The Clinical Impact of Clinical Informatics

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The Clinical Impact of Clinical Informatics

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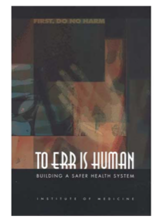
The clinical impact of clinical informatics

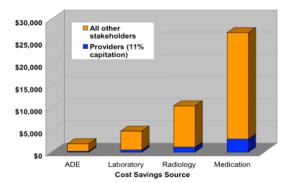
- Questions to ask
  - How did we get here?
  - Where are we now?
  - What does the future portend?
  - Are these still relevant in the era of COVID-19?

- Disclosure – Research support from Alnylam Pharmaceuticals

What a difference a decade makes – era of healthcare improvement

- Safety
  - IOM “errors report” documented 48-96K deaths per year due to medical errors (Kohn, 2000)
- Quality
  - Patients receive appropriate care only 55% of time (McGlynn, 2003)
- Access to information
  - Physicians unable to access known information about patients in 44% of ambulatory visits (Smith, 2005)
- Cost
  - Not only does US have highest costs, but
    - Electronic health records (EHRs) cost-effective overall, but benefits not accruing to those investing (Johnston, 2003)
    - Widespread interoperable EHRs could save $77B per year (Hillestad, 2005)
- Opportunities for the “tribes” of healthcare improvement (McKethan, 2010)





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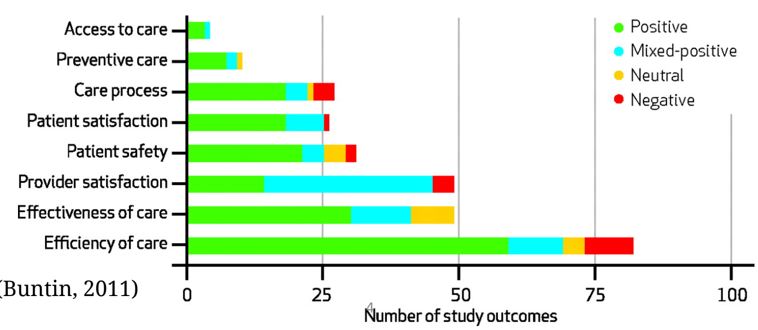
Based on evidence that information interventions part of solution

- Systematic reviews (Chaudhry, 2006; Goldzweig, 2009; Buntin, 2011)
  - Identified benefits in variety of areas, although
    - Quality of many studies suboptimal
    - Large number of early studies came from a small number of “health IT leader” institutions



(Buntin, 2011)

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And then a perfect storm of recession and healthcare reform

"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

American Recovery and Reinvestment Act (ARRA) allocated $30 billion in incentives for adoption of EHRs

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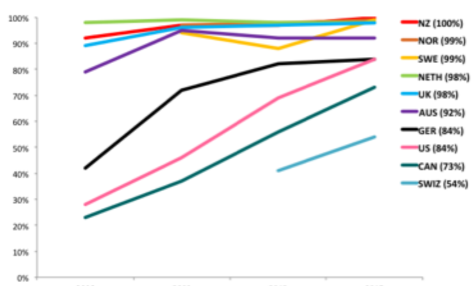
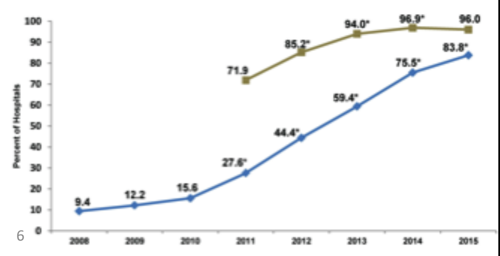
Leading us to where we are now



(Osborn, 2015)

(Henry, 2016)



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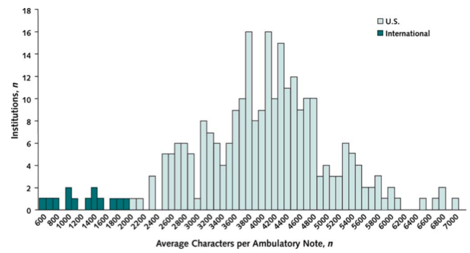
But not without challenges


Death By 1,000 Clicks: Where Electronic Health Records Went Wrong

The U.S. government claimed that turning American medical charts into electronic records would make health care better, safer, and cheaper. Ten years and $36 billion later, the system is an unholy mess. Inside a digital revolution that took a bad turn.

By Fred Schulte and Erika Fry, Fortune • MARCH 18, 2019



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Combined Time-Motion and Work Sampling Study In A General Medicine Clinic

JOSEPH J. MAMLIN, M.D.,* AND DUKE H. BAKER, M.D.†

(Mamlin, 1973; Toll, 2012; Downing, 2018; Schulte, 2019)

Are there still promises for clinical informatics?

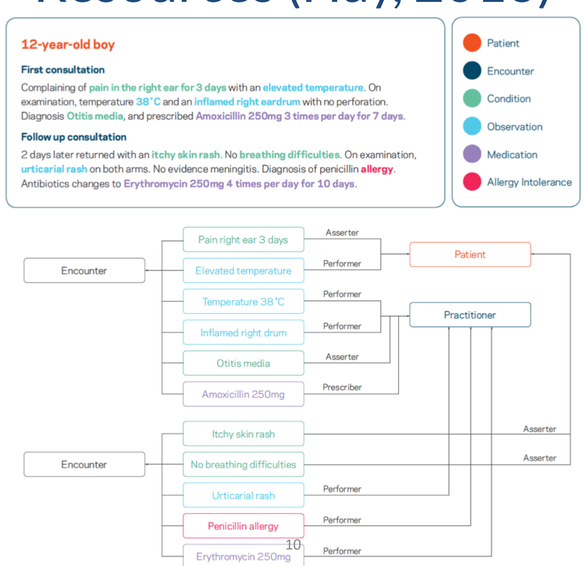
- Yes!

- Clinical data interoperability
- Machine learning and artificial intelligence
- Opportunities for physicians (and others) in clinical informatics

Another shortcoming of HITECH was poor interoperability

- Many re-uses (or secondary uses) of EHR data not primarily collected for research (Safran, 2007)
  - ”Computational” re-uses of data require standardized data and terminology
- Emergence of new standard
  - Fast Healthcare Interoperability Resources (FHIR)
  - http://hl7.org/fhir/
- 21st Century Cures Act
  - “Correction” of interoperability and other EHR improvements (Mandl, 2017)

From patient story to FHIR Resources (Hay, 2016)

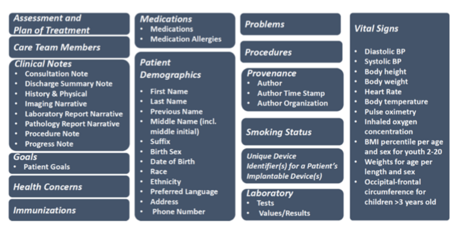


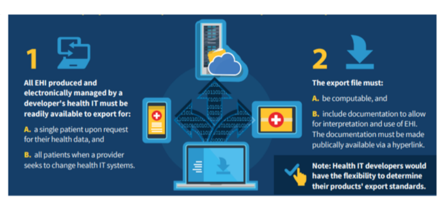
Substitutable Medical Apps, reusable technologies (SMART)

- Based on paradigm of "apps" accessing a common data store (Mandl, 2015)
- Initial uptake modest but took off when combined with FHIR (Mandel, 2016)
  - SMART on FHIR – https://smarthealthit.org/
- New paradigm of EHR as "operating systems" with apps on top?

Getting new push in 21st Century Cures Act

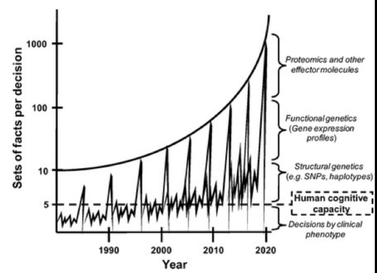
- EHR certification will require
  - FHIR-based access to all data elements
  - Open APIs
  - Easy export of data for patients and systems
  - No gag clauses or information blocking





Medicine is increasingly (and maybe always has been) a “data science”

- Data quantity overwhelming
  - Average pediatric ICU patient generates 1348 information items per 24 hours (Manor-Shulman, 2008)
  - Average hospital admission has 137,882 tokens (discrete pieces of data), which increased to 216,744 at discharge (Rajkomar, 2018)
- Clinicians challenged keeping up with knowledge
  - Average of 75 clinical trials and 11 systematic reviews published each day (Bastian, 2010)
- Data points per clinical decision increasing (Stead, 2011)
  - Especially in era of precision medicine (NEJM, 2019)



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Role of machine learning and artificial intelligence

- Data science
  - “The science of learning from data; it studies the methods involved in the analysis and processing of data and proposes technology to improve methods in an evidence-based manner” (Donoho, 2017)
- Machine learning (ML)
  - Ability of computer programs to learn without being explicitly programmed (McCarthy, 1990)
- Neural networks
  - Current most successful approaches for ML
  - When use deep layers, called deep learning (Esteva, 2019)
- Artificial intelligence (AI)
  - Older term referring to information systems and algorithms capable of performing tasks associated with human intelligence (Maddox, 2018; Topol, 2019)

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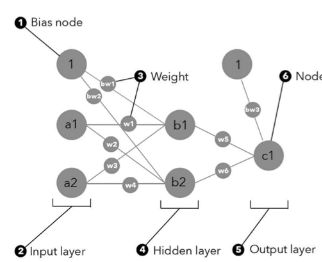
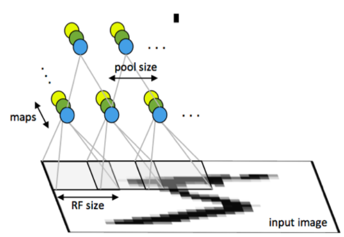
First era of AI was mostly a failure

- Focus on human-engineered “knowledge bases” and algorithms to provide “artificial intelligence”
- Origin of field attributed to Ledley and Lusted (1959)
  - Diagnosis via symbolic logic and probability
- Led to “expert systems”
  - Computer programs mimicking human expertise
    - Rule-based, e.g., MYCIN (Shortliffe, 1975)
    - Disease profiles and scoring algorithms, e.g., INTERNIST-1 (Miller, 1982) and DxPlain (Barnett, 1987)
- “Demise of the Greek Oracle” (Miller, 1990)
  - Evolution to more focused clinical decision support in 1990s and beyond (Greenes, 2014)

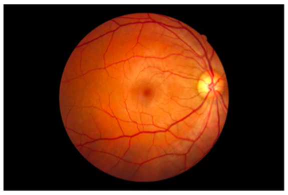
Modern era of success comes from neural networks and deep learning

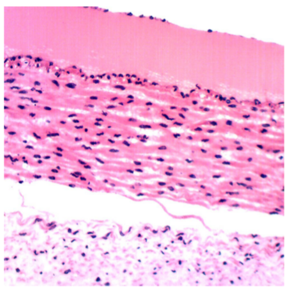
- Aided by large amounts of data and increased modern computing power (Taylor, 2017; Esteva, 2019)
  - Particular success has been achieved with deep learning (Goodfellow, 2016)
  - Neural networks had been around for many decades, but deep learning successes often attributed to work of Hinton (2006)
- Mathematics complex, but can understand what they do in context of ML tasks

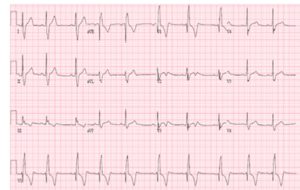




Most success (so far) in imaging and waveform (patterns)







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Beyond image classification

- Algorithm-assisted pathologists had higher accuracy than either deep learning algorithm or pathologist alone (Steiner, 2018)
  - Assistance reduced time compared to pathologist alone for positive (61 vs. 116 sec) and negative images (111 vs. 137 sec)
- "Weakly supervised" (using clinical diagnoses) had high AUC and would allow pathologists to exclude 65–75% of slides while retaining 100% sensitivity (Campanella, 2019)
- Automated capture of physician-patient dialogue in exam room (Rajmokar, 2019)
  - Get keyboard (not computer) out of exam room?

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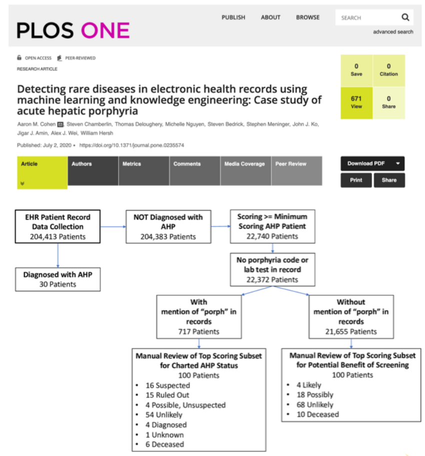
Many other uses for ML/AI

- Detection of rare diseases – often underdiagnosed
- Acute hepatic porphyria
  - Incidence 1/100,000
  - Typical 8-12 years to diagnosis
  - Defect in ALAS1 gene
  - Existing treatments available but RNAi drug givosiran more efficacious (Balwani, 2020)
- Applied ML to extract of 200K patients from OHSU (Cohen, 2020)
  - Identified 22 possible patients without diagnosis to explain symptoms
- Currently undertaking clinical investigation



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Challenges for ML/AI in medicine

- Maintain clinical perspective (Verghese, 2018)
  - Evaluation with clinical endpoints, e.g., patient outcomes (Parikh, 2019)
- Explain outputs, especially from neural networks (Ribiero, 2016; Price, 2018)
  - How to explain to patient when algorithm predicts what clinician cannot explain (Burt, 2018; Schiff, 2019)
- Racial bias in underlying data, e.g.,
  - Hospital utilization (Obermeyer, 2019)
  - Clinical algorithms (Vyas, 2020)
  - Hospital revenues (Kakani, 2020)
- Do we need “algorithmovigilance” (Raths, 2020)?

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Another requirement for success is competence in clinical informatics

- Clinical informatics is a core competency of health professionals education and practice (Hersh, 2014)
- Physicians and other professionals long known to be essential for success of IT in healthcare (Ash, 2003)
- Growing opportunities for training and careers in clinical informatics (Detmer, 2014)
  - Subspecialty is open to physicians of all primary specialties
    - But not those without a specialty or whose specialty certification has lapsed

History of clinical informatics subspecialty

- 2009 –AMIA develops and publishes plans
  - Core curriculum (Gardner, 2009) and training requirements (Safran, 2009)
- 2011 –ABMS approves; ABPM becomes administrative home
- 2013 – First annual certification exam offered via “grandfathering” pathway
  - 456 physicians pass and board-certified
- 2014 – ACGME fellowship accreditation rules released
- 2015 – OHSU among first 4 fellowships launched (Longhurst, 2016)
- 2020 – now 2000+ board-certified and 46 fellowships; updated practice analysis (Silverman, 2019)
- 2022 – last year for “grandfathering” pathway

Is all of this relevant in the era of COVID-19?

- Using data
- Rapid expansion of telemedicine
- Challenges for science in pandemics

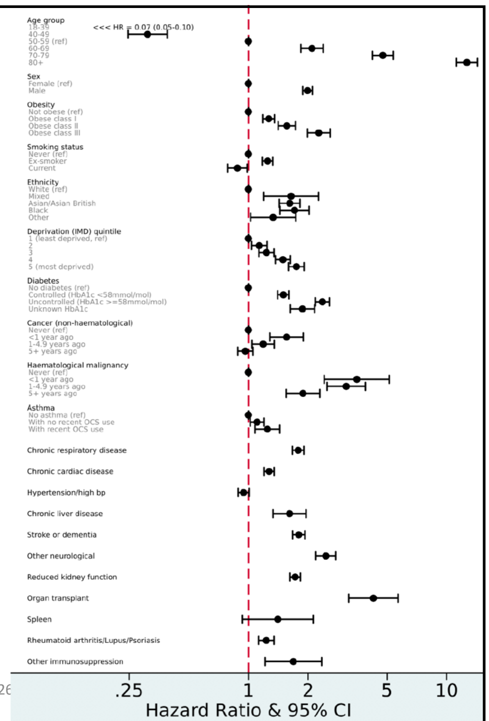
Many roles for informatics in COVID-19 (Budd, 2020)

Using data

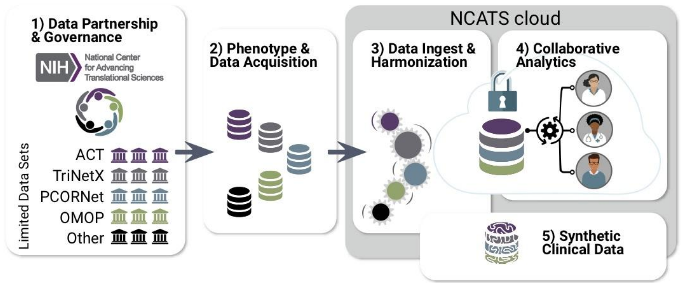
- Public health reporting has been an ”information catastrophe” (McKenna, 2020)
  - Public health informatics infrastructure historically under-resourced, but probably not wise to change course in middle of pandemic (Huang, 2020)
- Some other countries and academics doing better
  - UK OpenSAFELY (Williamson, 2020)
  - NIH National COVID Cohort Collaborative (N3C; Haendel, 2020)

UK OpenSAFELY

- (Williamson, 2020)
- Primary care records of 17M adults in NHS England, linked to COVID-19 registry
- Hazard ratio (95% CI) calculated for risk factors



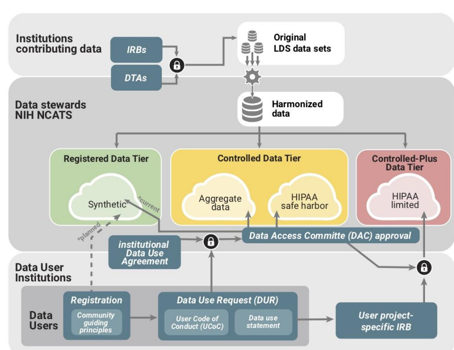
N3C – five workstreams



- Collaborative analytics
  - Secure data enclave (N3C Enclave), from which data cannot be removed, houses analytical tools and supports reproducible and transparent workflows
  - Formulation of clinical research questions and development of prototype machine learning and statistical workflows collaboratively coordinated
  - Portals and dashboards support resource, data, expertise, and results navigation and reuse

N3C data entry, stewardship, and use

- Sign data transfer agreement (DTA)
- Obtain Institutional Review Board (IRB) approval
- Deposit limited data set (LDS)
- Data harmonized and deposited into three tiers
- Tiers have different requirements for access

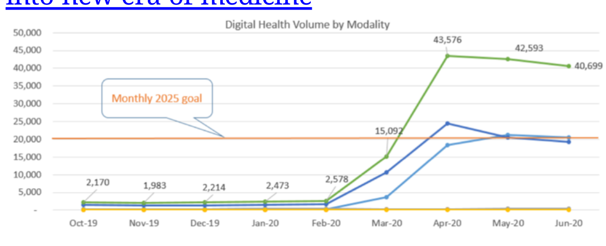


Rapid expansion of telemedicine

- Prior to COVID-19, moderate availability and niche use
  - Evidence base prior to COVID-19 (Totten, 2020)
- In 2018, accounted for 2.4% of all healthcare claims (encounters) (Rae, 2020)
- Hospitals use (Jain, 2020)
  - Any use – 47.6%
  - Intensive care unit – 26.8%
- Physician use (Kane, 2018)
  - Physician-to-patient – 15.4% overall, highest among radiology, psychiatry, pathology
  - Physician-to-physician – 11.2% overall, highest in pathology, emergency medicine, radiology

Rapid expansion of telemedicine

- CMS allowed telemedicine for all Medicare visits; other insurers followed (Verma, 2020)
- Leading to rapid uptake
  - Massive increase, especially for non-urgent care (Mann, 2020)
  - 48% of physicians now using (Merritt Hawkins, 2020)
  - Including at OHSU
    - https://news.ohsu.edu/2020/04/13/ohsu-telehealth-rockets-into-new-era-of-medicine



Challenges for science in a pandemic

- Covid-19 pandemic has tested conduct of science
- Science normally proceeds slowly, often with dead-ends (Mogensen, 2020)
  - But urgent situations may require change evidence requirements (Schünemann, 2020)
- Modern communications have led to
  - "Toxic legacy of poor-quality research, media hype, lax regulatory oversight, and vicious partisanship" (Lenzer, 2020)
  - Leading to proliferation of pseudoscience (Caulfield, 2020) and conspiracy theories (Allen, 2020; Neil, 2020)
- Exacerbated by some advances in open science, such as preprints (Majumder, 2020; Fraser, 2020)
- "Panic and disorganization" (Herper, 2020) and "waste and duplication" (Glasziou, 2020) in studies of drugs
- Need to preserve clinical trial integrity (McDermott, 2020; Califf, 2020)

How will clinical informatics impact clinical medicine in future?

- "AI won't replace radiologists, but radiologists who use AI will replace radiologists who don't," Langlotz, Stanford radiologist (Reardon, 2019)
  - True for all physicians, even Dr. McCoy?
- Must be "democratizing" role for all in healthcare (Allen, 2019)
- Many opportunities for collaboration!

Questions?

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