Leveraging EHRs to advance research and improve healthcare: Challenges & Opportunities

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In the next 30 min…

- Changing landscape in healthcare and research
- Emergent need/investments to leverage EHRs
- Case for a Research-Practice paradigm shift
  - To enable “learning health system”
  - Some examples of ongoing work
- Discussion
Clinical and Translational Research

- Substantial biomedical science progress in last 50 years
- Major investment in Biomedical Research
  - Over $100 billion annually on biomedical research in the US
  - Research funding more than tripled from ’94-’04
  - Major efforts to advance translational science since ’05 (CTSA)
  - ARRA provided a 1-time significant increase to NIH Budget
- Investments in data-driven research initiatives rely on leveraging ongoing Health IT investments
  - e.g. comparative effectiveness research, pharmacovigilance, etc.
  - Building upon ongoing Health IT investments
- Advancing research and health clearly a priorities for our institutions and our country
  - But, many challenges and obstacles exist…
Clinical Research Continuum & Recognized Challenges

- IOM’s Clinical Research Roundtable:
  - Challenges fall into two translational blocks:
    - **Bench** ↔ **Clinical Studies** ↔ **Clinical Practice**

- Challenges:
  - Public Participation in Clinical Research
  - Developing Information Systems
  - An Adequately Trained Workforce
  - Funding

- Removing these blocks requires collaboration by multiple system stakeholders

- Lag time of 17 years to achieve 30% penetration of clinical research findings into practice

- Major investments to address challenges…

Sung NS et al. JAMA, 2003
Initiatives/Investments to Accelerate Research and Improve Care

- Ongoing Health IT and Informatics initiatives
  - EHR adoption, HIE expansion, Standards, NwHIN

- National Research Initiatives:
  - National Institutes of Health (NIH):
    - CTSA, caBIG, etc.
  - Food and Drug Administration (FDA):
    - Drug development, testing, surveillance
  - ARRA (Stimulus) related funding for research:
    - Biomedical, health services, etc.
    - Comparative effectiveness research
    - Push to advance community-based research
  - Affordable care act:
    - Patient-centered outcomes research institute (PCORI)
    - Research-specific informatics efforts…
Multiple challenges to such research

- Leveraging existing data for research (e.g. Outcomes, CER, Epi, etc.) and QI – an opportunity
  - Clinical phenotype and outcomes
  - Administrative and fiscal variables
  - Bio-molecular markers
  - Patient-reported variables

- Data often collected, stored for clinical care, administrative, not research purposes
  - Data often incomplete, unreliable
  - Key data often stored narratively, not discretely
  - Data often difficult to access for research
  - Research often requires integration across sites

- Informatics efforts address some of these…
Efforts to address challenges

- Initiatives aim to leverage increasingly digital clinical data for research and improvement
  - EHR implementation and meaningful use
  - Data Warehousing Efforts
  - Registries and Data Networks
  - Health Information Exchange
  - Outcomes and CER initiatives

- Many trying to engage practitioners and leverage point-of-care systems, data for research

- Progress being made, but remains very challenging
  - Many, not all challenges are “technical”
  - Many socio-organizational, regulatory, cultural
    - Make leveraging existing systems for research difficult
    - Embedding research into systems/workflow, a major challenge
Research and care: a flawed paradigm?

Emergent conclusion…

- As a society/community, we haven’t quite decided how we feel about research at point-of-care
  - We’re counting on it…
  - Investing in initiatives that require we do a better job at it…
  - But, we’re not fully embracing/supporting it
    - Even creating barriers to this – many “headwinds”

- Underlying reason?

- Current research-practice paradigm states relationship between research and practice is:
  - The need to bring “Evidence” to Practice via EBM
  - The relationship of research to practice based on EBM and in traditional practice is uni-directional…
Traditional path from generation of evidence to its application

The Current Research-Practice Paradigm

- Informed by EBM, the current Research-Practice relationship suggests that:
  - Clinical care and research are distinct activities
  - Activities overlap mainly at application of evidence
  - Information flow/influence is unidirectional
    - Research influences Practice (e.g. EBM)

- We know this is no longer the case, but
- Persistence of this paradigm impedes progress
Effects of Current, Flawed Research-Practice Paradigm

- Effects of this existing paradigm include:
  - Little-to-no consideration of research during planning/ implementations of health systems
  - Limits our ability to invest in and leverage clinical resources to advance research
  - No incentives for non-researchers to engage in research activities
    - Even if part of our institutional mission
  - Prevents stakeholders (physicians, patients, health systems, policy makers) from recognizing reality that:
    - To practice EBM, we first have to generate the evidence base
    - This requires changes to the way we practice, invest, etc.
Effects of Current, Flawed Research-Practice Paradigm

- Informaticians positioned to recognize particular problems from current paradigm:
  - Current data often contain errors, quality issues that are problematic for research purposes
  - Much information (e.g. billing data) does not reflect clinical truth
  - Simply digitizing more information will enable “mining” our way to advanced research – not quite
    - Natural Language Processing advances very promising
    - Even if perfected, can only assess what’s collected and
    - What’s collected often isn’t done so with research in mind…
Effects of Current, Flawed Research-Practice Paradigm

- Effects go beyond data collection:
  - Regulatory confusion resulting from flawed paradigm often leads to pitting of privacy against research endeavors
    - Both are essential and good, must be reconciled
    - Strong incentives to err toward conservative interpretation, creating onerous policies, limiting access, etc.
    - Not reconciling lead to wasted investments and delays in advancing medical science
  - Healthcare system/financing models lead to lack of involvement in research activities

- So, what’s the answer?
Recognizing the need for a Paradigm Shift

- Thomas Kuhn
  - Science historian, philosopher, (Cincinnatian)

- Described how science advances through periodic revolutions or “paradigm shifts”

- When defects with an existing paradigm build-up, they require and lead to a shift to a new paradigm

- Much like it did for the 30 years preceding-1991 when the paradigm of EBM was put forth

- I believe we’re there…
A paradigm shift: It’s foundations…

- Research is increasingly complex and advancing too rapidly for our current “system” to support
  - Research activity being driven out of AHCs and even out of USA to other countries
- Need to accelerate our Research pipeline
- Need to maximize investments in health/research
- Need to drive more effective care to communities
- Innovations offer new ways of engaging clinicians and patients in research
- Current paradigm creating headwinds to realizing goals
- New paradigm needed to allow them to be applied
New Paradigm: Evidence Generating Medicine

- Recognizes that:
  - Clinical care activities not entirely distinct from research activities
  - We must bring research into consideration when we practice in order to advance science and health care
  - Many EGM activities ongoing and need support to achieve our collective goals:
    - Identifying subjects for research studies
    - Collecting phenotypic information to advance efforts
    - Conducting outcomes research, surveillance, and CER
  - Advancing EGM critical to completing EBM lifecycle
    - Without it, answer to the EBM applicability question is likely to be “no”
New Research-Practice Evidence Cycle

Research → Evidence Based Medicine
National Health IT for a Learning Health System

“A nationwide network. Meaningful use of EHRs, widespread participation by multiple diverse entities, and an appropriate technical architecture can spur the construction of a highly participatory rapid learning system that stretches from coast to coast.”

Friedman CP et al. Sci Transl Med 2010
Federal Health IT Strategic Plan 2011-15

1. **Goal I:** Achieve Adoption and Information Exchange through Meaningful Use of Health IT
2. **Goal II:** Improve Care, Improve Population Health, and Reduce Health Care Costs through the Use of Health IT
3. **Goal III:** Inspire Confidence and Trust in Health IT
4. **Goal IV:** Empower Individuals with Health IT to Improve their Health and the Health Care System
5. **Goal V:** Achieve Rapid Learning and Technological Advancement

Federal Health IT Strategic Plan 2011-2015
Realizing Evidence Generating Medicine to Enable the Learning Health System
Advancing the EGM model

- Several elements key to advancing an EGM model
  - Informatics
  - Fiscal
  - Cultural
  - Socio-organization
Realizing EGM: Informatics
Leveraging EHRs: Data Re-use

- Much promise to clinical data available for “re-use”
  - Early reports indicating good ability to identify diseases across sites with different EMRs
    - e.g. Kho et al. Sci Trans Med. 2011
  - But, also limitations of data for (many) research purposes…
    - “Garbage in, Garbage out” still an issue
      - Multiple studies show poor correlation b/w dx codes, truth
    - Limitations of “general” clinical data vs. specialty registry data for certain questions…
      - “noise” or error in general database much higher than registry – even with same patients

- Conclusion: To be valuable for (many) research purposes, data collection must be systematic
Realizing EGM: Informatics
Leveraging EHRs: Data Re-use

- Operationalizing EGM – a case example
  - American College of Rheumatology – RISE project
    - Rheumatology Informatics System for Effectiveness
  - Opportunity/goal: To “learn from every patient” across sites
  - Develop virtual registry, platform independent
    - Leveraging Informatics/Grid resources
    - Agreed upon data elements across sites
    - Ongoing EHR adoption, an opportunity
  - Principles:
    - Collect data once, use multiple times
      - Reporting for quality programs, meaningful use, MOC, etc.
      - Research use case as well
      - Enabling de-identified, limited, or identifiable, as appropriate
    - Minimize “extra” data collection to essentials
Realizing EGM: Informatics

Leveraging EHRs: Participant Recruitment

- EGM beyond data collection, re-use…

- Identifying participants for research studies
  - Mining data for subjects is one method
  - Real-time, point-of-care another matter

- Example case 2: Clinical trial alert
  - Leveraging features of EHR for this problem…
Realizing EGM: Informatics

Clinical Trials and Recruitment

- Clinical Trials are critical to the:
  - Advancement of medicine
  - Missions of academic health centers, funding agencies, etc.

- Growing rate of biomedical discoveries, associated costs
  - >$800 million to bring a drug to market
  - Recruitment is major bottleneck in trial conduct
  - Privacy regulations have added to recruitment challenges
  (Ness RB. JAMA. 2007)

- Recognition of increasing costs to Universities
  - Nov ’11 Acad Med – in 2009, OHSU ~$1M costs for failed trials
    - Many due to little-to-no recruitment
  - Delays are common…
Realizing EGM: Informatics
Recruitment delays very common

Distribution of Delays in U.S. Site Enrollment Timelines
(Percent of Sites)

Source: Parexel's Bio/Pharmaceutical R&D Statistical Sourcebook 2009/2010
Realizing EGM: Informatics

Clinical Trials and Recruitment

- Inadequate recruitment can:
  - In addition to increased costs ...
  - Delay study completion
  - Lead to trial failure
  - Weaken results
  - Introduce bias
  - Slow scientific progress
  - Limit availability of beneficial therapies

- Traditional recruitment methods notoriously variable

Realizing EGM: Informatics

Clinical Trials Recruitment: Challenges

- Clinicians play an important role in recruitment
  - Subject ID during clinical encounters is often optimal
  - Patients are more likely to enroll if the physician recruits

- Traditional recruitment during busy practice is difficult
  - Remember active protocols
  - Take time to explain/perform recruitment
  - Communicate with the study coordinator

Realizing EGM: Informatics

Clinical Trial Recruitment: Challenge, Opportunity

- Comprehensive EHRs offer opportunity:
  - Leverage EHR features for recruitment:
    Clinical Decision Support + Communications Capabilities
    = Clinical Trial Alert

- Overcome known recruitment challenges and take advantage of predictors of success
  - Remind physicians of trial
  - At point-of-care
  - Minimize physician workload (30-60 seconds max)
  - Involve patients in process

- Comply with privacy regulations (HIPAA)
Realizing EGM: Informatics
Clinical Trial Alert

- First Intervention study
  - EHR-based CTA applied in busy outpatient settings
  - “Before-after” study of CTA to 114 MDs
  - Applied to an NIH-sponsored Type 2 diabetes mellitus trial
  - Using EpicCare EMR

- Results
  - **10-fold increased** monthly referral rate
    - (5.7 before, 59.5 after; P<0.001)
  - **Doubling** of monthly enrollment rate
    - (2.9 before, 6.0 after; P=0.007)
  - **8-fold increase** in number of physicians referring
    - (5 before, 42 after; P<0.001)
  - Some differences between generalists/subspecialists

Embi PJ et al. Arch Internal Med. October 24, 2005
Realizing EGM: Informatics
Clinical Trial Alert RCT

- Addressed key generalizability questions; rigorous design
  - Applied to different diseases
    - Insulin Resistance In Stroke (IRIS)
  - Using different EHR (GE Centricity vs. Epic)
  - Across University and Community settings
  - With randomized controlled methodology

- Phase 1 findings revealed:
  - Significant (~20 fold) increased referrals with CTA (p<0.0002)
  - Significant (~9 fold) increased enrollments with CTA (p<0.006)
Realizing EGM: Informatics
Clinical Trial Alert RCT - w/ Epic 2010

BestPractice Advisory - Embitesteight, Joe

Research (1 Advisory)

Patient meets initial screening criteria for the INSULIN RESISTANCE AFTER STROKE (IRIS) clinical trial being conducted at OSU.

Please take a few seconds to ASK if your patient is interested in this opportunity, SELECT ONE of the responses below, then hit ACCEPT. You don't need to obtain informed consent for the trial. The study coordinator will do this if the patient eventually qualifies and agrees.

OPTIONAL: Link to full study criteria FYI (note: will open in Internet Explorer; to return here, click Hyperspace tab at bottom of screen)

- Initiate: 1. patient **is** interested and will allow further eligibility assessment by the study coordinator
- Initiate: 2. patient **is not** interested (or does not qualify)

The following actions were applied automatically:

☑ Scheduled: If you select option #1 above: An InBasket message will be sent to the study coordinator. Also, brief information about the trial opportunity will autoprint for the patient at your After Visit Summary printer.
Advancing EGM: Socio-organizational issues & EGM

- Information issues only part of the solution
- Must consider EGM issues at several levels
  - Policy level
  - Systems level
  - Individual level
- By valuing EGM as part of Evidence cycle, we can begin to assure proper alignment of goals and systems
Realizing EGM: Regulations, culture and ethics

- **Privacy issues**
  - Respect for privacy essential to any healthcare and research endeavor, and research is a priority for our nation.
  - EGM paradigm makes clear - we **must** reconcile these and resolve the sometimes conflicting regulations and policies to enable valid research.

- **The Ethical Case**
  - Standard view: research participation is above & beyond duty.
  - If biomedical research is a public good, all have a duty to participate, unless they have a good reason not to.
  - This “public good” argument has been put forth for patients.
    - (Schaefer et al. JAMA. 2009).
  - One could argue it applies equally to providers, practices, IT, etc.
  - This fits with the EGM paradigm.
Realizing EGM: Organizational and Fiscal realities and EGM

- Incentives and healthcare system structures currently mal-aligned for EGM
  - At Academic Health Centers and in Community

- For example: Payment structures are currently not based on practicing EGM
  - Productivity RVU-based compensation is common
  - Hence comment by physicians that:
    - “Research is not my job” even at AHC
    - And, they’re sort of right…
  - If EGM is valued, why not incentivize EGM?
    - RRUs – Relative Research Units – one concept
      (Embi & Tsevat, Acad Med, Jan 2012)
Realizing EGM

- With EGM paradigm in mind, solutions are not only possible, but **imperative**
  - EGM is **necessary** to achieve goals set for research and healthcare enterprises, for the nation
  - Improved **systems** that facilitate improved and efficient data collection for multiple uses are essential
  - Increased **resources** devoted to research/improvement must be applied to “clinical” projects, e.g. EHR implementation

- Driven by EGM, we shouldn’t be apologetic about this

- We must to do this across institutions, communities
  - It is necessary to maximize our investments
    - Research, healthcare, health IT
  - Goes beyond research – to quality improvement
  - It will enable us to do what’s being asked of us
Conclusions

- Progress being made to identify and address the challenges to leveraging clinical data for research
- Current research-practice paradigm impedes progress
- Informatics methods and resources can help enable the information-intensive processes inherent to EBM & EGM
- Much work remains, much opportunity
- Leveraging EHRs and Information resources essential to advancing research and improving health for all
Thanks!

- Questions?
- Discussion…
Extra slides
Realizing EGM: Informatics

Leveraging EHRs: Federated Data

TRIAD

Secure Data Transfer

Shared Data Model & Dictionary

Mapping

Real-time Query & Integration Tools
Realizing EGM: Informatics
CTA Physician Participant Survey

- Most felt that CTA was
  - Easy to use, Minimally intrusive, and appreciated receiving alerts
  - Most would like to use in future – more so if made more specific
  - Top reason for not using CTAs – lack of time

- Specialists and generalists differed somewhat in various ways
  - Level of comfort discussing clinical trial participation with patients
  - Perceptions about the CTA

- Others have since also studied CTA approach, such as…
  - Rollman RB. JGIM. 2008
  - Grundmeier RW. Proc AMIA. 2007

- Ongoing studies using RCT approach…
Realizing EGM: Factors that Influence CTA-facilitate Recruitment at the Point-of-Care: Emerging Conceptual Model

Point-of-care Trial Recruitment Steps:

**Clinician:**
- Specialization
- Affiliation with Trial
- EHR experience
- Attitudes

**Organizational:**
- Workload
- Time Constraints
- Clinic Workflow
- Division of Labor

**Contextual:**
- Patient interest
- Status of Condition
- Other health conditions
- Risks/benefits

**EHR-specific:**
- Database contents
- Capabilities & features
- Usability of CTA

**Researcher Steps:**

**Patient Referral**

**Full Screening**

**Enrollment**

**Patient Identification**

**Trial Awareness**