint)

- Consider including automated machine-generated information views and automatic context-specific data display functions
- Infobuttons
- Potential conflict indicators
- Machine generated alternatives
- Automated content specific data display
- Dynamic close/range verifications
- Visual cue based feedback
- Alert

Least intrusive: Low severity
Most intrusive: High severity
Inspired EHRs

• Co-funded by California HealthCare Foundation and SHARPC
• Aspirational and provocative: imagines what an evidence-based EHR interface might look like and outlines the case for better design
• Interfaces outlined in the book were not formally tested, but were reviewed by experts
• Free online book and PDF download at http://inspireddehrs.org/
Figure 2.1 Before: An Awful Medication List

Current medications: (selected)

Prescriptions Ordered
- albuterol HFA prn (90 mcg/spray) (ProAir HFA) oral spray; 90 mcg/spray, 2 puffs, oral, every 4 hours as needed, 21.6 mg/1 unit
- beclomethasone HFA (QVAR 40 HFA) oral spray; 40 mcg/spray, 2 puffs, oral, twice a day, 9.6 mg/1 unit
- carvedilol 25 mg oral tablet; 25 mg 1 tablet, oral, 2 times a day, 180 tablets
- chlorthalidone 25 mg oral tablet; 20 mg, 1 tablet, oral, daily, 90 tablets
- citalopram 20 mg oral tablet; 20 mg, 1 tablet, oral, daily, 90 tablets
- gabapentin 600 mg oral tablet; 600 mg, 1 tablet, oral, 2 times a day, 180 tablets
- Insulin glargine (Lantus) 40 units subcut at bedtime, 10 ml
- losartan 100 mg oral tablet; 100 mg, 1 tablet, oral, daily, 90 tablets
- metformin 1000 mg oral tablet; 1000 mg, 1 tablet, oral, 2 times a day, 180 tablets
- naproxen 500 mg oral tablet; 500 mg, 1 tablet, oral, 2 times a day, 60 tablets
- nitroglycerin 0.4 mg pm oral tablet; 0.4 mg, 1 tablet, under tongue, every 5 minutes as needed, 25 tablets
- prednisone 20 mg pm oral tablet; 20 mg, 2 tablets daily, oral, pm, 10 tablets
- simvastatin 80 mg oral tablet; 80 mg, 1 tablet, oral, daily, 90 tablets
- terbinafine 150 mg oral tablet; 150 mg, 1 tablet, oral, daily for 12 weeks, 84 tablets
- zolpidem 5 mg oral tablet; 5 mg, 1 tablet, oral, at bedtime, 90 tablets

Documented Medications

Prescribed
- aspirin 81 mg oral tablet; 1 tablet, oral, daily
- omeprazole 40 mg oral tablet; 1 tablet, oral, daily

Figure 2.2 After: Simple Medication List Makeover

Medications

Last updated 1 month ago

- albuterol HFA 90 mcg/spray 2 puffs every 4 hr as needed
- aspirin 81 mg daily
- beclomethasone HFA (QVAR HFA) 40 mcg/spray 2 puffs daily
- carvedilol 25 mg daily
- chlorthalidone 25 mg daily
- citalopram 20 mg daily
- gabapentin 600 mg daily
- insulin glargine (Lantus) 40 units 1 at bedtime
- losartan 100 mg daily
- lisinopril 20 mg daily
- metformin 1000 mg daily
- naproxen 500 mg daily
- nitroglycerin 0.4 mg as needed
- omeprazole 40 mg daily
- prednisone 20 mg daily as needed
- simvastatin 80 mg daily
- terbinafine 150 mg daily
- zolpidem 5 mg 1 at bedtime
### Figure 2.3 Before: The Frame Creates Visual Noise

<table>
<thead>
<tr>
<th>Name of medication</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>albuterol HFA</td>
<td>2 puffs every 4 hours as needed</td>
</tr>
<tr>
<td>aspirin 81 mg</td>
<td>1 daily</td>
</tr>
<tr>
<td>beclomethasone HFA 40</td>
<td>2 puffs twice a day</td>
</tr>
<tr>
<td>carvedilol 25 mg</td>
<td>1 twice daily</td>
</tr>
<tr>
<td>chlorthalidone 25 mg</td>
<td>1 daily</td>
</tr>
<tr>
<td>citalopram 20 mg</td>
<td>1 daily</td>
</tr>
<tr>
<td>gabapentin 600 mg</td>
<td>1 twice daily</td>
</tr>
<tr>
<td>insulin glargine 28 units</td>
<td>28 units at bedtime</td>
</tr>
<tr>
<td>losartan 100 mg</td>
<td>1 daily</td>
</tr>
<tr>
<td>metformin 1000 mg</td>
<td>1 twice daily</td>
</tr>
<tr>
<td>naproxen 500 mg</td>
<td>1 twice daily</td>
</tr>
<tr>
<td>omeprazole 40 mg</td>
<td>1 daily</td>
</tr>
<tr>
<td>prednisone 20 mg</td>
<td>2 daily</td>
</tr>
<tr>
<td>simvastatin 40 mg</td>
<td>1 daily</td>
</tr>
<tr>
<td>terbinafine 250 mg</td>
<td>1 daily for 12 weeks</td>
</tr>
<tr>
<td>zolpidem 5 mg</td>
<td>1 at bedtime</td>
</tr>
</tbody>
</table>

### Figure 2.4 After: Cleaner, Data Takes Center Stage

<table>
<thead>
<tr>
<th>Medication</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>albuterol HFA 90</td>
<td>2 puffs every 4 hours as needed</td>
</tr>
<tr>
<td>aspirin 81 mg</td>
<td>1 daily</td>
</tr>
<tr>
<td>beclomethasone HFA 40</td>
<td>2 puffs twice a day</td>
</tr>
<tr>
<td>carvedilol 25 mg</td>
<td>1 twice daily</td>
</tr>
<tr>
<td>chlorthalidone 25 mg</td>
<td>1 daily</td>
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<tr>
<td>citalopram 20 mg</td>
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<tr>
<td>insulin glargine 28 units</td>
<td>28 units at bedtime</td>
</tr>
<tr>
<td>losartan 100 mg</td>
<td>1 daily</td>
</tr>
<tr>
<td>metformin 1000 mg</td>
<td>1 twice daily</td>
</tr>
<tr>
<td>naproxen 500 mg</td>
<td>1 twice daily</td>
</tr>
<tr>
<td>omeprazole 40 mg</td>
<td>1 daily</td>
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<tr>
<td>prednisone 20 mg</td>
<td>2 daily</td>
</tr>
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<tr>
<td>terbinafine 250 mg</td>
<td>1 daily for 12 weeks</td>
</tr>
<tr>
<td>zolpidem 5 mg</td>
<td>1 at bedtime</td>
</tr>
</tbody>
</table>
Visual Display of Data

- Topic mentioned throughout SHARPC work and critically important to medicine, life sciences, and academia
- Perhaps the best known advocate is Edward Tufte
Challenger Disaster

In his book “Visual Explanations”, Tufte suggests that the booster rocket O-ring failure that led to the space shuttle Challenger explosion was a failure of telling the right story with data.

Original graphic obfuscated relationship between temperature and O-ring failure.
Information displays should serve the analytic purpose at hand; if the substantive matter is a possible cause-effect relationship, then graphs should organize data so as to illuminate such a link. Not a complicated idea, but a profound one. Thus the little rockets must be placed in order by temperature, the possible cause. Above, the rockets are so ordered by temperature. This clearly shows the serious risks of a cold launch, for most O-ring damage occurs at cooler temperatures. Given this evidence, how could the Challenger be launched at 29°?

In the haplessly dequantified style typical of iconographic displays, temperature is merely ordered rather than measured; all the rockets are adjacent to one another rather than being spaced apart in proportion to their temperature. Along with proportional scaling—routinely done in conventional statistical graphs—it is particularly revealing to include a symbolic pair of rockets way over at 29°, the predicted temperature for the Challenger launch. Another redrawing:
O-ring damage index, each launch

Tufte’s final, simplified graphic, showing increasing rates of O-ring failure Below 65 degrees.

The 26-29 degree bar shows the temperature on the day of the Challenger launch.
If Tufte designed EHRs (you be the judge...)

End of Lecture
Suggested Additional Reading

• Zhang, J. & Walji, M. *Better EHR*. NCCD 2014. [Free PDF Download]
• Belden B et al. *Inspired EHRs*. U Missouri, 214. [Online and PDF]
Self-Directed Learning

• The curriculum on Usability.gov is a great resource


• For board review, consider:
  – Modules on Usability Evaluation
  – Wireframing & Prototyping

• Jakob Nielsen on Paper Prototyping
  – [https://www.nngroup.com/articles/paper-prototyping/](https://www.nngroup.com/articles/paper-prototyping/)
4D: Project Management

Alexis Carter, MD
Physician Informaticist
Children’s Healthcare of Atlanta
Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
   1.1.1. The discipline of informatics
   1.1.2. Key informatics concepts, models, and theories
   1.1.3. Clinical informatics literature
   1.1.4. International clinical informatics practices
   1.1.5. Ethics and professionalism
   1.1.6. Legal and regulatory issues
   1.2. The Health System
   1.2.1. Determinants of individual and population health
   1.2.2. Primary domains, organizational structures, cultures, and processes
   1.2.3. The flow of data, information, and knowledge within the health system
   1.2.4. Policy & regulatory framework
   1.2.5. Health economics and financing
   1.2.6. Forces shaping health care delivery
   1.2.7. Institute of Medicine quality components

2. Clinical Decision Making and Care Process Improvement
   2.1. Clinical Decision Support
   2.1.1. The nature and cognitive aspects of human decision making
   2.1.2. Decision science
   2.1.3. Application of clinical decision support
   2.1.4. Transformation of knowledge into clinical decision support tools
   2.1.5. Legal, ethical, and regulatory issues
   2.1.6. Quality and safety issues
   2.1.7. Supporting decisions for populations of patients
   2.2. Evidence-based Patient Care
   2.2.1. Evidence sources
   2.2.2. Evidence grading
   2.2.3. Clinical guidelines
   2.2.4. Implementation of guidelines as clinical algorithms
   2.2.5. Information retrieval and analysis
   2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
   2.3.1. Methods of workflow analysis
   2.3.2. Principles of workflow re-engineering
   2.3.3. Quality improvement principles and practices

3. Health Information Systems
   3.1. Information Technology Systems
   3.1.1. Computer Systems
   3.1.2. Architecture
   3.1.3. Networks
   3.1.4. Security
   3.1.5. Data
   3.1.6. Technical approaches that enable sharing data
   3.2. Human Factors Engineering
   3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
   3.2.2. HCI Evaluation, usability testing, study design and methods
   3.2.3. Interface design standards and design principles
   3.2.4. Usability engineering
   3.3. Health Information Systems and Applications
   3.3.1. Types of functions offered by systems
   3.3.2. Types of settings where systems are used
   3.3.3. Electronic health/medical records systems as the foundational tool
   3.3.4. Telemedicine
   3.4. Clinical Data Standards
   3.4.1. Standards development history and current process
   3.4.2. Data standards and data sharing
   3.4.3. Transaction standards
   3.4.4. Messaging standards
   3.4.5. Nomenclatures, vocabularies, and terminologies
   3.4.6. Ontologies and taxonomies
   3.4.7. Interoperability standards
   3.5. Information System Lifecycle
   3.5.1. Institutional governance of clinical information systems
   3.5.2. Clinical information needs analysis and system selection
   3.5.3. Clinical information system implementation
   3.5.4. Clinical information system testing, before, during and after implementation
   3.5.5. Clinical information system maintenance
   3.5.6. Clinical information system evaluation

4. Leading and Managing Change
   4.1. Leadership Models, Processes, and Practices
   4.1.1. Dimensions of effective leadership
   4.1.2. Governance
   4.1.3. Negotiation
   4.1.4. Conflict management
   4.1.5. Collaboration
   4.1.6. Motivation
   4.1.7. Decision making
   4.2. Effective Interdisciplinary Teams
   4.2.1. Human resources management
   4.2.2. Team productivity and effectiveness
   4.2.3. Group management processes
   4.2.4. Managing meetings
   4.2.5. Managing group deliberations
   4.3. Effective Communications
   4.3.1. Effective presentations to groups
   4.3.2. Effective one-on-one communication
   4.3.3. Writing effectively for various audiences and goals
   4.3.4. Developing effective communications program to support system implementation
   4.4. Project Management
   4.4.1. Basic principles
   4.4.2. Identifying resources
   4.4.3. Resource allocation
   4.4.4. Project management tools (non-software specific)
   4.4.5. Informatics project challenges
   4.5. Strategic and Financial Planning for Clinical Information Systems
   4.5.1. Establishing mission and objectives
   4.5.2. Environmental scanning
   4.5.3. Strategy formulation
   4.5.4. Action planning and strategy implementation
   4.5.5. Capital and operating budgeting
   4.5.6. Principles of managerial accounting
   4.5.7. Evaluation of planning process
   4.6. Change Management
   4.6.1. Assessment of organizational culture and behavior
   4.6.2. Change theories
   4.6.3. Change management strategies
   4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core Content

4. 4 Project Management

4.4.1 Basic principles
4.4.2 Identifying resources
4.4.3 Resource allocation
4.4.4 Project management tools (non-software specific)
4.4.5 Informatics project challenges
  - Scope creep
  - Managing expectations
  - Balancing competing priorities
Key Topics

- Basic Principles of Project Management
- Common constraints in Project Management planning
- The Project Management Lifecycle
- Project Process Groups
- Components of an effective Project Plan
- Tools useful in Project Planning
- Managing / Avoiding Scope Creep
BASIC PRINCIPLES
Project Management Institute

- [http://www.pmi.org](http://www.pmi.org)
- Certifies project management professionals (PMP)
- Produces standards which are considered the *de facto* standards for project management by many
- Primary resource:
  - NOTE: There is also a software extension for this guide, but it focuses on software development rather than installation and configuration informatics projects.
Project

• Definition
  – Temporary endeavor
  – Defined beginning and end
  – Goal to complete specific objectives that bring beneficial change or added value
  – PMI: a temporary endeavor undertaken to create a unique product, service or result
Project

• A successful project…
  – Has high quality
  – Completes expected deliverables to the satisfaction of the stakeholders and customer
  – On time
  – Is in compliance with budget
Organizational Project Management

• Strategy execution framework utilizing project, program and portfolio management as well as organizational enabling practices

• Goal: consistently and predictably deliver organizational strategy

• Produce better performance, results and a sustainable competitive advantage
Terms

• Portfolio
  – Collection of projects, programs, subportfolios and operations managed as a group to achieve strategic objectives

• Program
  – Collection of subprograms, projects and other work that are managed in a coordinated fashion in support of the portfolio

• Project Governance
  – Process of ensuring that the project is in alignment of the project with stakeholders' needs or objectives
  – Provides framework for project manager and sponsors to make decisions
Project Management

• Application of knowledge, skills, tools and techniques to project activities to meet the project requirements
• Accomplished through application and integration of many distinct project management processes
Project Management

• These processes are categorized into 5 groups (**Process Groups**)
  – Initiation
  – Planning
  – Execution
  – Monitoring and Controlling
  – Closing
Project Life Cycle

- Initiating
- Planning
- Monitoring & Controlling
- Executing
- Closing

# Project Life Cycle

<table>
<thead>
<tr>
<th>Order</th>
<th>Life cycle major phase</th>
<th>Cost and Staffing Level</th>
<th>Project Management Output</th>
<th>Risk and Uncertainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Starting the Project</td>
<td>+</td>
<td>Project Charter</td>
<td>++++</td>
</tr>
<tr>
<td>2</td>
<td>Planning (Organizing and Preparing)</td>
<td>++</td>
<td>Project Management Plan</td>
<td>+++</td>
</tr>
<tr>
<td>3</td>
<td>Executing (Carrying out the work)</td>
<td>++++</td>
<td>Accepted Deliverables</td>
<td>++</td>
</tr>
<tr>
<td>4</td>
<td>Closing the project</td>
<td>++</td>
<td>Archived Project Documents</td>
<td>+</td>
</tr>
</tbody>
</table>

- Monitoring and controlling processes occur in all major phases
- Phases may be sequential or overlapping
# Types of Project Life Cycles

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Predictive**     | • Project scope, time and cost required to deliver that scope are determined early and are predictable  
                     • Scope is relatively fixed                                                                                                              |
| **Iterative and incremental** | • Project phases repeat iteratively over a relatively long period of time (months)  
                     • Each iteration brings the project towards its defined deliverables in an incremental fashion  
                     • Scope is elaborated with each iteration                                                                                           |
| **Adaptive / Agile** | • a.k.a. change-driven project life cycles  
                     • Rapid iteration version of iterative and incremental project life cycle (2-4 weeks per iteration)  
                     • Intended for projects where a high level of change and adaption are anticipated between project initiation and closure  
                     • Utilizes **rolling wave planning** (iterative planning technique where near term iterations are planned in detail and future iterations are planned at a higher level) |
## Activities specific to Clinical Information System Projects

<table>
<thead>
<tr>
<th>Activity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unit testing</strong></td>
<td>Testing the new software or system within itself</td>
</tr>
</tbody>
</table>
| **Integration Testing**| Testing the integration of the new system or software and its communications with other systems and software  
  • May require a Project Integration Management Plan |
| **Regression testing** | Testing current state functions that you expect to keep to ensure that they have not been altered by the new system or software |
| **Parallel testing**   | Testing functions and data entry in the new system or software in parallel with using the same functions (entering the same data) into the production system you are about to replace  
  • Usually try to do 10-20% of cases/actions through the new system in parallel with the soon-to-be-old system  
  • See if the software performs as expected  
  • Can help detect serious performance load issues  
  • Hardest testing to do but the most valuable |
# Project vs. Operations

<table>
<thead>
<tr>
<th>Project</th>
<th>Business Operations (a.k.a keep-the-lights-on or KLO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporary endeavor</td>
<td>Ongoing and repetitive</td>
</tr>
<tr>
<td>Defined beginning and end</td>
<td>No defined beginning or end</td>
</tr>
<tr>
<td>Meet time-limited goals and objectives</td>
<td>Have ongoing objectives (produce repetitive outputs)</td>
</tr>
<tr>
<td>Uses Project Management skills</td>
<td>Uses Operations Management skills</td>
</tr>
</tbody>
</table>

A project and operations intersect at various points in the project life cycle.
# Project Terminology

<table>
<thead>
<tr>
<th>Deliverable</th>
<th>Product, result or capability that is produced to complete a project</th>
</tr>
</thead>
</table>
| Scope       | Work needed to deliver a product, service or result with the specified features and functions  
  • Additional work that does not directly contribute to required deliverables is "out-of-scope" |
| Baseline    | Approved version of work product  
  Can be changed but needs formal change control procedures  
  Used for comparison to final results |
| Constraint  | Limiting factor that impacts the execution of a project  
  • Most projects have a triple constraint  
  ○ Cost + schedule + scope = quality  
  ○ Money + time + people = scope/quality |
Project Resources

Scope of Work

Not enough people
Not enough money
Not enough time

AMIA
Informatics Professionals. Leading the Way.
Project Resources

Scope of Work

More Function
Less Functions at Go Live

Not enough resources

Time
Money
People
Scope of Work

Components

Money

Time

People

Work

Work

Work
Scope of Work

Components

Work
Work
Work
Work

Money
Time
People
Scope of Work

Components

- Add Time / $$$ / People
- Time
- Money
- Human Resources

Work
Work
Work
Work
### More terms

<table>
<thead>
<tr>
<th><strong>Milestone</strong></th>
<th>A significant point in the project's execution Occurs when one or more pre-defined tasks in the project have been completed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Activity</strong></td>
<td>Distinct, scheduled portion of work performed during the course of a project in order to produce project deliverables</td>
</tr>
<tr>
<td></td>
<td>• An activity may contain one or more tasks</td>
</tr>
<tr>
<td><strong>Task</strong></td>
<td>Part of a set of actions which accomplish a job, problem or assignment</td>
</tr>
<tr>
<td><strong>Resource</strong></td>
<td>Anything needed to complete a project. This can be a person, supplies, equipment, money, facilities, etc.</td>
</tr>
</tbody>
</table>
And more terms

<table>
<thead>
<tr>
<th>Assumption</th>
<th>Information in a project which is considered to be real and true without proof or demonstration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk</td>
<td>Uncertain event or condition that, if it occurs, will have a positive or negative impact on one or more project objectives</td>
</tr>
<tr>
<td>Opportunity</td>
<td>Risk that would have a positive effect on one or more project objectives</td>
</tr>
<tr>
<td>Threat</td>
<td>Risk that would have a negative effect on one or more project objectives</td>
</tr>
<tr>
<td>Issue</td>
<td>Threat to the successful completion of the project which has already occurred</td>
</tr>
<tr>
<td>Quality</td>
<td>The degree to which the completed project satisfies its requirements</td>
</tr>
</tbody>
</table>
Question: **Cost and staffing levels are generally inversely proportional to which of the following in a project:**

A. Time  
B. Output  
C. Achievement of deliverables  
D. Risk and uncertainty
Answer: **Cost and staffing levels are generally inversely proportional to which of the following in a project:**

A. Time  
B. Output  
C. Achievement of deliverables  
D. Risk and uncertainty
IDENTIFYING RESOURCES
# Human Resources

<table>
<thead>
<tr>
<th><strong>Project Management Office</strong></th>
<th>Management structure that standardizes project-related governance processes and facilitates sharing of resources, methodologies, tools and techniques</th>
</tr>
</thead>
</table>
| **Project Manager**           | Person assigned to lead the team that is responsible for achieving the project objectives.  
• Have responsibility to satisfy needs for tasks, team and individuals *(See Action-Centered Leadership Model)* |
| **Stakeholder**               | Individual, group or organization who may affect, be affected by or perceive itself to be affected by a decision, activity or outcome of a project |
# Human Resources

## Types of Stakeholders

<table>
<thead>
<tr>
<th>Stakeholder Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor</td>
<td>Person or group who provides resources and support for the project. Accountable for enabling project success. Can be internal or external.</td>
</tr>
<tr>
<td>Customers / users</td>
<td>Persons or organizations who will approve and manage the project's product, service or result.</td>
</tr>
<tr>
<td>Sellers</td>
<td>Vendors, suppliers, contractors, etc.</td>
</tr>
<tr>
<td>Business Partners</td>
<td>External organizations that have a special relationship with the enterprise that provide specialized expertise for installation, customization, training or support.</td>
</tr>
<tr>
<td>Organizational groups</td>
<td>Internal stakeholders who are affected by activities of the project team.</td>
</tr>
<tr>
<td>Functional managers</td>
<td>Key individuals who play management role within administrative or functional area of the business (e.g., human resources, finance, accounting, procurement).</td>
</tr>
<tr>
<td>Other</td>
<td>e.g., government regulators, subject matter experts, consultants, etc.</td>
</tr>
</tbody>
</table>
### Human Resources

- Competency of team members to perform their tasks is critical
  - Lack of competence can delay a project as well as increase its risk

### Teams

| Project Management Team | • Leadership team for the project  
|                         | • For small projects, this may just be the project manager  
|                         | • Responsible for all project phases as well as monitoring and controlling |
| Project Team            | All team members involved in completing the project |
Other resources

- **Supplies and Equipment Resources**
- **Facilities Resources**
- **Funding Resources**
  - Sponsor has responsibility for allocating and releasing funds for the project
- Every resource may have constraints in their availability
- **Bottom-up estimating**
  - Method of estimating requirements for a component of work
  - Costs (including of resources) are estimated to the greatest detail possible for each individual activity
  - These costs are summarized ("rolled up") to higher levels to estimate overall costs of the project
RESOURCE ALLOCATION
Resource Allocation

- Projects need resources to be completed
- Resources have to be reserved and allocated
- Projects without sufficient resources for the deliverables FAIL
- Allocation of resources may require negotiation, especially if resources are limited in availability
- May need to hire or subcontract for resources from another organization
Resource Allocation

• Multi-Criteria Decision Analysis
  – Can be used to determine which resources to allocate when multiple resources are available
  – Example criteria

<table>
<thead>
<tr>
<th>Availability</th>
<th>Experience</th>
<th>Does the resource have experience relevant to the project?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td>Ability</td>
<td>Does the resource have the competence needed for the project?</td>
</tr>
<tr>
<td>Skills</td>
<td>Knowledge</td>
<td>Relevant to project</td>
</tr>
<tr>
<td>Attitude</td>
<td>International factors</td>
<td>time zone, language or location constraints</td>
</tr>
</tbody>
</table>
PROJECT MANAGEMENT TOOLS
Project Initiation Tools

• Project Charter
  – Document that formally authorizes the existence of a project
  – Provides project manager with authority to apply organizational resources to project activities
  – Establishes partnership between performing and requesting organization
  – Should be authored by the sponsoring entity
Project Charter Components

• **Statement of Work**
  – Purpose of project
  – Description of project
  – Deliverables and related success criteria
  – Scope (what’s in and out)
  – Assumptions
  – Constraints
  – Risks
  – Summary milestone schedule
  – Summary budget $$$
  – Stakeholder list
  – Project approval requirements
  – Project manager
  – Project Charter Authorization

• **Business Case** - may include:
  – Market demand
  – Organizational need
  – Customer request
  – Technological advance
  – Legal requirement
  – Ecological impact
  – Social Need

• **Agreements**
  – Contracts, MOUs, service level agreements (SLA), etc.

• **Environmental factors**
  – Standards, Regulations, Organizational culture/structure, Marketplace conditions

• **Process Assets**
  – Existing processes used (e.g., policies, procedures, templates, knowledge base)
Project Initiation Tools

• Context Diagram
  – Visual representation of project scope
  – Shows inputs to the system and actor(s) providing input as well as outputs to the system and actor(s) providing output
Project Initiation Tools

- **Stakeholder register:** List of stakeholders including...
  - Demographics: roles, departments, contact information
  - Assessment information: major/minor requirements, main expectations, influence and impact levels for a particular project as well as project phase of most interest
  - Classification
    - internal/external
    - Engagement level
      - Unaware, Resistant, Neutral, Supportive, Leading
  - May be represented as a grid (e.g., power/interest grid, salience model)
Project Planning/Execution Tools

• Project management plan
  – Central document which defines the basis of all project work
  – Describes how the project will be executed, monitored and controlled
  – Defines baselines for scope, schedule and cost
  – May contain subsidiary plans such as…
    • Communications management plan
    • Risk management plan
    • Cost management plan
    • Etc.
Project Planning/Execution Tools

- **Resource Calendar**
  - Identifies availability of each specific resource (human resources, supplies, equipment, facilities, funding)
  - Used to estimate resource utilization during planning

Image from https://www.odoo.com/page/project-management
Project Planning/Execution Tools

• **Resource Leveling**
  – Technique where start and finish dates are adjusted based on resource constraints
  – Goal is to balance demand for resources within the resources available
  – Resources may be constrained by being
    • Available only at certain times
    • Limited in number
    • Over-allocated by being assigned to multiple activities/tasks at one time
  – Often causes the critical path to INCREASE (not decrease)
Project Planning/Execution Tools

• **Budget**
  – Allocation of funding resources

• **Use cases**
  – Scenarios of operation between a user (actor) and the software
  – Can use Unified Modeling Language (UML) or SysML diagrams to visualize

• **Traceability Matrix**
  – Grid that links product requirements from their origin to the deliverables that satisfy them
  – Helps ensure that each requirement adds value
  – Used to track requirements
  – Provides structure for managing changes to scope
Project Planning/Execution Tools

• **Project Evaluation and Review Technique (PERT)** [PERT 2016]
  – Network model developed in late 1950s
  – Estimates minimum project duration and amount of scheduling flexibility
  – Allows **flexibility** in activity completion times
    • Each activity gets 3 times: Optimistic, Most likely, Pessimistic
    • Est. activity time = \( \frac{\text{optimistic} + (4 \times \text{Most Likely}) + \text{pessimistic}}{6} \)
  – Sequential and parallel activities are shown in the network
Project Planning/Execution Tools

• PERT
  – Critical path
    • The sequence of activities that represents the LONGEST path through a project (and therefore the shortest possible duration)
  – Very similar to Critical Path Method (also late 1950s) EXCEPT critical path method requires fixed time estimates for each activity

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Node</th>
<th>numbered in rough sequence of expected completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity</td>
<td>Line</td>
<td>time to complete activity is indicated on the line</td>
</tr>
</tbody>
</table>
Project Planning/Execution Tools

• **Critical Chain Method**
  - Schedule method
  - Allows project team to place buffers on any project schedule path to account for
    • limited resources
    • project uncertainties

• **Schedule Network Analysis**
  - Technique that generates the project schedule model using one or more of the following:
    • Critical Path method
    • Critical chain method
    • What-if analysis
    • Resource optimization techniques
Project Planning/Execution Tools

Work Breakdown Structure (WBS)

• Decomposition
  – *Not just an autopsy term…*
  – The process of subdividing work into smaller, manageable and achievable components

• Use it to estimate task duration, assign resources, perform cost and schedule estimate

• WBS contains 5 components, organized in this hierarchy:
  1. Project Title
  2. Project Subsystems (may be more than one) = “subprojects”
  3. Major Deliverables
  4. Sub-deliverables
  5. Work packages
Project Planning/Execution Tools

• **Gantt charts** (a.k.a. Bar charts)
  – Developed by Henry Gantt in 1910
  – Visual representation of tasks and their durations
  – Tasks listed on the left and time scale on the right with bars indicating each tasks expected duration
  – Include milestones
  – Includes **Work-Breakdown Structure (WBS)**
  – **Milestone chart**
    • Gantt chart where only the milestones or high level deliverables display
## Work Breakdown Structure: Example with Timeline (Gantt Chart)

<table>
<thead>
<tr>
<th>WBS</th>
<th>Task Name</th>
<th>January</th>
<th>February</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Define specifications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>Identify customers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td>Interview 10 customers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>Interpret requirements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4</td>
<td>Benchmark products</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5</td>
<td>Define target PDS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.6</td>
<td>Target PDS Released</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Generate concepts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1</td>
<td>Review comp products</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2</td>
<td>Search patents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.3</td>
<td>Brainstorm concepts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Select top 2 concepts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>MQ Presented</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Profile motor power</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1</td>
<td>Design test stand</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.2</td>
<td>Build test stand</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

http://www.me.umn.edu/courses/me4054/assignments/wbsgantt.html
Project Planning/Execution Tools

• Issue log
  – Issue
    • Threat to the successful completion of the project which has already occurred
  – Every project has issues that arise
  – Log used to document and monitor
    • Issue
    • Person responsible for getting issue resolved
    • How the issue was resolved (or not resolved)
    • Mitigation plan if issue is not able to be resolved
Project Monitoring/Controlling Tools

• Seven basic quality tools (7QC)
  – Used within the context of the PDSA cycle (covered elsewhere)
    • Cause-and-effect diagrams
    • Flowcharts
    • Check sheets
    • Pareto diagrams
    • Histograms
    • Control charts
    • Scatter diagrams

• Scope variance analysis
  – Determination of the cause and degree of difference between baseline scope and current scope (project performance)
  – Measure of **scope creep**
Question: A Gantt Chart is used:

A. To visually depict task sequence, phases, overlap and duration
B. To identify critical tasks or phases of a project
C. To evaluate project progress and deadlines
D. For project scheduling
E. All of the above
Answer: A Gantt Chart is used:

A. To visually depict task sequence, phases, overlap and duration
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C. To evaluate project progress and deadlines
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E. All of the above
Question: Which of the following types of testing are the most difficult yet the most valuable in the implementation of new software?

A. Integration testing
B. Parallel testing
C. Unit testing
D. Regression testing
Answer: Which of the following types of testing are the most difficult yet the most valuable in the implementation of new software?

A. Integration testing
B. Parallel testing
C. Unit testing
D. Regression testing
INFORMATICS PROJECT CHALLENGES
Scope Creep

• A condition in which the current scope of a project has expanded beyond its baseline scope
  – Often due to poor definition of scope
  – Even more often due to poor/no definition of what is out of scope

• Scope Management Plans are part of PMBOK
Scope Creep in Informatics

• Information systems have a lot of functionality
  – You will not be able to implement all new functions at one time
  – Change management (section 4F) and Process redesign (Section 2C-1) for each new function in workflow
  – Users may be inpatient to implement if functionality is appealing

• This requires constant management of expectations
Managing Expectations

• Communication skills (section 2C)
• Knowledge of project scope as defined in project charter
• Knowledge of project portfolio
  – Communicate to user if satisfaction of business need is scheduled in a later project
Balancing Competing Priorities

• Competing priorities may exist for
  – Resources (supply-demand issues)
  – Other projects
    • may be deemed more important to implement first
    • This can happen over and over

• Institutions without portfolio management are at much higher risk for this
  – Huge waste of resources and time

• Key to avoiding this
  – **Portfolio and Program Management**
  – Have a project management office knowledgeable about the PMBOK
Clinical Informatics
Specific Challenges

• Information systems are highly complex
  – Therefore a highly complex project
  – Information security components also required (adds to complexity)
• Integration and operation of information system with myriad other software, platforms, operating systems, etc.
• Software workflow vs. human workflow conflict
• Initial requirements often imprecise or lack sufficient detail
• Software requirements change as knowledge of the product (and particularly its constraints) increases
End of Lecture
Answer: **Cost and staffing levels are generally inversely proportional to which of the following in a project:**

A. Time  
B. Output  
C. Achievement of deliverables  

**D. Risk and uncertainty**

Risk and uncertainty are highest at the beginning of a project, while cost and staffing are the lowest. As time progresses, risk and uncertainty decrease while cost and staffing increase until project closure.
Answer: A Gantt Chart is used:

A. To visually depict task sequence, phases, overlap and duration
B. To identify critical tasks or phases of a project
C. To evaluate project progress and deadlines
D. For project scheduling
E. All of the above

A Gantt chart is a visual tool that outlines the plan for and shows the progress of a project. It provides a snapshot of the progress of the various phases of a project comprised of several tasks. However, it leaves little room for uncertainty. See the following reference for more detail: [http://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/gantt-chart](http://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/gantt-chart)
Answer: **Which of the following types of testing are the most difficult yet the most valuable in the implementation of new software?**

A. Integration testing  

B. **Parallel testing**  

C. Unit testing  

D. Regression testing  

Parallel testing is testing functions and data entry in the new system or software in parallel with using the same functions (entering the same data) into the production system you are about to replace. On a busy clinical service, it can be impossible to get people to do this because it significantly increases workload with 10-20% duplicative work. However, it is one of the best ways to discover bugs and snags prior to go-live. Unit testing is testing within the new application. Integration testing is testing the new software’s communications and integration with other systems/software. Regression testing is testing current state functions that you expect to keep in the new software to ensure that they have not been altered.
4D-Project Management


References

Free online resources


Other resources (not free)

2B: Evidence-Based Practice and Information Retrieval

William Hersh, MD, FACP. FACMI
Oregon Health & Science University
Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
   1.1.1. The discipline of informatics
   1.1.2. Key informatics concepts, models, and theories
   1.1.3. Clinical informatics literature
   1.1.4. International clinical informatics practices
   1.1.5. Ethics and professionalism
   1.1.6. Legal and regulatory issues
   1.2. The Health System
   1.2.1. Determinants of individual and population health
   1.2.2. Primary domains, organizational structures, cultures, and processes
   1.2.3. The flow of data, information, and knowledge within the health system
   1.2.4. Policy & regulatory framework
   1.2.5. Health economics and financing
   1.2.6. Forces shaping health care delivery
   1.2.7. Institute of Medicine quality components

2. Clinical Decision Making and Care Process Improvement
   2.1. Clinical Decision Support
   2.1.1. The nature and cognitive aspects of human decision making
   2.1.2. Decision science
   2.1.3. Application of clinical decision support
   2.1.4. Transformation of knowledge into clinical decision support tools
   2.1.5. Legal, ethical, and regulatory issues
   2.1.6. Quality and safety issues
   2.1.7. Supporting decisions for populations of patients
   2.2. Evidence-based Patient Care
   2.2.1. Evidence sources
   2.2.2. Evidence grading
   2.2.3. Clinical guidelines
   2.2.4. Implementation of guidelines as clinical algorithms
   2.2.5 Information retrieval and analysis
   2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
   2.3.1. Methods of workflow analysis
   2.3.2. Principles of workflow re-engineering
   2.3.3. Quality improvement principles and practices

3. Health Information Systems
   3.1. Information Technology Systems
   3.1.1. Computer Systems
   3.1.2. Architecture
   3.1.3. Networks
   3.1.4. Security
   3.1.5. Data
   3.1.6. Technical approaches that enable sharing data
   3.2. Human Factors Engineering
   3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
   3.2.2. HCI Evaluation, usability testing, study design and methods
   3.2.3. Interface design standards and design principles
   3.2.4. Usability engineering
   3.2.5. Health Information Systems and Applications
   3.2.6. Types of functions offered by systems
   3.2.7. Types of settings where systems are used
   3.3. Electronic health/medical records systems as the foundational tool
   3.3.1. Types of functions offered by systems
   3.3.2. Types of settings where systems are used

4. Leading and Managing Change
   4.1. Leadership Models, Processes, and Practices
   4.1.1. Dimensions of effective leadership
   4.1.2. Governance
   4.1.3. Negotiation
   4.1.4. Conflict management
   4.1.5. Collaboration
   4.1.6. Motivation
   4.1.7. Decision making
   4.2. Effective Interdisciplinary Teams
   4.2.1. Human resources management
   4.2.2. Team productivity and effectiveness
   4.2.3. Group management processes
   4.2.4. Managing meetings
   4.2.5. Managing group deliberations
   4.3. Effective Communications
   4.3.1. Effective presentations to groups
   4.3.2. Effective one-on-one communication
   4.3.3. Writing effectively for various audiences and goals
   4.3.4. Developing effective communications program to support system implementation
   4.4. Project Management
   4.4.1. Basic principles
   4.4.2. Identifying resources
   4.4.3. Resource allocation
   4.4.4. Project management tools (non-software specific)
   4.4.5. Informatics project challenges
   4.5. Strategic and Financial Planning for Clinical Information Systems
   4.5.1. Establishing mission and objectives
   4.5.2. Environmental scanning
   4.5.3. Strategy formulation
   4.5.4. Action planning and strategy implementation
   4.5.5. Capital and operating budgeting
   4.5.6. Principles of managerial accounting
   4.5.7. Evaluation of planning process
   4.6. Change Management
   4.6.1. Assessment of organizational culture and behavior
   4.6.2. Change theories
   4.6.3. Change management strategies
   4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core content covered

2.2. Evidence-based Patient Care
   2.2.1 Evidence sources
   2.2.2 Evidence grading
   2.2.3 Clinical guidelines
   2.2.4 Implementation of guidelines as clinical algorithms
   2.2.5 Information retrieval and analysis
      2.2.5.1 Search skills
      2.2.5.2 Critical analysis of biomedical literature
Key topics

• Formulating an appropriate clinical question to finding and applying evidence
• Critical appraisal of a study addressing one of the fundamental clinical question types: treatment, diagnosis, harm, and prognosis
• Evidence grading schemes
• Structure, function, and limitations of clinical practice guidelines
• Content, indexing, retrieval, and evaluation of information retrieval (search) systems
2B – Evidence-Based Practice and Information Retrieval

• Evidence-based medicine
• Using EBM to answer questions about intervention (treatment)
  – Diagnosis statistics covered in 2A-1
• Summarizing evidence
• Clinical practice guidelines
• Information retrieval and analysis
Evidence-based medicine (EBM)

- A set of tools and disciplined approach to informing clinical decision-making
  - Applies the best evidence available
  - Most recent textbooks – manual (Guyatt, 2014); handbook (Guyatt, 2015)
- Allows clinical experience (art) to be integrated with best clinical science
- Makes biomedical literature more clinically applicable and relevant
- Cannot forget the caveat: “Absence of evidence is not evidence of absence” (Carl Sagan)
Hierarchy of evidence

Started as “4S” (Haynes, 2001), subsequently updated to “5S” (Haynes, 2006) and now “6S” (DiCenso, 2009)

- Systems – actionable knowledge
  - Summaries – evidence-based textbooks and collections
  - Synopses of syntheses – evidence-based abstracts
  - Syntheses – systematic reviews and evidence reports
  - Synopses of studies – evidence-based journal abstracts
  - Studies – original articles published in journals
Sources of evidence

- Systems
- Summaries
- Syntheses
- Studies

Guidelines, rules, order sets
Textbooks, compendia, guidelines
Systematic reviews
MEDLINE
Journal articles

Clinical Informatics Board Review Course
Overview of the application of EBM

• Steps include
  – Phrasing a clinical question that is pertinent and answerable
  – Identifying evidence to address the question
  – Critically appraising the evidence to determine if it applies to the patient

• Background vs. foreground questions
  – Background questions ask for general knowledge about a disorder
    • Usually answered with textbooks and classical review articles
  – Foreground questions ask for knowledge about managing patients with a disorder
    • Answered with EBM techniques
Foreground questions

• Have three or four essential components (PICO)
  – Patient and/or problem
  – Intervention
  – Comparison intervention (if appropriate)
  – Outcomes

• Example
  – In an elderly patient with congestive heart failure, are beta blockers helpful in reducing morbidity and mortality without excess side effects?

• Recent addition of timing and setting, i.e., PICOTS (Buckley, 2014)
Four categories of foreground questions

• Intervention (or Treatment or Therapy) – benefit of treatment or prevention
• Diagnosis – test diagnosing disease
• Harm – etiology or cause of disease
• Prognosis – outcome of disease course
Questions to ask about the results from any study

• Are the results valid?
• Are the results important?
• Can the results be applied to patient care?

• Specific sub-questions depend on type of question and study
Using EBM to assess questions about interventions

- Questions concerning benefit of a clinical intervention to treat or prevent disease
- Can include drug therapy, diet therapy, surgery, alternative medicine, etc.
- Usually want to know treatment effect and precision
- Best evidence comes from a randomized controlled trial (RCT) or meta-analysis of RCTs
  - Patients similar in all regards with exception of intervention applied
Treatment effect

• Usually measured in terms of risk of undesired outcomes, e.g., mortality, recurrence, complications, etc.

• Relative measures – relative to control
  – Relative risk (RR, risk ratio) – risk relative to control
    • Relative risk reduction
  – Odds ratio (OR) – odds of having vs. not having event
  – Hazard ratio (HR) – relative risk adjusted for time

• Absolute measures – overall population
  – Absolute risk reduction (ARR, risk difference) – absolute difference of risk
  – Number needed to treat (NNT) – how many must be treated for one person to benefit
Measurement of treatment effect

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Had event</th>
<th>No event</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>a</td>
<td>b</td>
<td>a+b</td>
</tr>
<tr>
<td>Control</td>
<td>c</td>
<td>d</td>
<td>c+d</td>
</tr>
<tr>
<td>Total</td>
<td>a+c</td>
<td>b+d</td>
<td>a+b+c+d</td>
</tr>
</tbody>
</table>

Events – e.g., death, complication, progression of disease, etc.

Assuming statistical significance:

- Experimental event rate (EER) = $\frac{a}{a+b}$ (risk of event from exp. intervention)
- Control event rate (CER) = $\frac{c}{c+d}$ (risk of event from control intervention)
- Relative risk (RR) or risk ratio = EER / CER
- Relative risk reduction (RRR) = 1 - RR
- Absolute risk reduction (ARR) or risk difference = CER - EER
- Number needed to treat (NNT) = $\frac{1}{\text{ARR}}$
Precision of estimate of treatment effect

• True risk for population is unknown; need to assess with sample
• Study result gives point estimate, but true result can vary due to chance (and bias if study not performed properly)
• Assess possible range of results by calculating confidence interval (CI)
  – Range of values that includes true value 95% of the time
Example: Standard vs. intensive blood pressure control in elderly

(Wright, 2015)

- Elderly with systolic BP >130 mm Hg and increased cardiovascular risk, but without diabetes, to systolic BP target of
  - <120 mm Hg (intensive treatment) vs.
  - <140 mm Hg (standard treatment)

- Primary composite outcome – myocardial infarction, other acute coronary syndromes, stroke, heart failure, or death from cardiovascular causes

- Study stopped early after 3.26 years – intensive treatment group had HR = 0.75, 95% CI 0.64-0.89)
Class interaction

<table>
<thead>
<tr>
<th>Group</th>
<th>CV outcome</th>
<th>No CV outcome</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensive</td>
<td>243</td>
<td>4435</td>
<td>4678</td>
</tr>
<tr>
<td>Standard</td>
<td>319</td>
<td>4364</td>
<td>4683</td>
</tr>
</tbody>
</table>

Answer the following for standard vs. intensive blood pressure (BP) control in elderly
• What is the relative risk reduction of intensive treatment?
• How many people must be treated to reduce one CV outcome?
Summarizing evidence

- For many tests and treatments, there are multiple studies such that one study does not tell the whole story.
- As such, there has been a growing trend towards “systematic reviews” or “evidence reports” to bring all the evidence on a treatment or test together (Nelson, 2014).
- Per 6S model, syntheses bring primary data together while summaries make it available to users in highly digested form.
Results from a systematic review

- Often use meta-analysis, which combines results of multiple similar studies
- Systematic review ≠ meta-analysis
  - Studies may be too heterogeneous in terms of patient characteristics, settings, or other factors, e.g., telemedicine (Hersh, 2006); health information exchange (Hersh, 2015)
- When meta-analysis is done, summary measures employed usually include
  - Odds ratio (OR) or relative risk/risk ratio (RR) for dichotomous variables (i.e., events)
  - Mean difference (MD) or standardized mean difference (SMD) for continuous variables
One large producer of systematic reviews is Cochrane Collaboration

- [www.cochrane.org](http://www.cochrane.org)
- Most reviews include meta-analysis
  - Logo based on review of steroids in preterm labor
- Each horizontal line represents a single RCT
  - Span of line indicates CI
- All study questions configured relative to vertical line
  - Line represents OR=1 or MD/SMD=0
  - Treatment benefit is to left of line
  - CI not touching line indicates statistical significance
Clinical practice guidelines (CPGs)

• CPGs are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” (Field, 1990; IOM, 2011)
  – Usually aim to “normalize care”
• May consist of
  – Series of steps for providing clinical care
  – Represented as text/tables or algorithms
• Steps in construction include
  – Gathering evidence for important outcomes
  – Grading quality of that evidence
  – Ascertaining balance of benefits and harms
  – Determining strength of recommendation
  – Implementing and evaluating
Grading levels of evidence in studies: GRADE

- Grading of Recommendations Assessment, Development, and Evaluation (GRADE) (Guyatt, 2011; Neumann, 2016)
- [www.gradeworkinggroup.org](http://www.gradeworkinggroup.org)

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Quality of Evidence</th>
<th>Lower if</th>
<th>Higher if</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized trial</td>
<td>High</td>
<td>Risk of bias</td>
<td>Large effect</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1 Serious</td>
<td>+1 Large</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-2 Very serious</td>
<td>+2 Very large</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>Inconsistency</td>
<td>Dose response</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1 Serious</td>
<td>+1 Evidence of a gradient</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-2 Very serious</td>
<td>All plausible confounding</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>Indirectness</td>
<td>+1 Would reduce a demonstrated effect or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1 Serious</td>
<td>+1 Would suggest a spurious effect when results show no effect</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-2 Very serious</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Very low</td>
<td>Imprecision</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1 Serious</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-2 Very serious</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Publication bias</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1 Likely</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-2 Very likely</td>
<td></td>
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</tbody>
</table>
U.S. Preventive Services Task Force (USPSTF) recommendations

- Recommendations based on grading evidence derived from a commissioned systematic review
  - Grade A – certainty of evidence is high that the magnitude of net benefits is substantial
  - Grade B – certainty of evidence is moderate that the magnitude of net benefits is either moderate or substantial, or that the certainty of evidence is high that the magnitude of net benefits is moderate
  - Grade C – certainty of the evidence is either high or moderate that the magnitude of net benefits is small
  - Grade D – certainty of the evidence is high or moderate that the magnitude of net benefits is either zero or negative
  - Grade I – the evidence is insufficient to determine the relationship between benefits and harms (i.e., net benefit)

- [http://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions](http://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions)
Limitations of guidelines

• May not apply in complex patients – for 15 common diseases, following best-known guidelines in elderly patients with comorbid diseases may have undesirable effects and implications for pay-for-performance schemes (Boyd, 2005)

• May be incomplete or inaccurate – of 11 guidelines for oral medications in Type 2 diabetes, several varied from known best evidence, with those having evidence-based processes being judged of higher quality (Bennett, 2012)

• Difficult to implement in EHRs – issues include precise coding of logic and integration into workflow (Maviglia, 2003)

• Conflict of interest – For 17 American College of Cardiology/American Heart Association guidelines, 56% of authors had a reported conflict of interest, most commonly being a consultant or a member of an advisory board (Mendelson, 2011)
Where does one find CPGs?

• Medical literature, i.e., PubMed/MEDLINE
• National Guidelines Clearinghouse (NGC) – www.guideline.gov
• From many organizations
  – Medical specialty societies, e.g.,
    • American College of Physicians - https://www.acponline.org/clinical-information/guidelines
    • American Heart Association/American College of Cardiology - http://professional.heart.org/professional/GuidelinesStatements/UCM_316885_Guidelines-Statements.jsp
  – Government and related organizations, e.g.,
  – Healthcare delivery organizations and others
Information Retrieval and Analysis

• Basic concepts
• Content
• Indexing
• Retrieval
• Evaluation
Basic concepts: information retrieval (IR) system (Hersh, 2009)

- Retrieval
- Metadata
  - Queries
  - Content
- Indexing
  - Search engine
Intellectual tasks of IR

• Indexing
  – Assigning metadata to content items
  – Can assign
    • Subjects (terms) – words, phrases from controlled vocabulary
    • Attributes – e.g., author, source, publication type

• Retrieval
  – Most common approaches use
    • Boolean – use of AND, OR, NOT
    • Natural language – words common to query and content
A classification of knowledge-based content

• Bibliographic
  – By definition rich in metadata

• Full-text
  – Everything on-line

• Annotated
  – Non-text annotated with text or structured text

• Aggregations
  – Bringing together all of the above
MEDLINE

• References to biomedical journal literature
  – Original medical IR application – launched in 1971, with literature dating back to 1966 (and now some older)
  – Free to world since 1997 via PubMed – pubmed.gov
• Produced by National Library of Medicine (NLM)
• Statistics
  – Over 22 million references to peer-reviewed literature
  – Over 5,000 journals, mostly English language
  – Over 750,000 new references added yearly
• Links to full text of articles and other resources
Annotated content

- Non-text annotated with text or structured text, e.g.,
  - Image collections, usually from “visual” specialties
  - Citation databases, e.g., Science Citation Index
  - Evidence-based medicine databases, e.g., JAMA Evidence
  - Clinical decision support, from publishers or vendors
  - Genomics databases, from NLM and others
  - Other databases, e.g., ClinicalTrials.gov
Aggregations – integrating many resources

• Clinical – major publishers now “bundle” their collections

• Biomedical research – example is linked databases of NCBI

• Consumer – example is MEDLINEplus from NLM
  – medlineplus.gov
Indexing

• Assignment of metadata to content to facilitate retrieval

• Two major types
  – Human indexing with controlled vocabulary
    • Best known approach is MEDLINE applied by professional indexers using Medical Subject Headings (MeSH) vocabulary
  – Automated indexing of all words
Medical Subject Headings (MeSH) vocabulary (*Coletti, 2001*)

- Over 26,000 terms, with many synonyms for those terms
- Hierarchical, based on 16 trees, e.g., Anatomy, Diseases, Chemicals and Drugs
- Contains 83 subheadings, which can be used to make a heading more specific, such as Diagnosis or Therapy
- Also includes Publications Types, important for EBM, e.g., Randomized Controlled Trial, Systematic Review
- MeSH browser allows exploration
A slice of MeSH

C Diseases

C1 Bacterial and Fungal Diseases

C14 Cardiovascular Diseases

C20 Immunologic Diseases

C14.240 Cardiovascular Abnormalities

C14.280 Heart Diseases

C14.907 Vascular Diseases

C14.907.055 Aneurysm

C14.907.489 Hypertension

C14.907.940 Vasculitis

C14.907.489.330 Malignant Hypertension

C14.907.489.430 Portal Hypertension

C14.907.489.631 Renal Hypertension
Automated indexing

• Indexing of all words that occur in content items
  – In bibliographic databases, will usually include title, abstract, and sometimes other fields, e.g., author or subject heading
  – In full-text documents, will usually include all text and title
• Often use a stop word list to remove common words (e.g., the, and, which)
• Some systems “stem” words to root form (e.g., coughs or coughing to cough)
Retrieval

• Two general approaches
  – Boolean, set-based, exact-match
  – Natural language, automated, partial-match
• They are not mutually exclusive, e.g., PubMed
• Early systems tended to be Boolean
  – Preferred by power users?
• More recently have seen growth of natural language systems
  – Popular for Web searching
Boolean operators – build sets and combine

• **AND** – only content items that have all terms

• **OR** – content items that have any term

• **NOT** – content items with one term but not other

- NLM system for searching MEDLINE and related databases
  - Includes some OLDMEDLINE (before 1966) as well as other records not indexed in MEDLINE
- Based on Boolean heritage but has added a number of features of natural language searching over the years
  - Search algorithm tries to map input to MeSH terms, author name, and other phrases
  - Has traditional Boolean set capability in Advanced interface but essentially unnecessary now
- Default output order is reverse chronological
Evaluation

• Questions often asked (Hersh, 2009)
  – Is system used?
  – Are users satisfied?
  – Do they find relevant information?
  – Do they complete their desired task?
• Most studied group is physicians, with systematic reviews of results (Hersh, 1998, Pluye, 2005)
• Most IR evaluation research has focused on retrieval of relevant documents, which may not capture full spectrum of usage
Relevance-based measures

• Most common approach to evaluation
  – Recall (equivalent to sensitivity)
    \[ R = \frac{\text{#retrieved and relevant documents}}{\text{#relevant documents in collection}} \]
  – Precision (equivalent to positive predictive value)
    \[ P = \frac{\text{#retrieved and relevant documents}}{\text{#retrieved documents}} \]

• Example:
  – 100 known relevant documents
  – 50 documents retrieved
  – 25 documents retrieved are relevant
  – Recall = 25/100 = 25%
  – Precision = 25/50 = 50%
Class interaction

• What is the best approach for searching in the following situations?
  – Finding the best evidence for treatment of hypertension in the elderly
  – Performing a systematic review of all studies of value of screening for prostate cancer
  – Finding an overview of congestive heart failure etiology, diagnostic methods, and treatment
Additional suggested readings

• Key

• Supplemental
Class interaction: Answer

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</tbody>
</table>

Answer the following for standard vs. intensive blood pressure (BP) control in elderly

What is the relative risk reduction of intensive treatment?

- EER = 243 / 4678 = 0.052 (5.2%)
- CER = 319 / 4683 = 0.068 (6.8%)
- RR = EER / CER = 0.76 (76.0%)
- RRR = 1 − RR = 0.24 (24.0%)

How many people must be treated to reduce one CV outcome?

- ARR = CER − EER = 0.068 − 0.052 = 0.016 (1.6%)
- NNT = 1 / ARR = 62


4B: Building Effective Healthcare IT Teams

4C: Effective Communications
Alexis Carter, MD
Physician Informaticist
Children’s Healthcare of Atlanta
### Core Content Covered in this Lecture

#### 1. Fundamentals

1.1. Clinical Informatics

- 1.1.1. The discipline of informatics
- 1.1.2. Key informatics concepts, models, and theories
- 1.1.3. Clinical informatics literature
- 1.1.4. International clinical informatics practices
- 1.1.5. Ethics and professionalism
- 1.1.6. Legal and regulatory issues

1.2. The Health System

- 1.2.1. Determinants of individual and population health
- 1.2.2. Primary domains, organizational structures, cultures, and processes
- 1.2.3. The flow of data, information, and knowledge within the health system
- 1.2.4. Policy & regulatory framework
- 1.2.5. Health economics and financing
- 1.2.6. Forces shaping health care delivery
- 1.2.7. Institute of Medicine quality components

#### 2. Clinical Decision Making and Care Process Improvement

2.1. Clinical Decision Support

- 2.1.1. The nature and cognitive aspects of human decision making
- 2.1.2. Decision science
- 2.1.3. Application of clinical decision support
- 2.1.4. Transformation of knowledge into clinical decision support tools
- 2.1.5. Legal, ethical, and regulatory issues
- 2.1.6. Quality and safety issues
- 2.1.7. Supporting decisions for populations of patients

2.2. Evidence-based Patient Care

- 2.2.1. Evidence sources
- 2.2.2. Evidence grading
- 2.2.3. Clinical guidelines
- 2.2.4. Implementation of guidelines as clinical algorithms
- 2.2.5. Information retrieval and analysis

2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement

- 2.3.1. Methods of workflow analysis
- 2.3.2. Principles of workflow re-engineering
- 2.3.3. Quality improvement principles and practices

#### 3. Health Information Systems

3.1. Information Technology Systems

- 3.1.1. Computer Systems
- 3.1.2. Architecture
- 3.1.3. Networks
- 3.1.4. Security
- 3.1.5. Data
- 3.1.6. Technical approaches that enable sharing data

3.2. Human Factors Engineering

- 3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
- 3.2.2. HCI Evaluation, usability testing, study design and methods
- 3.2.3. Interface design standards and design principles
- 3.2.4. Usability engineering
- 3.2.5. Health Information Systems and Applications
- 3.2.6. Electronic health/medical records systems as the foundational tool

3.3. Types of functions offered by systems

3.3.2. Types of settings where systems are used

3.4. Telemedicine

3.4.1. Standards development history and current process
- 3.4.2. Data standards and data sharing
- 3.4.3. Transaction standards
- 3.4.4. Messaging standards
- 3.4.5. Nomenclatures, vocabularies, and terminologies
- 3.4.6. Ontologies and taxonomies
- 3.4.7. Interoperability standards

3.5. Information System Lifecycle

- 3.5.1. Institutional governance of clinical information systems
- 3.5.2. Clinical information needs analysis and system selection
- 3.5.3. Clinical information system implementation
- 3.5.4. Clinical information system testing, before, during and after implementation
- 3.5.5. Clinical information system maintenance
- 3.5.6. Clinical information system evaluation

#### 4. Leading and Managing Change

4.1. Leadership Models, Processes, and Practices

- 4.1.1. Dimensions of effective leadership
- 4.1.2. Governance
- 4.1.3. Negotiation
- 4.1.4. Conflict management
- 4.1.5. Collaboration
- 4.1.6. Motivation

4.2. Effective Interdisciplinary Teams

- 4.2.1. Human resources management
- 4.2.2. Team productivity and effectiveness
- 4.2.3. Group management processes
- 4.2.4. Managing meetings
- 4.2.5. Managing group deliberations

4.3. Effective Communications

- 4.3.1. Effective presentations to groups
- 4.3.2. Effective one-on-one communication
- 4.3.3. Writing effectively for various audiences and goals
- 4.3.4. Developing effective communications program to support system implementation

4.4. Project Management

- 4.4.1. Basic principles
- 4.4.2. Identifying resources
- 4.4.3. Resource allocation
- 4.4.4. Project management tools (non-software specific)
- 4.4.5. Informatics project challenges

4.5. Strategic and Financial Planning for Clinical Information Systems

- 4.5.1. Establishing mission and objectives
- 4.5.2. Environmental scanning
- 4.5.3. Strategy formulation
- 4.5.4. Action planning and strategy implementation
- 4.5.5. Capital and operating budgeting
- 4.5.6. Principles of managerial accounting
- 4.5.7. Evaluation of planning process

4.6. Change Management

- 4.6.1. Assessment of organizational culture and behavior
- 4.6.2. Change theories
- 4.6.3. Change management strategies
- 4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core Content Covered

4.2  Effective Interdisciplinary Teams

4.2.1 Human resources management (e.g., hiring, performance reviews and feedback, professional development, termination)

4.2.2 Team productivity and effectiveness (e.g., articulating team goals, defining rules of operation, clarifying individual roles)

4.2.3 Group management processes (e.g., nominal group, consensus mapping, Delphi method)

4.2.4 Managing meetings

4.2.5 Managing group deliberations
Key Topics

• How to recruit and retain employees and team members
• Human resource factors for healthcare IT teams
• Factors critical for team effectiveness
Key Topics continued

- Structuring Team Goals to promote team effectiveness
- Processes commonly employed in Group Management
- Successful management of team meetings, and techniques for management of group deliberations
HUMAN RESOURCE MANAGEMENT
Human Resource Management

- Plan human resource needs
  - Identify objective(s) of the Team
  - Identify what resources are needed to meet objective(s):
    - Talent
    - Specific Skills
    - Expertise
    - Size of Team
Human Resource Management

- Technical Skills
  - Computer Skills
  - Current or future system

- Trusted, Seasoned Clinical Expertise
  - aka “Clinical Champions”
  - Critical for workflow considerations
  - Critical to preserve healthcare delivery outcomes
  - Critical to represent intended user group
Human Resource Management

- Formalize the process of team assembly
  - Follow existing organizational policies and procedures (save time, avoid headaches)

- Job description is critical
  - Qualifications: Education, Experience, Skill Sets
  - Duties and Performance Expectations
  - Reporting Requirements
  - Organizational Responsibilities: Budget, Workspace/Overhead

- Internal Recruitment vs. External Hires
Human Resource Management

<table>
<thead>
<tr>
<th></th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Internal Recruitment</strong></td>
<td>• Personnel already know organizational history,</td>
<td>• May spread internal talent too thinly</td>
</tr>
<tr>
<td></td>
<td>• Strengths &amp; weaknesses</td>
<td>• Personnel may be rooted in approaches that are already ineffective</td>
</tr>
<tr>
<td></td>
<td>• Trusted from within</td>
<td></td>
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<tr>
<td></td>
<td>• May be more cost effective</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Known operator</td>
<td></td>
</tr>
<tr>
<td><strong>External Recruitment</strong></td>
<td>• Can hire specific talent if you don’t have it in-house (or your</td>
<td>• Costs $$$</td>
</tr>
<tr>
<td></td>
<td>internal talent is spread too thin)</td>
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<tr>
<td></td>
<td>• Fresh perspective</td>
<td>• Lack of knowledge of organizational history and culture</td>
</tr>
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<td></td>
<td></td>
<td>• Abilities and weaknesses are unknown</td>
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</table>
Human Resource Management

• Recognition and rewards
  – For desirable behavior and completion of work
  – May be tangible (e.g., $$$) or intangible (opportunities for growth, new challenges)
    • Sometimes intangible are more valuable and long-lasting in effect
  – Only effective if it satisfies a need of that individual and makes them feel valued
    • See Motivation in Leadership lecture (section 4A)
  – Small rewards given periodically are more effective than one large reward at the end of a project
Human Resource Management

• Performance reviews
  – Performance assessments best when measured against pre-defined and agreed-upon objectives, cost boundaries and timeliness
  – Indicators
    • Demonstrable skill/competency improvements
  – Personal
  – Teams
    • Performance indicators specific to teams
      – Decreased staff turnover rate
      – Examples of increased team cohesiveness
Human Resource Management

- **Professional Development**
  - Performance reviews should be used to help determine professional development needed or desired by an individual or team
  - Results of professional development should be measurable
    - Skill assessments
    - Examinations
    - Personal observation
  - Coaching vs. counseling

<table>
<thead>
<tr>
<th>Coaching</th>
<th>Counseling</th>
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<tbody>
<tr>
<td>Developing an individual or team to higher levels of competency and performance</td>
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<td>Focuses on resolving what an individual or team can't do</td>
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<tr>
<td>Powerful motivator</td>
<td>Focuses on what an individual or team can do, but won't</td>
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</table>
Human Resource Management

• Chronically poor performers due to poor “fit”: relocate to better fit
• Chronically poor performers due to other factors (behavioral, poor qualifications, etc):
  – involve HR early, employ performance improvement plan
  – provide opportunity for remediation, re-assess
  – follow-through to removal (including termination) if indicated
Human Resources Management: Personnel Termination

- Make sure your organization has clearly stated policies and procedures
- Follow them
- Communicate and Document
- Involve your HR department early
TEAM PRODUCTIVITY AND EFFECTIVENESS
Team Productivity and Effectiveness

- Specify Team Goals
- Define Team Rules – how will team operate
- Clarifying Individual Roles on the team
Team Goal Setting

- Team’s goals are set based on required deliverables
- Goals/deliverables should be
  - Specific
  - Have a timeline/Deadline
  - Who on team is responsible
- Identify and Conduct Measures of Success (outcome measures)
- Re-visit goals periodically. Effect mid-course corrections.
Team Rules of Operation

• a.k.a. Ground rules
• Rules which establish clear expectations regarding acceptable behavior by team members
  – Decrease misunderstandings
  – Increase productivity

▪ Document:
  – Team members, Team Roles, Reporting lines
  – Approach to Decision Making
  – Resources, Timelines and Deliverables
  – Meeting Schedule and requirements for Independent Work
▪ One way to do this is to use a Team Charter
Team Charter Components

1. Purpose
2. Stakeholders
3. Membership
4. Responsibility
5. Decision Making
6. Team Name
7. Life Expectancy
8. Communication
9. Financial Resources
Clarifying individual roles

- **Organization charts**
  - a.k.a. Organizational Breakdown Structure (OBS)
  - Traditionally represented as a hierarchical diagram
  - Organized into departments, units and/or teams with bosses and subordinates
Clarifying individual roles

• Responsibility Assignment Matrix (RAM)
  – Shows resources assigned to each responsibility
  – Shows
    • Resources assigned to a project listed in the column headers
    • Responsibilities/activities on the left
    • Box data indicates level of responsibility
      – Can use the RACI

<table>
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<tr>
<th></th>
<th>Responsible</th>
<th>Accountable</th>
<th>Consult</th>
<th>Inform</th>
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</table>
Clarifying individual roles

• Position Descriptions
  – Text document that lists the specific responsibilities of an individual position
  – Important to have a complete list of responsibilities
  – Can be used as a benchmark for employee performance and evaluations
GROUP MANAGEMENT PROCESSES

MANAGING GROUP DELIBERATIONS
Group Management / Deliberations

• Organizational theory
  – Provides information on the way in which people, teams and organizational units behave
  – Effective use can shorten time, cost and effort needed for projects and operations

• Team development
  – Tuckman ladder
    • Five stages of development (Tuckman 1965, Tuckman & Jensen 1977)
# Group Management / Deliberations

- **Tuckman Ladder**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>Forming</strong></td>
<td>Team meets and learns about the project, roles and responsibilities</td>
</tr>
<tr>
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<td>Team members independent and less open</td>
</tr>
<tr>
<td><strong>Storming</strong></td>
<td>Team begins work</td>
</tr>
<tr>
<td></td>
<td>Collaboration and openness to different ideas important</td>
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<tr>
<td></td>
<td>Lack of this --&gt; counterproductive</td>
</tr>
<tr>
<td><strong>Norming</strong></td>
<td>Team members begin to adjust work habits and behaviors to support</td>
</tr>
<tr>
<td></td>
<td>the team</td>
</tr>
<tr>
<td></td>
<td>Trust begins</td>
</tr>
<tr>
<td><strong>Performing</strong></td>
<td>Team operates as well-organized unit</td>
</tr>
<tr>
<td></td>
<td>Team members are inter-dependent rather than independent</td>
</tr>
<tr>
<td><strong>Adjourning</strong></td>
<td>Team members leave as the project closes</td>
</tr>
</tbody>
</table>
Building Team Effectiveness

• Training
  – Team trains together toward a common goal
• Team-building activities
• Colocation teams (a.k.a. tight matrix)
  – Places most if not all team members in the same physical space (e.g., "war room")
  – Goal is to enhance performance as a team
  – Advantages
    • Personal communication
    • Non-verbal cues that may be missed when using conference calls or even video conferencing
    • Improves focus for team members who are otherwise in high-distraction environments
Building Team Effectiveness

• Virtual teams
  – Teams with a shared goal that fulfill their roles with little or no time spent meeting face to face
  – Email, web conferencing, instant message, social media, etc.
  – Advantages
    • Geographically agnostic
    • Increases availability of experts who are not local
    • Allows teleworking
    • Allows flexibility of staff shift schedules
    • Facilitates inclusion of individuals with limited mobility and certain disabilities
    • More cost efficient (reduces/eliminates travel expenses)
Building Team Effectiveness

- Conflict Management and some group decision making (brief) in section 4A Leadership.
Group Decision Making

- Advantages
  - Diversity in groups may generate wider variety & higher quality of decision alternatives than individuals or homogeneous groups
  - Greater collective understanding of the eventual course of action chosen - improve buy-in and adoption
Group Decision Making

- Disadvantages
  - Group decision making is a slower process
  - "Groupthink" - individuals pressured to conform to "dominant view" in group; dissenting views suppressed; alternative courses of action not fully explored.
  - Group polarization - tendency of a group to entertain more risky or extreme solutions to a problem
Common Approaches to Group Decision Making

- Nominal Group Technique
- Consensus Mapping
- Delphi Method
Group Decision Making: Nominal Group

- Group members individually & privately develop ideas or proposed solutions in writing

- Then, each group member in turn shares one item from their list until all ideas/alternatives are publicly recorded (white board, flip chart, etc.) - no criticism or analysis at this stage

- Group engages in discussion/analysis of these options

- Conclude with group members ranking or rating all options – highest ranked option(s) are chosen
Group Decision Making: Nominal Group

- **Pro:** Promotes participation of all team members and considers all ideas

- **Con:** Approach is not very flexible, Not efficient for addressing different ideas about multiple related subjects or problems

- **Best application:** to generate efficient discussion regarding single problem or situation
Group Decision Making: Consensus Mapping

- A facilitator and group reach consensus about how best to arrange or sequence multiple inter-related activities into a useable plan of action

- Example of use for consensus mapping: implementing a new information system department-wide or facility-wide

- Based on expectation of compromise:
  Not everyone gets everything they want out of final decision, but everyone gets a final decision they can support
Group Decision Making: Consensus Mapping

1. Create a master list of all ideas, tasks or projects under consideration

2. Form small groups: 2 to 4 task groups, each 5-9 people
   - Clustering – individuals within the small groups attempt to group the ideas into related clusters or categories.
   - Sub-groups of 2 or 3 people share each other’s clusters
   - Sub-groups merge their individual clusterings into a shared clustering they can all live with

3. Large Group review and re-evaluation of the original ideas, in light of the new clustering activity
Group Decision Making: Consensus Mapping

4. Facilitator(s) create ‘Strawman’ integrated map
   • consolidate the group maps into single overall cluster map, containing all ideas, categories & relationships from small groups
   • Facilitator presents Strawman Map to whole group

5. Map reconfiguration (by Small Group)
   • small task groups reconvene & use Strawman Map to develop their own sequential maps

6. Large Group presentation
   • each small task group shares its map of sequentially linked clusters

7. Map consolidation
   • Representatives from each small group meet to construct one final map that combines features of all maps.
Group Decision Making: Consensus Mapping

- **Pro**: Useful to organize a large number of inter-related or inter-dependent elements into one executable plan

- Each team member has opportunity to provide input and opinions; Solution predicated on the agreement or acceptance of all team members

- **Con**: Works best with a trained, experienced group
Group Decision Making: Delphi Method

- A systematic, interactive forecasting method which relies on a panel of experts

- Originally developed by RAND Corporation in 1950s to forecast impact of technology on warfare
Group Decision Making: Delphi Method

1. Experts answer questionnaires individually in two or more rounds.

2. After each round, a facilitator provides an anonymous summary of the experts’ forecasts from the previous round and any reasons the experts may have provided for their judgments.

3. Then, the experts are encouraged to revise their earlier answers in light of the replies of other members of the panel.
Group Decision Making: Delphi Method

4. The goal is that during the iterative process the range of the answers will decrease and the group opinion will move toward a final answer.

5. The process stops when a pre-defined criterion is reached (e.g. number of rounds, achievement of consensus).

6. The mean or median scores of the final rounds determine the results.
Group Decision Making: Delphi Method

- **Pros:** can be conducted without face to face meetings; can accommodate opinions from a large number of SMEs; can be conducted anonymously (helpful for politically charged issues or groups); minimizes “bandwagon” effect

- **Cons:** Range of opinions are only as diverse as the experts in the group; best written opinions may sway group opinion
Group Decision Making

- Project management decision making
  - Six phase model
  - Phases:
    1. Problem definition
    2. Solution generation (brainstorming)
    3. Ideas to action (evaluate solutions and pick one)
    4. Solution action planning (implement solution)
    5. Solution evaluation planning (evaluate solution)
    6. Evaluation of the outcome and process (evaluate how well problem solved, how well process worked)
### Group Decision Making

**Other methods**

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brainstorming</td>
<td>Collect all ideas from group members regardless of merit. Does not include voting or prioritization. Often used with other techniques.</td>
</tr>
<tr>
<td>Idea/mind mapping</td>
<td>Ideas are visually mapped into parent-child and other relationships to reflect commonality and differences.</td>
</tr>
<tr>
<td>Affinity Diagram</td>
<td>Allows large numbers of ideas to be classified into groups for review. Similar to mind-mapping.</td>
</tr>
<tr>
<td>Multicriteria decision analysis</td>
<td>Uses a decision matrix to provide systematic analytical approach for establishing criteria to evaluate and rank many ideas.</td>
</tr>
<tr>
<td>Process decision program charts (PDPC)</td>
<td>Used to understand goal in relation to steps needed to achieve it. Useful for contingency planning.</td>
</tr>
<tr>
<td>Interrelationship digraphs</td>
<td>Adaptation of relationship diagrams for complex problem solving for up to 50 relevant items; may be developed from other tools.</td>
</tr>
</tbody>
</table>
Question: Which of the following group decision making methods is based on the expectation of compromise?

A. Delphi method  
B. Consensus mapping  
C. Group think  
D. Nominal group
Answer: **Which of the following group decision making methods is based on the expectation of compromise?**

A. Delphi method  
B. Consensus mapping  
C. Group think  
D. Nominal group
MANAGING MEETINGS
Managing Meetings

- Determine if a meeting is the best way to accomplish a specific task or outcome
- Determine venue: face to face versus teleconference versus web-based
- Choose meeting frequency and required attendees wisely
Meeting Preparation

- Develop and distribute clear agenda based on desired goal(s) and outcome(s)
- Identify stakeholders needed to accomplish agenda
- Gather and distribute the materials and “pre-work” needed to accomplish agenda
During the Meeting

• Assign the following responsibilities to one or more members of the group:
  – **Facilitator** (leads the meeting)
  – **Time-keeper** (makes sure that the groups sticks to the times allocated on the agenda)
  – **Scribe** (writes down minutes of meeting)
• Review agenda at the top of the meeting
  – Be clear about why the team is meeting
• Introduce any new members and guests
• Accommodate detours from agenda when needed to meet goal(s)
During the Meeting

- Adhere to your Rules of Operation during meeting
  - Re-direct behaviors that break the ground rules
- Record key points during the meeting (whiteboard, flip chart, shared web-based screen)
- Restate decisions arrived at during meeting
- At meeting end, review action plan
  - Action item
  - Person responsible
  - Date of expected completion
After Each Meeting: Follow-up

- Generate minutes
  - Give opportunity for revision
- Document: Decisions, Tasks and who is responsible, Target dates/deadlines, Next Steps
- Distribute any material you promised during meeting or needed prior to next meeting
- Make arrangements to handoff assignments as needed to any team member who was not present at past meeting
Managing Group Deliberations

• See also in section 4A (Leadership)
  – Negotiation
  – Conflict Management
COMMUNICATIONS
Core Content Covered

4.3 Effective Communications

4.3.1 Effective presentations to groups
4.3.2 Effective one-on-one communication
4.3.3 Writing effectively for various audiences and goals
4.3.4 Developing effective communications program to support system implementation
Key Points

• Communication method depends on audience and other factors

• A comprehensive communication plan is a critical element in any successful information management project plan
Communication

• **Effective communication**
  – Information that is provided...
    • In the *right* format
    • At the *right* time
    • To the *right* audience
    • With the *right* impact

• **Efficient communication**
  – Only providing the information that is needed
Spectra of communications

Internal ↔ external
Formal ↔ informal
Vertical ↔ horizontal
Official ↔ unofficial
Written ↔ oral
Verbal ↔ nonverbal
Model of Communication

Basic Communication Model

- Sender (encodes) message which is sent to Receiver (decoder) (Berlo, 1960)
  - Sender produces message
  - Transmitter encodes message
  - Message transmits (with noise)
  - Receiver decodes message (filters noise)
  - Receiver acknowledges message
  - Feedback (new message) delivered by repeating the process
Successful Communication

Intended Meaning is preserved from sender to receiver
Types of Communication

- Oral
- Written
- Non-verbal (body language, facial expressions, vocal intonation)
Information Richness

• Media Richness Theory, Daft and Lengel, 1984
• Communication channels on spectrum from rich to lean
  – Auditory and non-verbal cues present ↓ Rich
    • Face-to-face (in person; video communication)
    • Least prone to communication error
    • Takes time and can be expensive
  – Audio without non-verbal cues ↓
    • telephone, voice mail, online real-time and IM
  – No audio or non-verbal cues ↓ Lean
    • email, memos, posters, flyers, etc.
    • Most prone to communication error
    • Fast and cheap
## Communication Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
<th>Pros</th>
<th>Cons</th>
<th>Examples</th>
</tr>
</thead>
</table>
| Interactive | Multidirectional exchange of information | • Most efficient way to ensure information was understood by recipients  
• Ensures receipt of information  | • Can ensure understanding of only a limited number of people at one time | • Meetings  
• Phone calls  
• Instant messaging  
• Video conferencing |
| Push    | Information pushed to specific people who need it | • Very efficient distribution | • Does not ensure understanding  
• May not know if message was received | • Letters  
• Reports  
• Faxes  
• Voicemail  
• Blogs  
• Press releases |
| Pull    | Recipients must initiate accessing the information | • Useful for large volumes of information  
• Useful for very large audiences  
• May be able to track who pulled the information  
• May include competency tests to ensure understanding | Recipients may...  
• Not know information exists to get it  
• Not have time (or will) or retrieve the information | • Intranet sites  
• e-learning  
• Knowledge repositories |

- WHAT is the message?
- WHY are you delivering the message? (what prompted message, what outcome do you want)
- WHO do you want to receive the message?
- HOW you choose to deliver the message should be dictated by What, Why, and Who
Preparing an Effective Communication Strategy: What is the Message and Why?

- Clearly identify the message
  - What has brought about need for the message
  - Identify primary point(s) you want to communicate, avoid too many agendas
  - What is the outcome you want to effect with the message
  - Educate your Implementation Team to be consistent with core message
Preparing an Effective Communication Strategy: Who is the Recipient?

- Identify and characterize the target audience – To Whom are you speaking?
  - Individual, Group, Age, Education, Socioeconomic and Cultural factors, Readiness to learn
  - Patients, Colleagues, Clinical, Non-Clinical, Technical, Front-end vs Back end users?
  - Anticipate natural points of resistance
  - Anticipate natural points of confusion

- Choose a Communication Channel suited to type of message and target audience

- Craft the language of the message based on the characteristics of your audience
EFFECTIVE PRESENTATIONS TO GROUPS
Effective Presentations to Groups

- Who is your audience – patients, colleagues, clinical, non-clinical, technical, front-end, back-end
- Choose Setting appropriate to size of audience, Allow adequate time
- Look for ready-made venues (example, already established meeting of the group)
- Cultural Issues (social culture, organizational or corporate culture)
  - Consider historical or recent events, politically or emotionally charged
- Use Rich Channel of Communication; Choose a well-suited messenger
- Practice Sessions with Feedback are advisable
EFFECTIVE ONE-ON-ONE COMMUNICATION
Effective One-on-One Communication

- Who is your one individual recipient?
- Choose setting / time convenient for the recipient
- Use Rich Channel of Communication; Choose a well-suited messenger
- Eye contact
- “On the fly” versus appointment
WRITING EFFECTIVELY
Writing Effectively for Various Audiences and Goals

- Choose wording, language, style appropriate to message and to your audience
- Patient audience: consider that average American comprehends at 8th grade level, some say 5th grade level
- Layout of written messages – simplicity, utility, purpose (technical manual different from general announcement)
- Error check before message goes out – spelling, grammar, typos
- Field test your communication before it goes out
- Written communication = Lean Channel of communication
Communication as it Relates to Change

- Communication of information or data is central to Healthcare practice, practice of Clinical Informatics, and Health IT projects.

- Purpose of communication in all 3 arenas often is to effect change.

- Want your communication to produce intended effect? …Need to understand change theory (so, refer to Change Management Lecture!)
Using Communication as a Central Tool in Change

- Create a compelling message why change needs to occur
- Create and communicate a vision of the change
- Understand and address feedback, the message(s) coming from those affected by change
- Communicate success
Electronic Health Records as a Communication Tool

- Can foster Ubiquitous Communication – communication anywhere, anytime, 24/7
- Simultaneous access to same information (if not same document) by multiple individuals (nurse, doctor, pharmacist, administrative support personnel, patient)
Electronic Health Record - Consequences for Communication

- Decreases human situational awareness, and interpersonal interaction with members of a healthcare team

- Current design not ideal in hectic environments (ER, ICU, code)
  - may require verbal communication, followed by electronic documentation & communication (Stat orders, or orders during emergency situation)

- May not support rapid transitions from one facility to another
  - or even one unit to another in same facility
  - verbal or manual documentation may be faster

- EHR can make or break communication with a patient
  - depending on how provider engages EHR as a third “participant” in the conversation

- Textual documentation in EHR tends to be very “lean”
Electronic Health Records – New Channels of Communication

- Messaging - between support staff and providers; provider & provider; patient & provider

- Hands-free communication devices – voice-activated, so “rich channel” communication; wearable; convenient
When is too much information too bad?

- Too much information → information overload → results in decreased communication
  - alert fatigue
  - decreased signal-to-noise ratio
- Example: erroneous documentation due to indiscriminate importing of too much information (cut and paste errors in EHR documentation)
DEVELOPING AN EFFECTIVE COMMUNICATIONS PROGRAM
Communication Plan

- Pre-defined agreement between parties on communication of information
- Includes
  - Scenario prompting communication (why)
    - Issues, periodic reports, etc.
  - Information to be included (what)
  - Necessary approvals of communication before it is sent
  - Method of communication (how)
  - Persons who will receive the information (who)
  - Timing of communication: immediate vs. periodic (when)
Communication Plan

• Also includes
  – Constraints on communication (who, how, when)
  – Escalation process for urgent issues
  – Change control for the communications plan
  – Flow charts of communication
  – Mechanism for receipt, review and response to feedback

• Stakeholder register (discussed in section 4D Project Mgmt) helps drive development of this document for a project
Question: Planning education and training for both non-clinical and clinical users is a critical component of any Communication Program for Clinical Information Systems Implementation. Training should be made available at the convenience of user, with the least disruption to their workflow. Additionally, the timing of education and training for users of a new clinical information systems should be offered and completed...

A. as early as possible prior to roll out of the new clinical information system to give users a chance to become familiar with the new system long before “go live” implementation
B. only following the roll out of the new system, “after the bugs are worked out,” to prevent wasting staff time
C. prior to roll out of the new system so that staff are prepared to use the new system at “go live” time, but not so early prior to roll out that staff will have forgotten their training on the new system
D. on a timeframe according to seniority of staff, so that staff who have been employed the longest should be trained first
Answer: Planning education and training for both non-clinical and clinical users is a critical component of any Communication Program for Clinical Information Systems Implementation. Training should be made available at the convenience of user, with the least disruption to their workflow. Additionally, the timing of education and training for users of a new clinical information systems should be offered and completed...

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End of Lecture
Answer: Which of the following group decision making methods is based on the expectation of compromise?

A. Delphi method
B. Consensus mapping
C. Group think
D. Nominal group

Consensus Mapping is a Group Decision Making process in which a facilitator and group reach consensus about how best to arrange or sequence multiple inter-related activities into a useable plan of action. The process is based on the expectation of compromise – not everyone is going to get everything they want out of the final decision, but everyone gets a final decision they can support. Group think is not a decision making methods but a concept whereby the opinions of the group are dominated by a single individual or party. The Delphi method is a forecasting method for decision making, and nominal group is a decision making method using multi voting to choose the highest-ranked option for a single decision.
Answer: Planning education and training for both non-clinical and clinical users is a critical component of any Communication Program for Clinical Information Systems Implementation. Training should be made available at the convenience of user, with the least disruption to their workflow. Additionally, the timing of education and training for users of a new clinical information systems should be offered and completed...

C. prior to roll out of the new system so that staff are prepared to use the new system at “go live” time, but not so early prior to roll out that staff will have forgotten their training on the new system

In general, the optimal timing to train users of a newly implemented clinical information system is shortly prior to roll out of the new system, which is considered “just in time” to imprint new learning and for the staff to be confident to use the system at roll-out. Knowledge acquired very early prior to roll out will have extinguished by the time the system goes live, leaving users frustrated at “go live” time. Longevity of employment usually is not a consideration for timing of staff training on use of a new CIS, although timing of training may be role dependent or department dependent if a CIS roll out will be gradual (so train first the users of a department or ward that will go live with the new system first).
References

Free online resources

Building Team Effectiveness

Group Decision Making

Meeting Effectiveness

Other resources (not free)

Human Resource Management

Group Management

Building Team Effectiveness

Meeting Effectiveness
4C – Communication Strategies

References

Free online resources


Communications Support Program for System Implementation


Other resources (not free)

3E-3: Evaluation of Clinical Information Systems

William Hersh, MD, FACP, FACMI
Oregon Health & Science University
Core Content Covered in this Lecture

1. Fundamentals
   1.1. Clinical Informatics
      1.1.1. The discipline of informatics
      1.1.2. Key informatics concepts, models, and theories
      1.1.3. Clinical informatics literature
      1.1.4. International clinical informatics practices
      1.1.5. Ethics and professionalism
      1.1.6. Legal and regulatory issues
   1.2. The Health System
      1.2.1. Determinants of individual and population health
      1.2.2. Primary domains, organizational structures, cultures, and processes
      1.2.3. The flow of data, information, and knowledge within the health system
      1.2.4. Policy & regulatory framework
      1.2.5. Health economics and financing
      1.2.6. Forces shaping health care delivery
      1.2.7. Institute of Medicine quality components

2. Clinical Decision Making and Care Process Improvement
   2.1. Clinical Decision Support
      2.1.1. The nature and cognitive aspects of human decision making
      2.1.2. Decision science
      2.1.3. Application of clinical decision support
      2.1.4. Transformation of knowledge into clinical decision support tools
      2.1.5. Legal, ethical, and regulatory issues
      2.1.6. Quality and safety issues
      2.1.7. Supporting decisions for populations of patients
   2.2. Evidence-based Patient Care
      2.2.1. Evidence sources
      2.2.2. Evidence grading
      2.2.3. Clinical guidelines
      2.2.4. Implementation of guidelines as clinical algorithms
      2.2.5. Information retrieval and analysis
   2.3. Clinical Workflow Analysis, Process Redesign, and Quality Improvement
      2.3.1. Methods of workflow analysis
      2.3.2. Principles of workflow re-engineering
      2.3.3. Quality improvement principles and practices

3. Health Information Systems
   3.1. Information Technology Systems
      3.1.1. Computer Systems
      3.1.2. Architecture
      3.1.3. Networks
      3.1.4. Security
      3.1.5. Data
      3.1.6. Technical approaches that enable sharing data
   3.2. Human Factors Engineering
      3.2.1. Models, theories, and practices of human-computer (machine) interaction (HCI)
      3.2.2. HCI Evaluation, usability testing, study design and methods
      3.2.3. Interface design standards and design principles
      3.2.4. Usability engineering
      3.3. Health Information Systems and Applications
         3.3.1. Types of functions offered by systems
         3.3.2. Types of settings where systems are used
         3.3.3. Electronic health/medical records systems as the foundational tool
      3.4. Telemedicine
      3.5. Information System Lifecycle
         3.5.1. Institutional governance of clinical information systems
         3.5.2. Clinical information needs analysis and system selection
         3.5.3. Clinical information system implementation
         3.5.4. Clinical information system testing, before, during and after implementation
         3.5.5. Clinical information system maintenance

4. Leading and Managing Change
   4.1. Leadership Models, Processes, and Practices
      4.1.1. Dimensions of effective leadership
      4.1.2. Governance
      4.1.3. Negotiation
      4.1.4. Conflict management
      4.1.5. Collaboration
      4.1.6. Motivation
      4.1.7. Decision making
   4.2. Effective Interdisciplinary Teams
      4.2.1. Human resources management
      4.2.2. Team productivity and effectiveness
      4.2.3. Group management processes
      4.2.4. Managing meetings
      4.2.5. Managing group deliberations
      4.3. Effective Communications
      4.3.1. Effective presentations to groups
      4.3.2. Effective one-on-one communication
      4.3.3. Writing effectively for various audiences and goals
      4.3.4. Developing effective communications program to support system implementation
   4.4. Project Management
      4.4.1. Basic principles
      4.4.2. Identifying resources
      4.4.3. Resource allocation
      4.4.4. Project management tools (non-software specific)
      4.4.5. Informatics project challenges
   4.5. Strategic and Financial Planning for Clinical Information Systems
      4.5.1. Establishing mission and objectives
      4.5.2. Environmental scanning
      4.5.3. Strategy formulation
      4.5.4. Action planning and strategy implementation
      4.5.5. Capital and operating budgeting
      4.5.6. Principles of managerial accounting
      4.5.7. Evaluation of planning process
   4.6. Change Management
      4.6.1. Assessment of organizational culture and behavior
      4.6.2. Change theories
      4.6.3. Change management strategies
      4.6.4. Strategies for promoting adoption and effective use of clinical information systems
Core content covered

3.5.6. Clinical information system evaluation

3.5.6.1 Outcomes relevant to the clinical goals and quality measures

3.5.6.2 Qualitative and quantitative methods for evaluating clinical information systems

3.5.6.3 Evaluation plan design
Key topics

• Measurement of usage, outcomes, and cost of clinical information systems
• Quantitative research methods
• Qualitative research methods
• Actionable evaluation research in operational settings
3E-3: Evaluation of Clinical Systems

• Clinical information system evaluation goals and measures
• Quantitative and qualitative evaluation methods
Evaluation goals and measures

- Usage – proportion of users
- Outcomes – measures of various clinical, operational, and other outcomes
- Cost – costs and cost-benefit
Usage

• Studies in different settings
  – Ambulatory
  – Hospital
  – International comparisons
Office-based usage growth over time (DesRoches, 2015)
International comparisons

(Osborn, 2015)
EHR adoption in US hospitals

- Nearly all US hospitals have adopted certified EHRs (Charles, 2015)
- About 95% of US hospitals achieved MU Stage 1 by end of 2015 but Stage 2 has been more difficult (Adler-Milstein, 2015)
HIMSS Analytics EMR Adoption Model (EMRAM)

<table>
<thead>
<tr>
<th>STAGE</th>
<th>CUMULATIVE CAPABILITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 7</td>
<td>Complete EMR, Data Analytics to Improve Care</td>
</tr>
<tr>
<td>Stage 6</td>
<td>Physician documentation (templates), full CDSS, Closed loop medication administration</td>
</tr>
<tr>
<td>Stage 5</td>
<td>Full R-PACS</td>
</tr>
<tr>
<td>Stage 4</td>
<td>CPOE, Clinical Decision Support (clinical protocols)</td>
</tr>
<tr>
<td>Stage 3</td>
<td>Clinical documentation, CDSS (error checking)</td>
</tr>
<tr>
<td>Stage 2</td>
<td>CDR, Controlled Medical Vocabulary, CDS, HIE capable</td>
</tr>
<tr>
<td>Stage 1</td>
<td>Ancillaries - Lab, Rad, Pharmacy - All Installed</td>
</tr>
<tr>
<td>Stage 0</td>
<td>All Three Ancillaries Not Installed</td>
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<tr>
<th>STAGE</th>
<th>2015 Q3</th>
<th>2015 Q4</th>
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<tr>
<td>Stage 0</td>
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</table>

[www.himssanalytics.com](http://www.himssanalytics.com)
We’ve come a long way!

<table>
<thead>
<tr>
<th>Stage</th>
<th>Requirement</th>
<th>2006 Final</th>
<th>2007 Final</th>
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<tbody>
<tr>
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<td>Medical record fully electronic; CDO able to contribute to EHR as byproduct of EMR</td>
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<td>0.0%</td>
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<tr>
<td>Stage 6</td>
<td>Physician documentation (structured templates), full CDSS (variance &amp; compliance), full R-PACS</td>
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<td>0.8%</td>
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<td>Stage 5</td>
<td>Closed loop medication administration</td>
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<td>1.4%</td>
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<tr>
<td>Stage 4</td>
<td>CPOE, CDSS (clinical protocols)</td>
<td>3.0%</td>
<td>2.2%</td>
</tr>
<tr>
<td>Stage 3</td>
<td>Clinical documentation (flow sheets), CDSS (error checking), PACS available outside Radiology</td>
<td>18.0%</td>
<td>25.1%</td>
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<tr>
<td>Stage 2</td>
<td>CDR, CMV, CDSS inference engine, may have Document Imaging</td>
<td>38.8%</td>
<td>37.2%</td>
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<td>Stage 1</td>
<td>Ancillaries – Lab, Rad, Pharmacy – All Installed</td>
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<td>All Three Ancillaries Not Installed</td>
<td>20.7%</td>
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Outcomes

• Series of systematic reviews (Chaudhry, 2006; Goldzweig, 2009; Buntin, 2011; Jones, 2014) have identified benefits in a variety of areas
  • Increasing studies moving beyond “health IT leaders” to using commercial systems

(Buntin, 2011) (Jones, 2014)
Qualitative research

• Qualitative studies, sometimes “triangulated” with other data, seek to uncover themes, interactions, and other observations of people and/or organizations (Ash, 2008)

• Some well-known results include
  – Importance of “special people” (Ash, 2003)
  – “Unintended consequences” of EHR systems (Ash, 2004) and CPOE (Campbell, 2006)
  – Mixed results from the UK National Program for HIT (Hendy, 2007; Greenhalgh, 2010)
EHR challenges

- Systematic review of EHR usability studies found problems of usability, effective information presentation, and lack of error prevention, minimization of cognitive load, and adequate feedback (Zahabi, 2015)
- Commercial EHR systems have deficiencies in adequate displays in graphical display of diagnostic test results (Sittig, 2015)
- Vendors do not consistently apply state-of-art user-centered design principles (Ratwani, 2015)
- In safety net clinics, decreased patient satisfaction in those implementing EHRs, attributed to increased attention to computer (Ratanawongsa, 2016)
- Survey of internists found 60% reported time loss with use of EHR, with estimated average time loss of 48 minutes per day for attending physicians and 18 minutes per day for trainees (McDonald, 2014)
- Emergency physicians found to spend 43% of time on data entry, making around 4000 clicks in 10-hour shift (Hill, 2013)
Costs

• Challenging to measure with different technologies, healthcare reimbursement models, etc.

• Some notable findings over the years
  – In outpatient settings, practices only get 11% of return on investment, with rest going to labs and insurers (Johnston, 2003)
  – Models of health information exchange show benefit (Pan, 2004; Hillestad, 2005), but have yet to yield benefits in reality (Kellermann, 2013)
Evaluation of systems is important on several levels

• Helping us experts determine what works best
• Allowing users (including organizations) to cut through the hype and decide what works for them
• Justifying the cost and/or making cost comparisons
General research

• Friedman and Wyatt (2014) – two broad approaches
  – Quantitative (objectivist)
    • Most common approach is comparative
  – Qualitative (subjectivist)

• Einstein (attributed): Not everything that can be counted counts and not everything that counts can be counted
General approach to comparative research

• Choose a research question and a population
• Select a sample from population
• Determine variables to measure
  – Dependent or outcome – measure difference
  – Independent or predictor – explain difference
• Randomize sample to experimental or control group
• Results show either truth or error
Experimental error

• Error can be due to bias or chance
• Bias is systematic error introduced by experiment whereas chance is random error
• Bias can be due to
  – Selection – e.g., subjects different
  – Measurement – e.g., measures applied differently
  – Confounders – other factor(s) cause differences
Other types of bias

- **Assessment bias**
  - Subjects allow feeling towards system influence their performance with it

- **Allocation bias**
  - Randomization “cheated” inadvertently or purposefully

- **Hawthorne effect**
  - Humans try harder when they know they are being observed (Hawthorne Factory, 1939)

- **Checklist effect**
  - Decision-making more complete with checklists
Chance

• Results obtained by chance
  – Minimized by statistical analysis
  – Two types of statistical error
    • Alpha – difference represents chance event
      – p value measures probability results are due to chance, aim to be < 0.05
    • Beta – there is an actual difference when none is detected, usually due to small sample size
      – Statistical power measures ability to detect a statistically significant difference
Validity

• Internal validity
  – Experimental methodology must be sound by avoiding bias and chance error

• External validity
  – Experimental results must have generalizability to real world and “clinical” significance
Some subjectivist research methods

• Ethnography
  – Observe users in their natural environment

• Focus groups
  – Convene individuals for focused discussion

• Usability studies
  – Give users tasks and watch what they do

• Protocol analysis
  – Ask users to “think aloud”
“Actionable” qualitative research approach (Ash, 2008)

• Tools and data collection include
  – Site inventory profiles
  – Ethnography guides
  – Interview question guides
  – Rapid survey instruments

• Has been successfully deployed for evaluation of clinical decision support (Ash, 2012) and EHR safety (Singh, 2013)

• Has led to elucidation of “unintended consequences” of HIT (Ash, 2004; Ash, 2009)
Additional suggested readings

• Key

• Supplemental


Johnston, D, Pan, E, et al. (2003). The Value of Computerized Provider Order Entry in Ambulatory Settings. Boston, MA, Center for Information Technology Leadership

Kellermann, AL and Jones, SS (2013). What will it take to achieve the as-yet-unfulfilled promises of health information technology? *Health Affairs*. 32: 63-68.


