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3D – Evaluation of Clinical Information Systems

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Clinical Informatics Board Review Course

Clinical Informatics Subspecialty Delineation of Practice (CIS DoP)

Domain 1: Fundamental Knowledge and Skills (no Tasks are associated with this Domain which is focused on fundamental knowledge and skills)

Clinical Informatics

K001. The discipline of informatics (e.g., definitions, history, careers, professional organizations)
K002. Fundamental informatics concepts, models, and theories
K003. Core clinical informatics literature (e.g., foundational literature, principle journals, critical analysis of literature, use of evidence to inform practice)
K004. Descriptive and inferential statistics
K005. Health Information Technology (HIT) principles and science
K006. Computer programming fundamentals and computational thinking
K007. Basic systems and network architectures
K008. Basic database structure, data retrieval and analytics techniques and tools
K009. Development and use of interoperability/exchange standards (e.g., Fast Health Interoperability Resources [FHIR], Digital Imaging and Communications in Medicine [DICOM])
K010. Development and use of transaction standards (e.g., American National Standards Institute X12)
K011. Development and use of messaging standards (e.g., Health Level Seven [HL7] v2)
K012. Development and use of ancillary data standards (e.g., imaging and Laboratory Information System[LIS])
K013. Development and use of data model standards
K014. Vocabularies, terminologies, and nomenclatures (e.g., Logical Observation Identifiers Names and Codes [LOINC], Systematized Nomenclature of Medicine --Clinical Terms [SNOMED-CT], RxNorm, International Classification Of Diseases[ICD], Current Procedural Terminology [CPT])
K015. Data taxonomies and ontologies
K016. Security, privacy, and confidentiality requirements and practices
K017. Legal and regulatory issues related to clinical data and information sharing
K018. Technical and non-technical approaches and barriers to interoperability
K019. Ethics and professionalism

The Health System

K020. Primary domains of health, organizational structures, cultures, and processes (e.g., health care delivery, public health, personal health, population health, education of health professionals, clinical research)
K021. Determinants of individual and population health
K022. Forces shaping health care delivery and considerations regarding health care access
K023. Health economics and financing
K024. Policy and regulatory frameworks related to the healthcare system
K025. The flow of data, information, and knowledge within the health system

Domain 2: Improving Care Delivery and Outcomes

K026. Decision science (e.g., Bayes theorem, decision analysis, probability theory, utility and preference assessment, test characteristics)
K027. Clinical decision support standards and processes for development, implementation, evaluation, and maintenance
K028. Five Rights of clinical decision support (i.e., information, person, intervention formats, channel, and point/time in workflow)
K029. Legal, regulatory, and ethical issues regarding clinical decision support
K030. Methods of workflow analysis
K031. Principles of workflow re-engineering
K032. Quality improvement principles and practices (e.g., Six Sigma, Lean, Plan-Do-Study-Act [PDSA] cycle, root cause analysis)
K033. User-centered design principles (e.g., iterative design process)
K034. Usability testing
K035. Definitions of measures (e.g., quality performance, regulatory, pay for performance, public health surveillance)
K036. Measure development and evaluation processes and criteria
K037. Key performance indicators (KPIs)
K038. Claims analytics and benchmarks
K039. Predictive analytic techniques, indications, and limitations
K040. Clinical and financial benchmarking sources (e.g., Gartner, Healthcare Information and Management Systems Society [HIMSS] Analytics, Centers for Medicare and Medicaid Services [CMS], Leapfrog)
K041. Quality standards and measures promulgated by quality organizations (e.g., National Quality Forum [NQF], Centers for Medicare and Medicaid Services [CMS], National Committee for Quality Assurance [NCQA])
K042. Facility accreditation quality and safety standards (e.g., The Joint Commission, Clinical Laboratory Improvement Amendments [CLIA])
K043. Clinical quality standards (e.g., Physician Quality Reporting System [PQRS], Agency for Healthcare Research and Quality [AHRQ], National Surgical Quality Improvement Program [NSQIP], Quality Reporting Document Architecture [QRDA], Health Quality Measure Format [HQMF], Council on Quality and Leadership [CQL], Fast Health Interoperability Resources [FHIR] Clinical Reasoning)
K044. Reporting requirements
K045. Methods to measure and report organizational performance
K046. Adoption metrics (e.g., Electronic Medical Records Adoption Model [EMRAM], Adoption Model for Analytics Maturity [AMAM])
K047. Social determinants of health
K048. Use of patient-generated data
K049. Prediction models
K050. Risk stratification and adjustment
K051. Concepts and tools for care coordination
K052. Care delivery and payment models

Domain 3: Enterprise Information Systems

K053. Health information technology landscape (e.g., innovation strategies, emerging technologies)
K054. Institutional governance of clinical information systems
K055. Information system maintenance requirements
K056. Information needs analysis and information system selection
K057. Information system implementation procedures
K058. Information system evaluation techniques and methods
K059. Information system and integration testing techniques and methodologies
K060. Enterprise architecture (databases, storage, application, interface engine)
K061. Methods of communication between various software components
K062. Network communications infrastructure and protocols between information systems (e.g., Transmission Control Protocol/Internet Protocol [TCP/IP], switches, routers)
K063. Types of settings (e.g., labs, ambulatory, radiology, home) where various systems are used
K064. Clinical system functional requirements
K065. Models and theories of human-computer (machine) interaction (HCI)
K066. HCI evaluation, usability engineering and testing, study design and methods
K067. HCI design standards and design principles
K068. Functionalities of clinical information systems (e.g., Electronic Health Records [EHR], Laboratory Information System [LIS], Picture Archiving and Communication System [PACS], Radiology Information System [RIS] vendor-neutral archive, pharmacy, revenue cycle)
K069. Consumer-facing health informatics applications (e.g., patient portals, mobile health apps and devices, disease management, patient education, behavior modification)
K070. User types and roles, institutional policy and access control
K071. Clinical communication channels and best practices for use (e.g., secure messaging, closed loop communication)
K072. Security threat assessment methods and mitigation strategies
K073. Security standards and safeguards
K074. Clinical impact of scheduled and unscheduled system downtimes
K075. Information system failure modes and downtime mitigation strategies (e.g., replicated data centers, log shipping)
K076. Approaches to knowledge repositories and their implementation and maintenance
K077. Data storage options and their implications
K078. Clinical registries
K079. Health information exchanges
K080. Patient matching strategies
K081. Master patient index
K082. Data reconciliation
K083. Regulated medical devices (e.g., pumps, telemetry monitors) that may be integrated into information systems
K084. Non-regulated medical devices (e.g., consumer devices)
K085. Telehealth workflows and resources (e.g., software, hardware, staff)

Domain 4: Data Governance and Data Analytics

K086. Stewardship of data
K087. Regulations, organizations, and best practice related to data access and sharing agreements, data use, privacy, security, and portability
K088. Metadata and data dictionaries
K089. Data life cycle
K090. Transactional and reporting/research databases
K091. Techniques for the storage of disparate data types
K092. Techniques to extract, transform, and load data
K093. Data associated with workflow processes and clinical context
K094. Data management and validation techniques
K095. Standards related to storage and retrieval from specialized and emerging data sources
K096. Types and uses of specialized and emerging data sources (e.g., imaging, bioinformatics, internet of things (IoT), patient-generated, social determinants)
K097. Issues related to integrating emerging data sources into business and clinical decision making
K098. Information architecture
K099. Query tools and techniques
K100. Flat files, relational and non-relational/NoSQL database structures, distributed file systems
K101. Definitions and appropriate use of descriptive, diagnostic, predictive, and prescriptive analytics
K102. Analytic tools and techniques (e.g., Boolean, Bayesian, statistical/mathematical modeling)
K103. Advanced modeling and algorithms
K104. Artificial intelligence
K105. Machine learning (e.g., neural networks, support vector machines, Bayesian network)
K106. Data visualization (e.g., graphical, geospatial, 3D modeling, dashboards, heat maps)
K107. Natural language processing
K108. Precision medicine (customized treatment plans based on patient-specific data)
K109. Knowledge management and archiving science
K110. Methods for knowledge persistence and sharing
K111. Methods and standards for data sharing across systems (e.g., health information exchanges, public health reporting)

Domain 5: Leadership and Professionalism

K112. Environmental scanning and assessment methods and techniques
K113. Consensus building, collaboration, and conflict management
K114. Business plan development for informatics projects and activities (e.g., return on investment, business case analysis, pro forma projections)
K115. Basic revenue cycle
K116. Basic managerial/cost accounting principles and concepts
K117. Capital and operating budgeting
K118. Strategy formulation and evaluation
K119. Approaches to establishing Health Information Technology (HIT) mission and objectives
K120. Communication strategies, including one-on-one, presentation to groups, and asynchronous communication
K121. Effective communication programs to support and sustain systems implementation
K122. Writing effectively for various audiences and goals
K123. Negotiation strategies, methods, and techniques
K124. Conflict management strategies, methods, and techniques
K125. Change management principles, models, and methods
K126. Assessment of organizational culture and behavior change theories
K127. Theory and methods for promoting the adoption and effective use of clinical information systems
K128. Motivational strategies, methods, and techniques
K129. Basic principles and practices of project management
K130. Project management tools and techniques
K131. Leadership principles, models, and methods
K132. Intergenerational communication techniques
K133. Coaching, mentoring, championing and cheerleading methods
K134. Adult learning theories, methods, and techniques
K135. Teaching modalities for individuals and groups
K136. Methods to assess the effectiveness of training and competency development
K137. Principles, models, and methods for building and managing effective interdisciplinary teams
K138. Team productivity and effectiveness (e.g., articulating team goals, defining rules of operation, clarifying individual roles, team management, identifying and addressing challenges)
K139. Group management processes (e.g., nominal group, consensus mapping, Delphi method)

Knowledge Statements from the DoP

K004. Descriptive and inferential statistics

K058. Information system evaluation techniques and methods

3E-3: Evaluation of Clinical Systems

Descriptive and inferential statistics

- Something you can learn in a short lecture (this), course, or degree (even a PhD!)
- For board exam, probably most important to understand major concepts

Information system evaluation techniques and methods

Descriptive and inferential statistics

Descriptive statistics

- Summarize and graph data for a group
- Allows understanding of a specific set of observations

Inferential statistics

- Takes data from a sample and makes inferences about the larger population from which sample was drawn
- Goal is to draw conclusions from sample and generalize them to a population
- Need to have confidence that sample accurately reflects the population

Descriptive statistics

Describes a sample; does not attempt to generalize to a population

Common measures

- Central tendency: Use the mean or the median to locate the center of the dataset. This measure tells you where most values fall.
- Dispersion: How far out from the center do the data extend? You can use the range or standard deviation to measure the dispersion. A low dispersion indicates that the values cluster more tightly around the center. Higher dispersion signifies that data points fall further away from the center. We can also graph the frequency distribution.
- Skewness tells you whether the distribution of values is symmetric or skewed

Measures can be presented as numbers or graphically

Inferential statistics

Because the goal of inferential statistics is to draw conclusions from a sample and generalize them to a population, we need to have confidence that our sample accurately reflects the population. This requirement affects our process.

At a broad level, we must do the following:

1. Define the population we are studying
2. Draw a representative sample from that population
3. Use analyses that incorporate the sampling error

Methodologies of inferential statistics

Hypothesis tests

Confidence intervals

Regression analysis

All can produce similar summary values as descriptive statistics, such as the mean and standard deviation but used very differently when making inferences.

Information system evaluation techniques and methods

Methods

Results

Well-known references from informatics

- Friedman and Wyatt textbook - current 2nd edition somewhat dated (2006); 3rd coming in 2022
- Friedman and Wyatt chapter in Shortliffe textbook (2021)

General research methods

Friedman and Wyatt (2021) – 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 qualitative (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 health IT (Ash, 2004; Ash, 2009)

Evaluation results

Usage – proportion of users

Outcomes – measures of various clinical, operational, and other outcomes

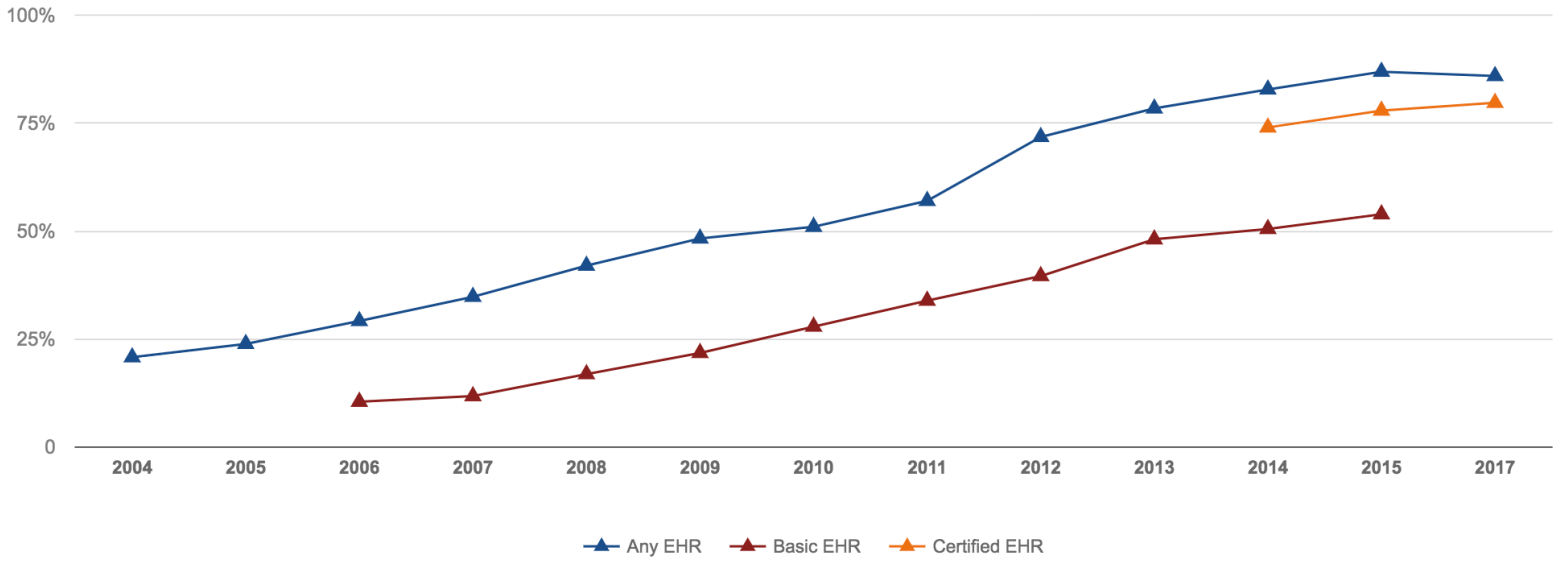
Example: EHR usage

Studies in different settings

- Ambulatory
- Hospital

Of note: few recent studies

Office-based usage growth over time



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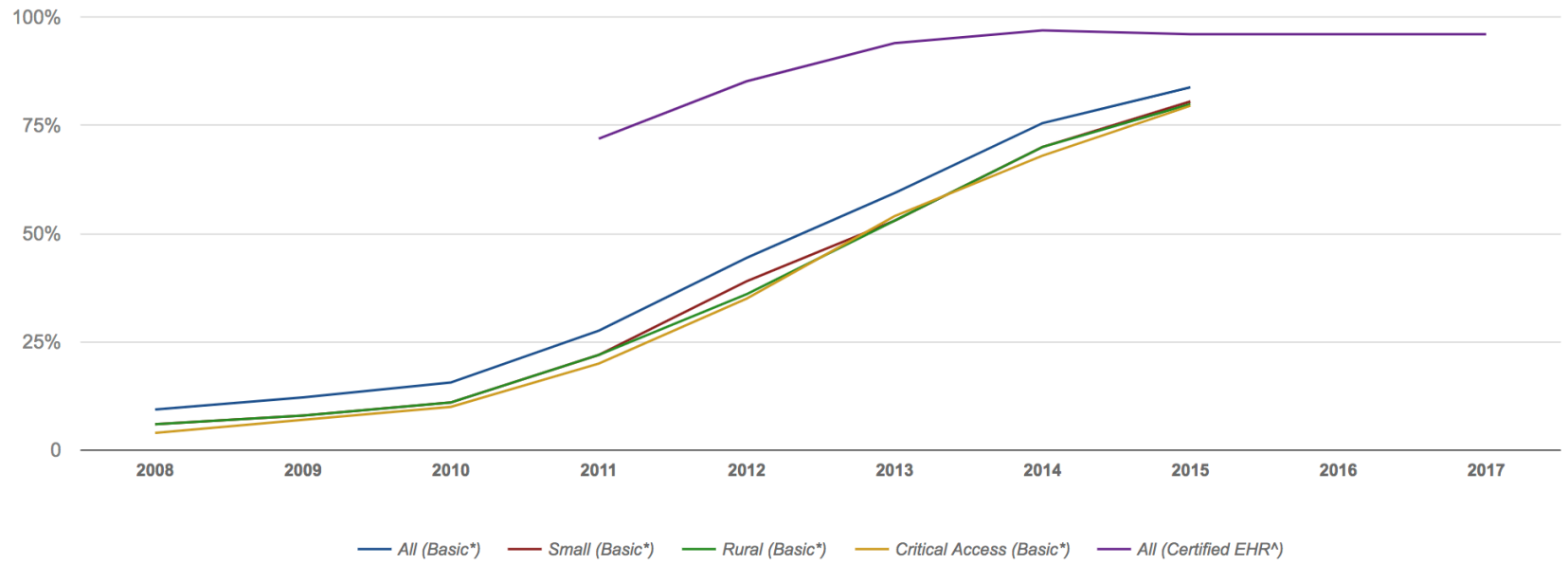
EHR adoption in US hospitals



https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php

HIMSS Analytics EMR Adoption Model (EMRAM)

United States EMR Adoption Model SM	
Stage	Cumulative Capabilities
Stage 7	Complete EMR; CCD transactions to share data; Data warehousing; Data continuity with ED, ambulatory, OP
Stage 6	Physician documentation (structured templates), full CDSS (variance & compliance), full R-PACS
Stage 5	Closed loop medication administration
Stage 4	CPOE, Clinical Decision Support (clinical protocols)
Stage 3	Nursing/clinical documentation (flow sheets), CDSS (error checking), PACS available outside Radiology
Stage 2	CDR, Controlled Medical Vocabulary, CDS, may have Document Imaging; HIE capable
Stage 1	Ancillaries - Lab, Rad, Pharmacy - All Installed
Stage 0	All Three Ancillaries Not Installed

STAGE	2017 Q2	2017 Q3
7	5.3%	6.1%
6	32.4%	32.7%
5	34.1%	33.5%
4	9.8%	10.1%
3	13.1%	12.6%
2	1.9%	1.9%
1	1.6%	1.5%
0	1.8%	1.6%
	N:5,478	N: 5,480

www.himssanalytics.com

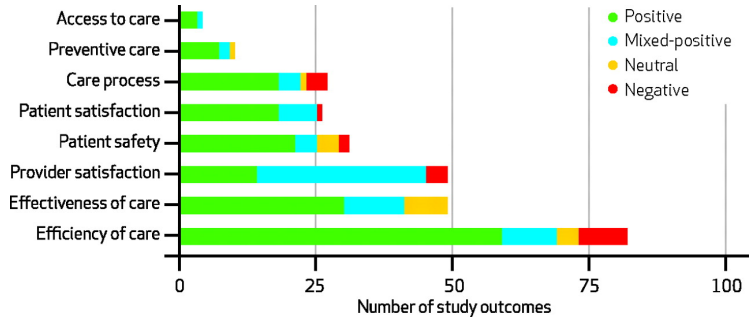
We've come a long way!

		2006 Final	2007 Final
Stage 7	Medical record fully electronic; CDO able to contribute to EHR as byproduct of EMR	0.0%	0.0%
Stage 6	Physician documentation (structured templates), full CDSS (variance & compliance), full R-PACS	0.1%	0.8%
Stage 5	Closed loop medication administration	0.5%	1.4%
Stage 4	CPOE, CDSS (clinical protocols)	3.0%	2.2%
Stage 3	Clinical documentation (flow sheets), CDSS (error checking), PACS available outside Radiology	18.0%	25.1%
Stage 2	CDR, CMV, CDSS inference engine, may have Document Imaging	38.8%	37.2%
Stage 1	Ancillaries – Lab, Rad, Pharmacy – All Installed	18.9%	14.0%
Stage 0	All Three Ancillaries Not Installed	20.7%	19.3%

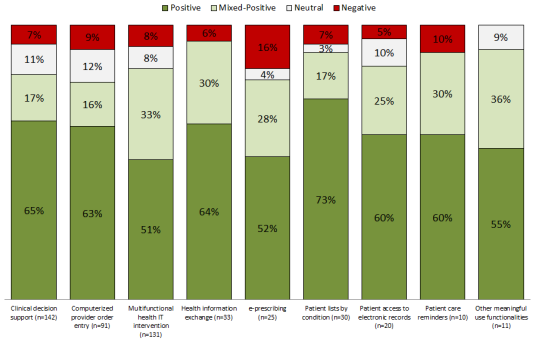
EHR outcomes

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 (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)

EHR challenges (cont'd)

Time-motion study of 57 outpatient physicians (Sinsky, 2016)

- 27% of time with patients and 49% with EHR and desk work
- In exam room, 53% direct clinical face time and 37% EHR and desk work
- About one-third reported 1-2 hours after work each night of mostly EHR tasks

EHR time-stamp log study of 471 physicians (Tai-Seale, 2017)

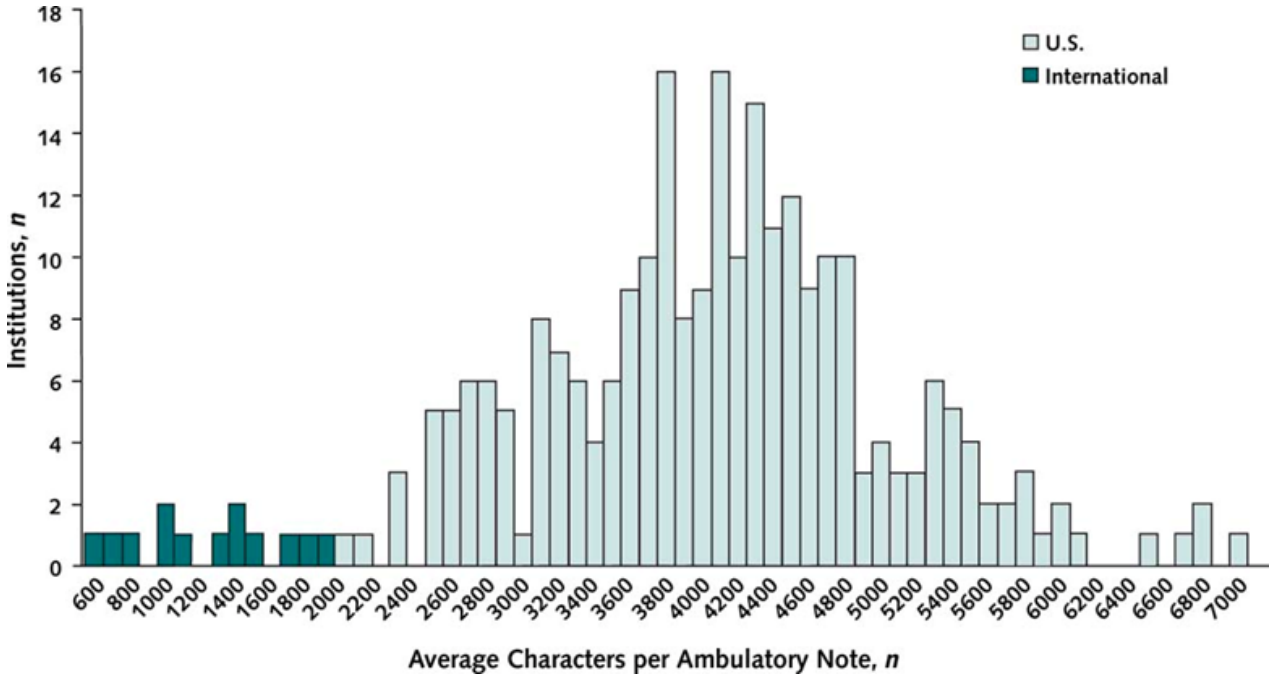
- 3.1 hours on office visits and 3.2 hours on desktop medicine each day
- Desktop medicine included interaction with patients
- Over 2011-2014, decline in visit and increase in desktop medicine

Major contributor to physician burnout (Gardner, 2019)

Physicians have always spent majority of time in "indirect care" (Tipping, 2010), but how much is too much?

- Mamlin (1973) found about 45% of time spent in indirect care of patients

Some EHR problems unique to US (Downing, 2018)



Evaluation of systems is important on several levels

Helping us experts determine what works best

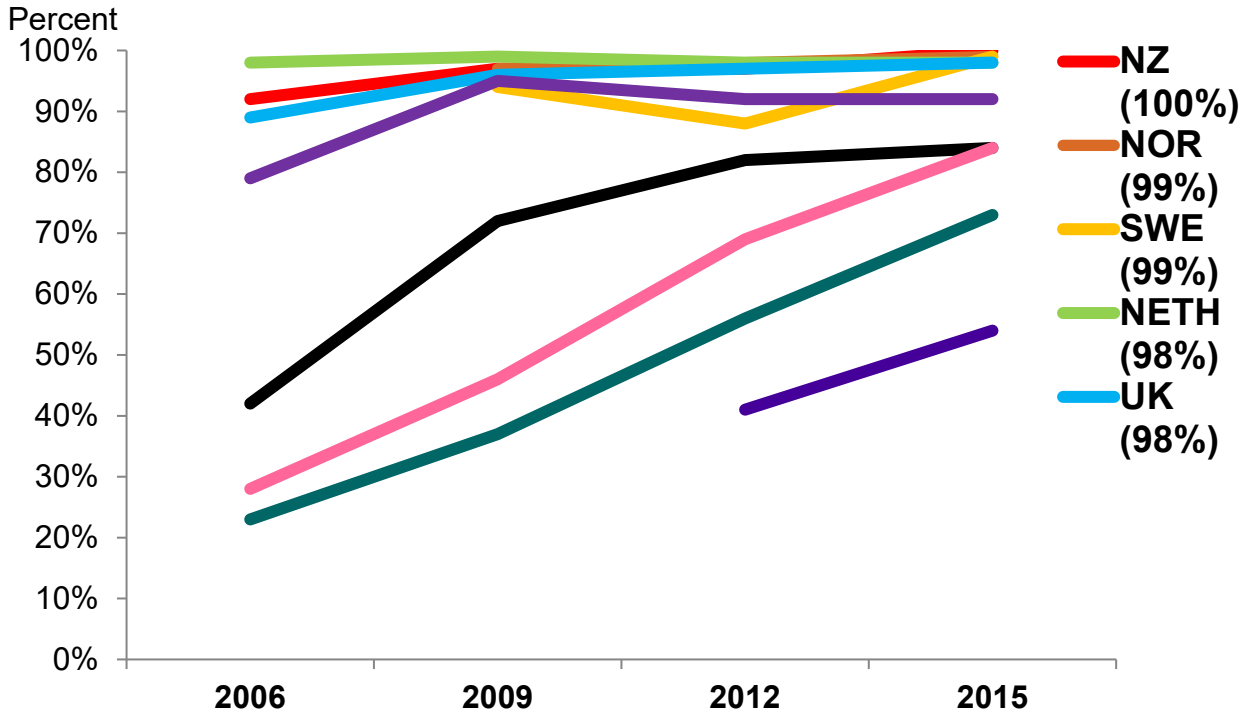
Allowing users (including organizations) to cut through the hype and decide what works for them

Justifying the cost and/or making cost comparisons

Appendix

Examples and additional information

International comparisons (Osborn, 2015)



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)
- Lowered costs from hospital implementation before and after EHR implementation (Zlabek, 2011)

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