The Research-Practice Paradigm and Governance Considerations for Data Re-use

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In the next 20 min…

- Current needs/challenges to data re-use
- Current EBM and research-practice paradigm
- Case for a new research-practice paradigm
  - Related informatics, organizational, fiscal, regulatory issues that must be addressed
- A local governance model to realize changes
- Conclusions and implications for policy changes
- 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)
- 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…
Multiple challenges to such research

- Leveraging existing data for research (e.g. Outcomes, CER, Epi, etc.) and QI, safety, etc. – 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

- Efforts 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 finding…

- 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

- 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, 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
  - And, 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
  - Information (e.g. billing data) often does not reflect clinical truth
  - Simply digitizing more information will enable “mining” our way to advanced research – not quite
    - Digital records certainly better than paper-based, and…
    - Natural Language Processing advances very promising
    - But…
    - Even if perfected, can only assess what’s collected, and…
    - What’s collected often isn’t done so with research (re-use) in mind…
Effects of Current, Flawed Research-Practice Paradigm

- Effects go beyond data collection:
  - Limits opportunities to engage patients in research
  - 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 creating onerous policies, unnecessarily limiting access
    - Not reconciling lead to wasted investments and delays in advancing medical science
  - Healthcare system/financing models lead to lack of involvement in research/re-use activities and planning

- So, what’s the answer?
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 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:
  - Collecting phenotypic information to advance efforts
  - Conducting outcomes research, surveillance, and CER
  - Identifying subjects for research studies

- Advancing EGM essential to Evidence Lifecycle
  - Without it, answer to EBM applicability question likely, “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
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

- Let’s look at each briefly…
Realizing EGM: Informatics Example

Leveraging EHRs for Data Re-use

- Goal: Collect data once, use multiple times

- Much promise to leveraging clinical data 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

- Still, challenges to leveraging clinical data for “re-use”
  - “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
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
- Systems and regulations often developed, implemented with little concern for research
  - Informaticians, researchers must be involved in design/implementation
- By valuing EGM as part of Evidence cycle
  - We begin to assure proper alignment of policies, systems, and practice
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, 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 provide incentives for it?
  - RRUs – Relative Research Units – one concept

Embi & Tsevat, Acad Med, Jan 2012
Realizing EGM: Incorporate into Education

- To achieve the widespread adoption of paradigm, must be modeled
- Teaching housestaff value of EGM will be part of this
  - Role modeling
  - Teach it as we teach EBM – and educational imperative
  - Expectation that they will continue in their practice settings
- EGM should not be seen as license to ignore challenging realities of practice and impose upon clinicians
- As Informaticians, we must support EGM
  - Need ways to make “doing” EGM easier at point-of-care
  - Design and develop systems/approaches that facilitate EGM recognizing the challenging realities of practice
  - New GME Fellowships in Clinical Informatics should incorporate
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 better, more 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, safety, value…
  - It will enable us to do what’s being asked of us
Advancing the EGM Locally: A leadership model…

- Great, but…
  - Lots of changes
  - Very challenging

- Who will drive such efforts
  - Informed creation of new role…
  - Leader charged with advancing this agenda
Chief Research Information Officer (CRIO)

- Tri-partite missions of Academic Health Centers
  - Healthcare, Research, Education

- Increasing demand to:
  - Leverage Health IT Investments
  - Create learning health system
  - Focus on improving IT infrastructure for basic, clinical and translational research enterprise

- We created CRIO position to address this…
  - CIO and CMIO positions not focused primarily on “research” portions of mission
  - Distinct, emerging skill-set needed to focus on this area
  - Current initiatives (e.g. CTSA) -> greater imperative
CRIO @ The Ohio State University

- Senior leadership position at OSUMC
- Leads research-related IT governance, operations and strategy spanning OSUMC, CCTS, related groups
- Advocates and promotes use of IT for research purposes
- Partners with other IT groups to ensure research IT strategy supported across information systems
- Oversees implementation of information systems, functions, services and processes to support research (Research IT and Informatics)
- Leads innovations in research IT/Informatics
CRIO Role: Gaining in popularity…

- New role dedicated to increasingly complex research IT enterprise needs/institutional goals

- Early experiences positive; already reaping benefits

- Others have adopted CRIO model, similar success
  - U. Wisconsin, U. Chicago, U. Illinios-Chicago
  - Interest growing across multiple organizations with active job postings

- Expect growth given increasing demand and need for dedicated expertise
Conclusions

- Current research-practice paradigm impedes progress
- Applying the *Evidence Base* requires us to first *Generate Evidence* in a way that completes the “evidence cycle”
- Informatics methods and resources can help enable the information-intensive processes inherent to EBM & EGM
- Policy considerations follow from EGM concept
  - Changes to data infrastructure and sharing arrangements
  - Changes to incentive structures to encourage better data collection
  - Changes to privacy/regulations and public engagement
  - Changes to medical care and education – making EGM part of practice
- Advancing an EGM paradigm should help us:
  - Reframe approaches to research & practice across AHCs, communities
  - Lead advances in translational science & personalized medicine
  - Enable re-use and advance the “learning health system”
- New positions like CRIO can help operationalize
Thanks

- Questions?
- Discussion…