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

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Improving People's Lives
through innovations in personalized health care

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University of Cincinnati
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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
- Disussion

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 investements
- Advancing research and health clearly a priorities for our institutions and our country
  - But, many challenges and obstacles exist…

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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 Sung NS et al. JAMA, 2003
- Lag time of 17 years to achieve 30% penetration of clinical research findings into practice
- Major investments to address challenges…

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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…

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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

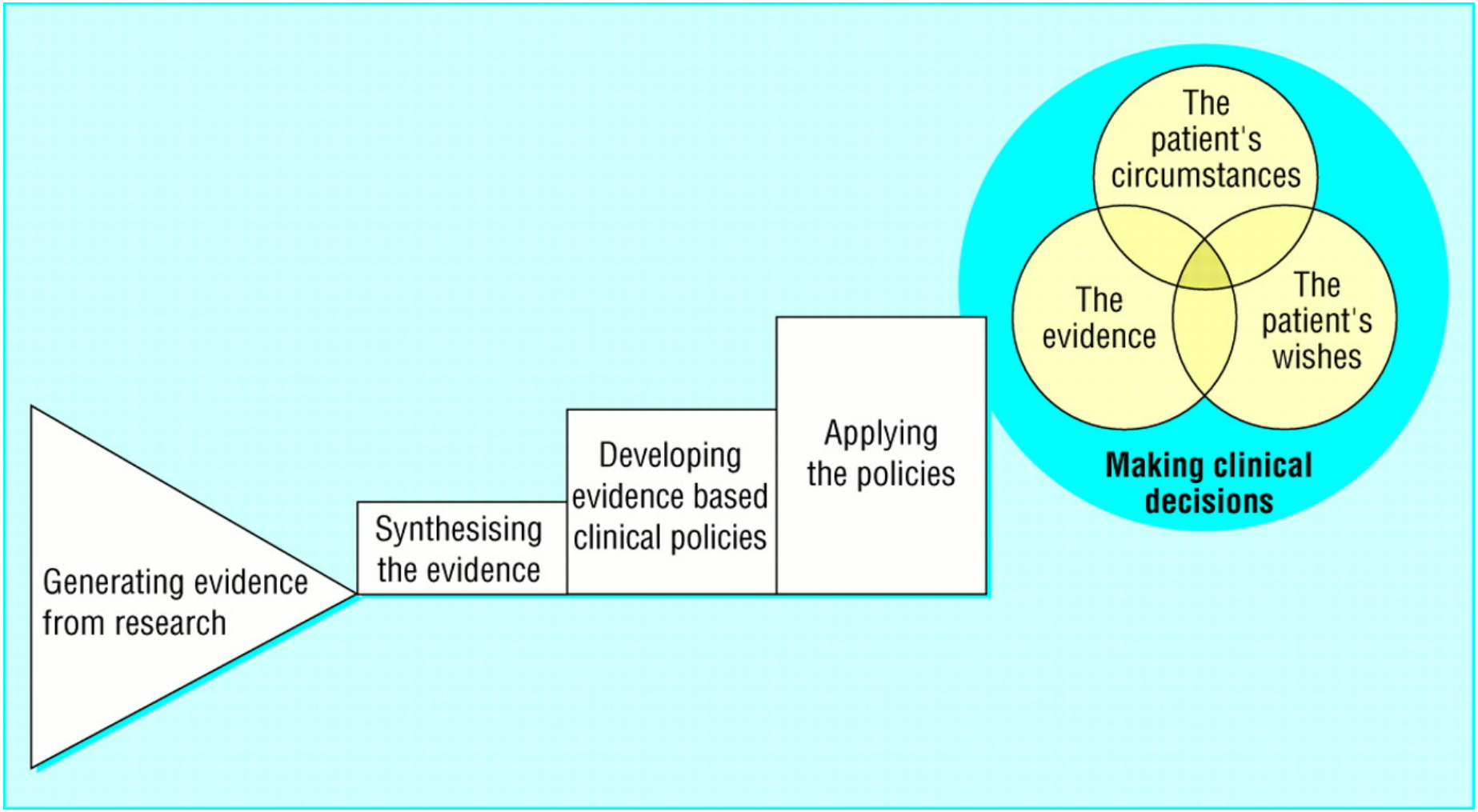
- Initiatives aim to leverage increasingly digital clinical data for research and improvement
  - EHR implementation and meaningful use
  - Data Warehousing Efforts
  - Registries and Data Networks
  - Health Information Exchange
  - Outcomes and CER initiatives
- Many trying to engage practitioners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

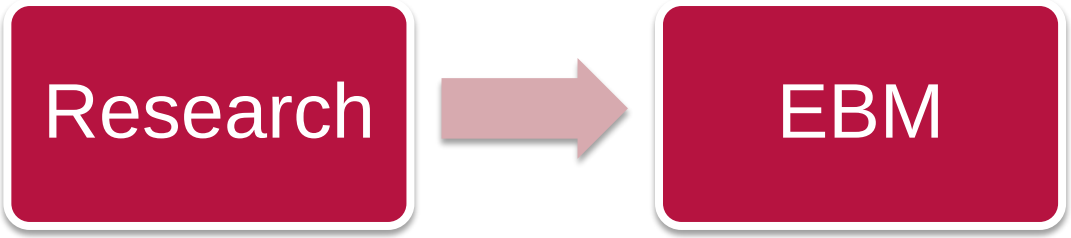
Traditional path from generation of evidence to its application



Haynes, B. et al. BMJ 1998;317:273-276

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 preceeding-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”

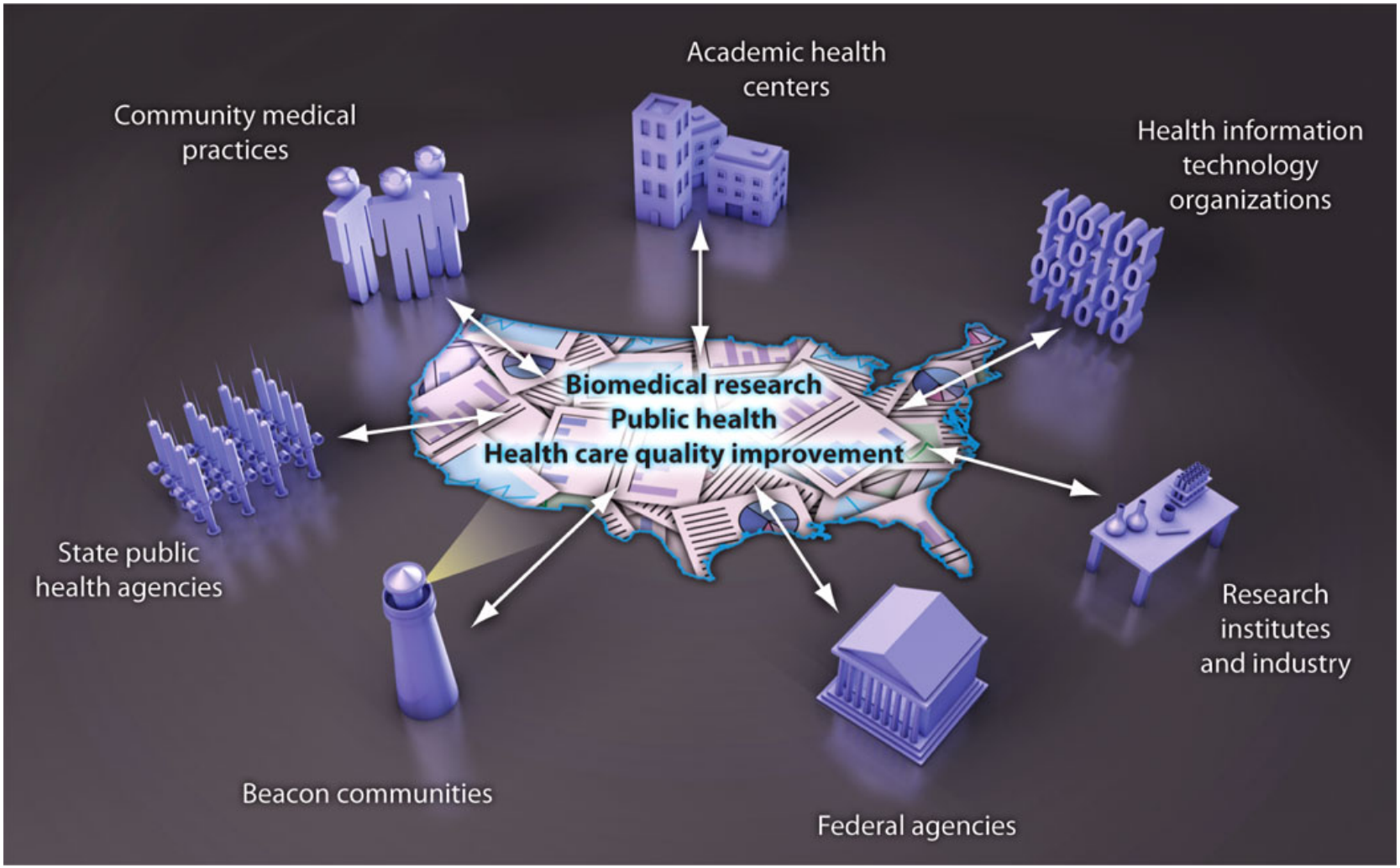
New Research-Practice Evidence Cycle

Research

Evidence Based Medicine

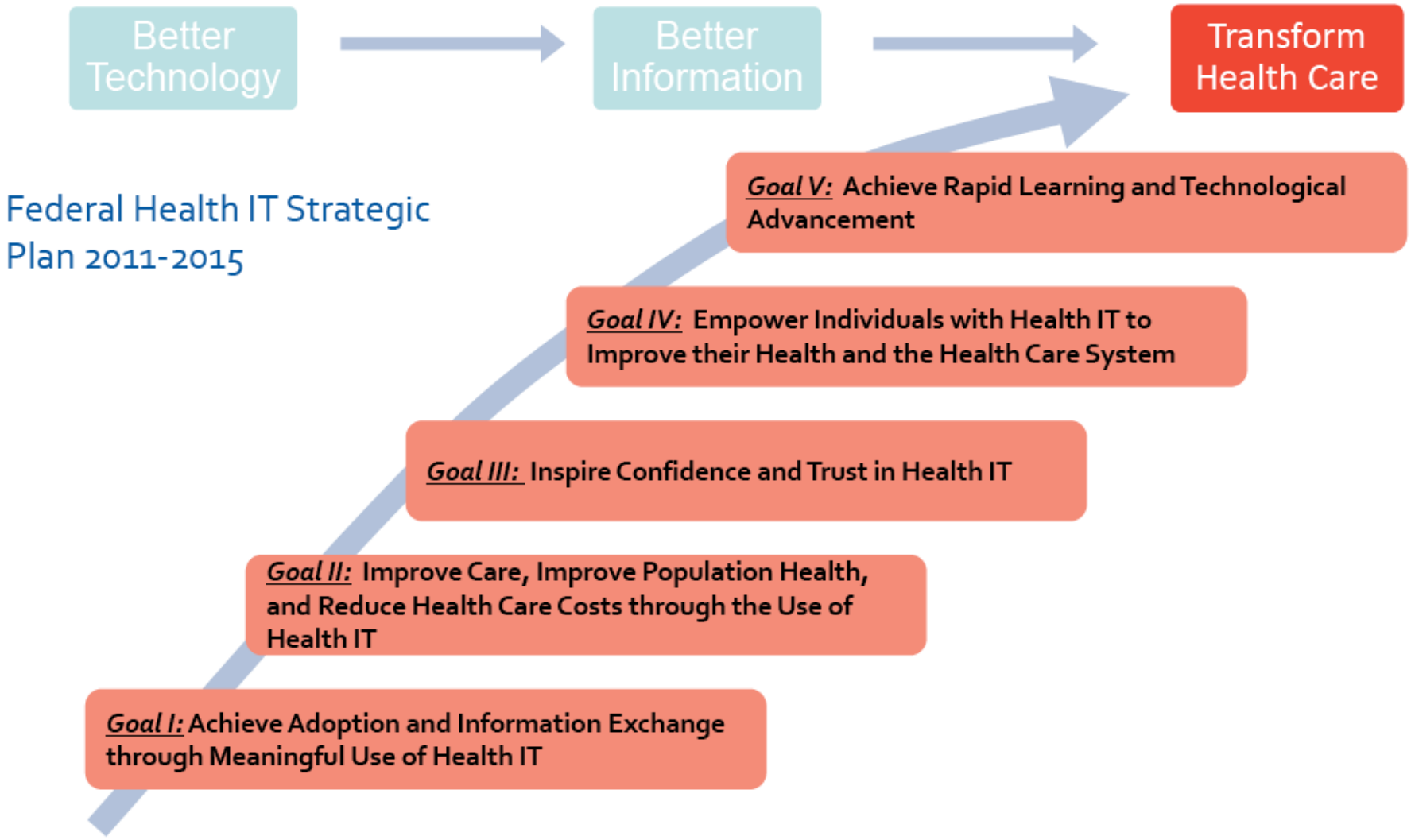
National Health IT for a Learning Health System

"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."

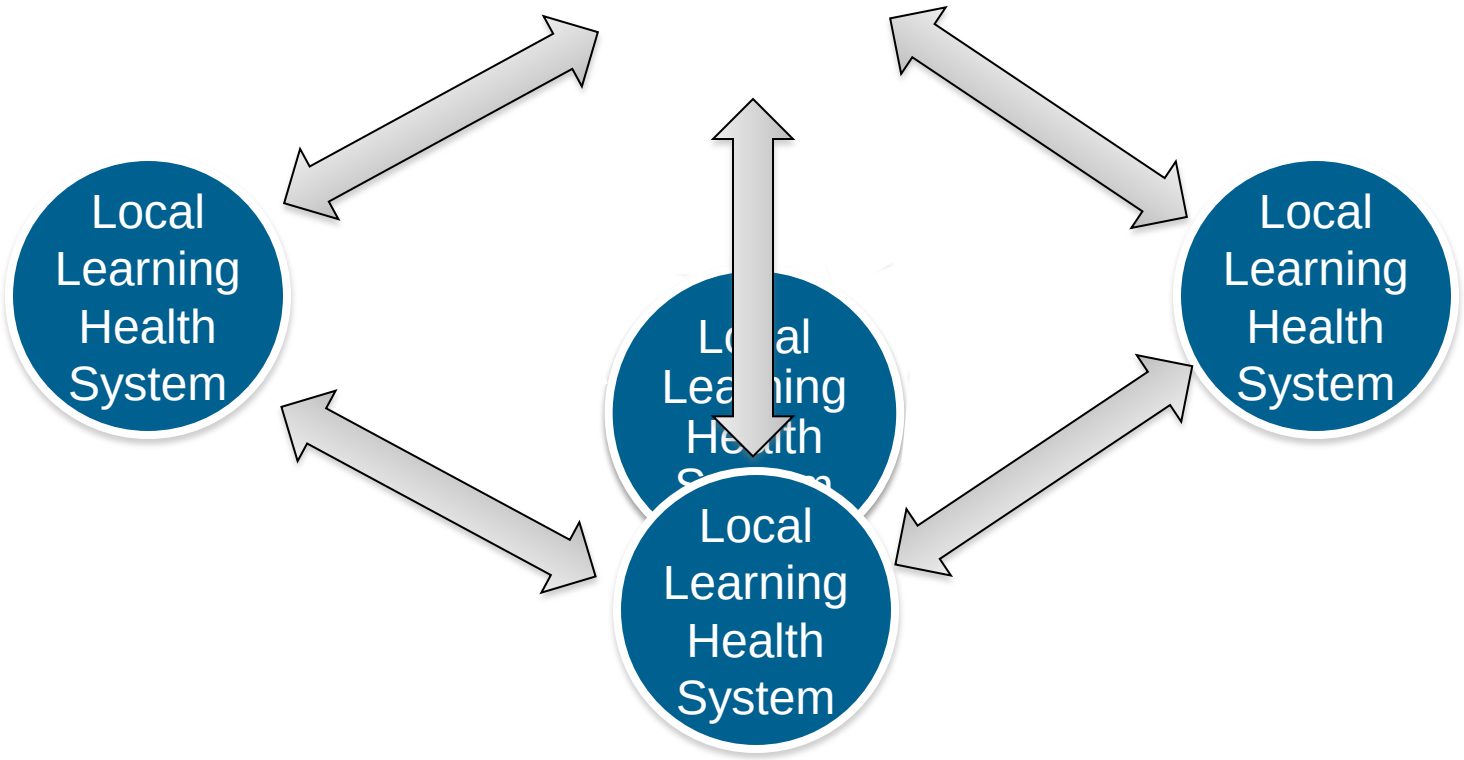


Friedman CP et al. Sci Transl Med 2010

Federal Health IT Strategic Plan 2011-15



Realizing *Evidence Generating Medicine* to Enable the Learning Health System

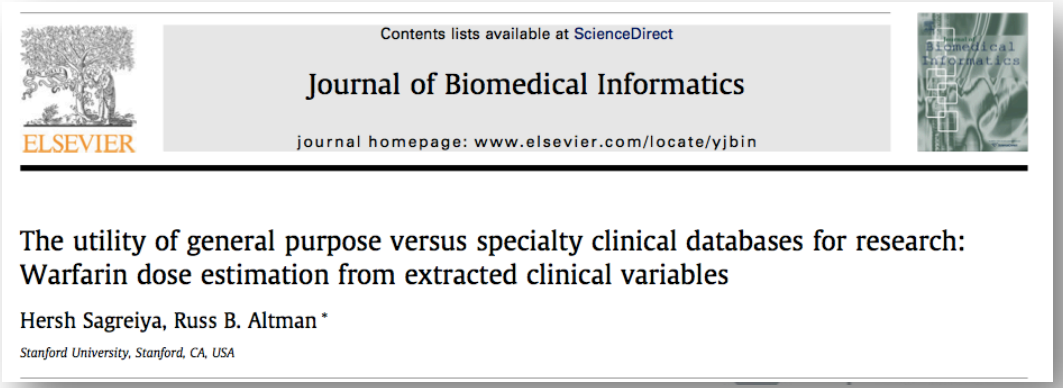


Advancing the EGM model

- 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


Contents lists available at ScienceDirect

Journal of Biomedical Informatics

journal homepage: www.elsevier.com/locate/yjbin

ELSEVIER

The utility of general purpose versus specialty clinical databases for research: Warfarin dose estimation from extracted clinical variables

Hersh Sagreiya, Russ B. Altman *

Stanford University, Stanford, CA, USA

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…

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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…

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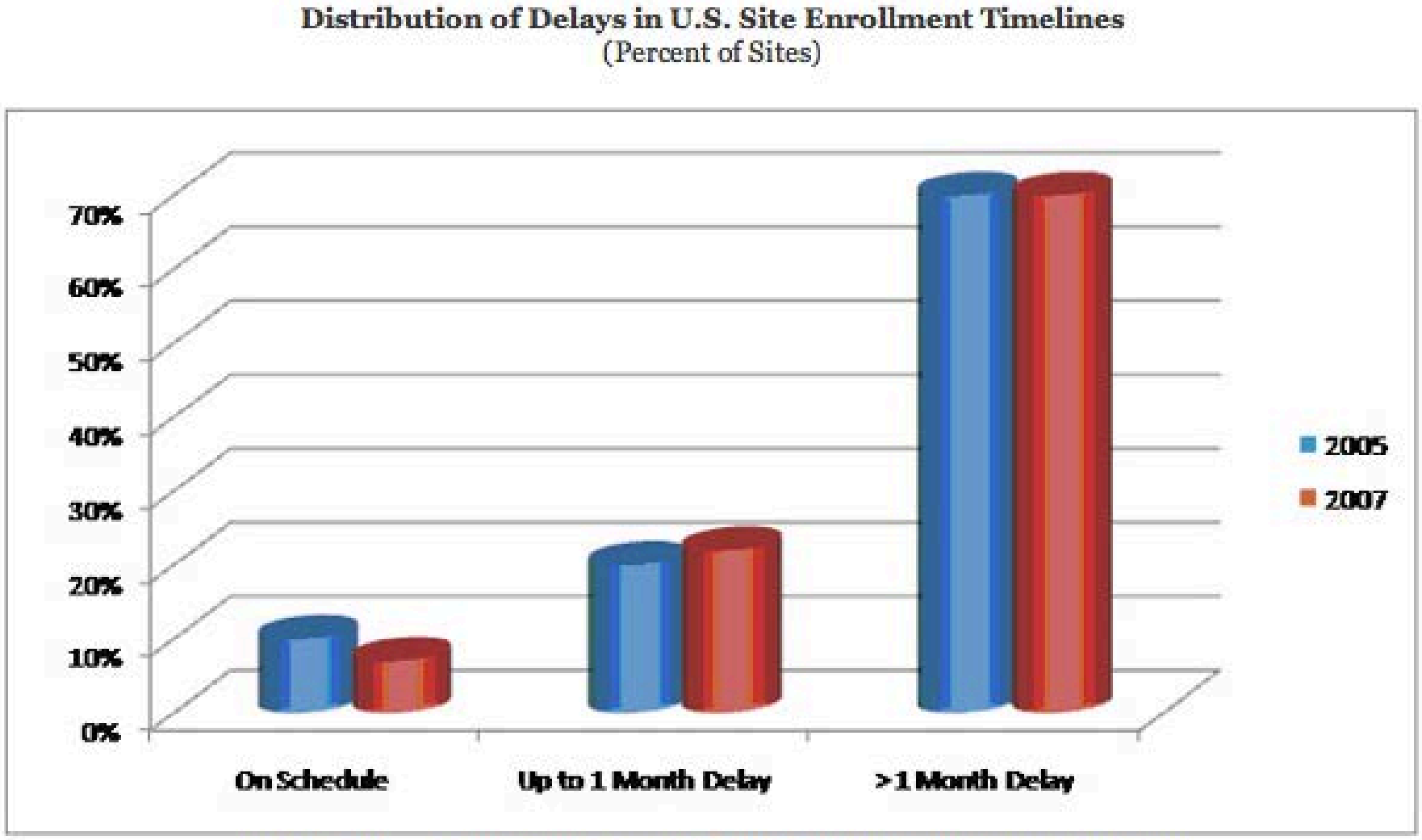
Realizing EGM: Informatics
Recruitment delays very common



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

Adams J, et al. Controlled Clinical Trials. 1997

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Realizing EGM: Informatics
Clinical Trials Recruitment: Challenges

- Clinicians play important role in recruitment
  - Subject ID during clinical encounters often optimal
  - Patients more likely to enroll if physician recruited

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

Siminoff LA, et al. J Clin Oncol. 2000
Butte AJ, et al. Proc AMIA Symp. 2000
Weiner DL, et al. Annals of Emerg Med. 2003
Winn RJ. *Seminars in Oncology*, 1994.

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)

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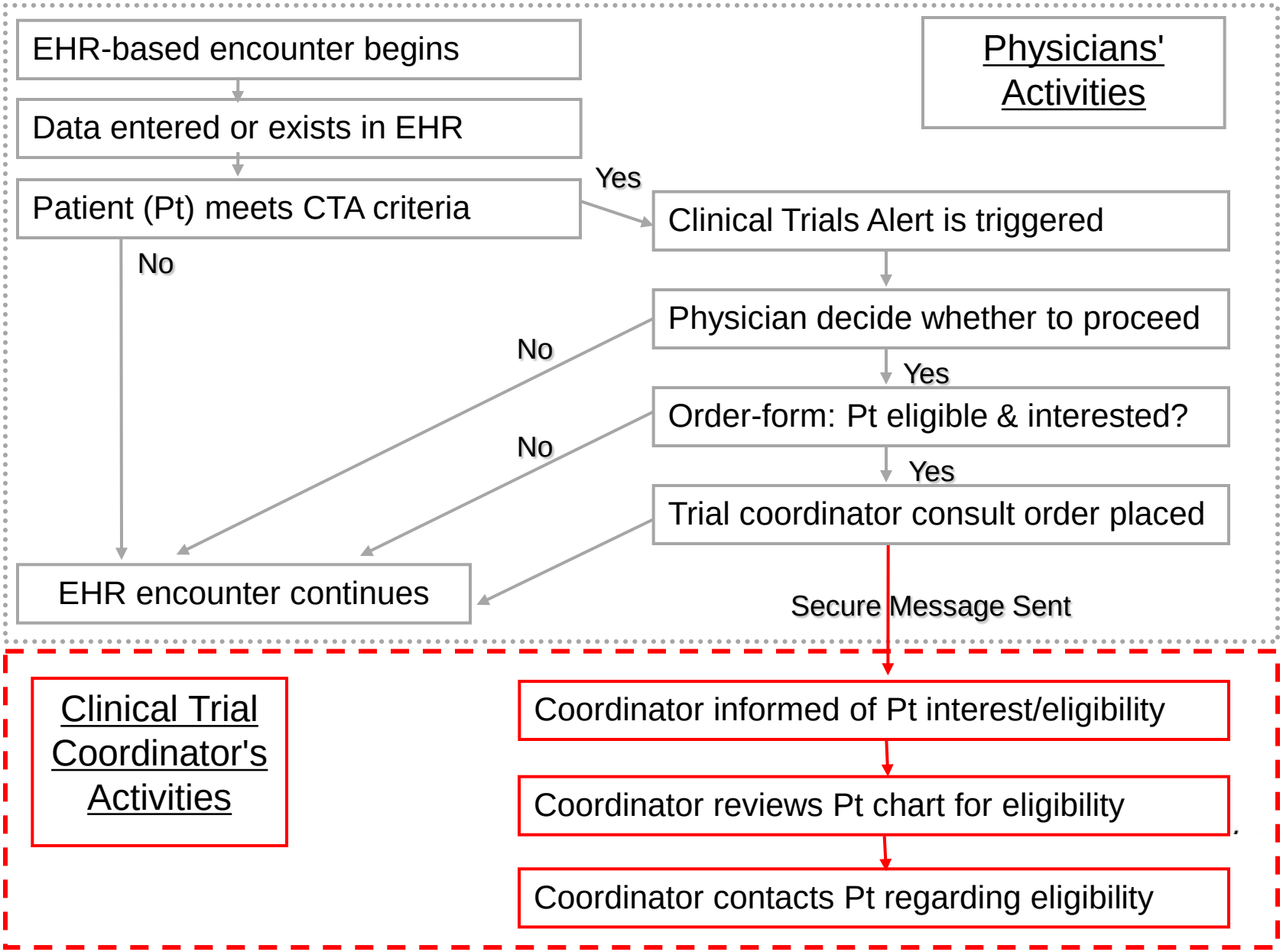
Clinical Trial Alert Process



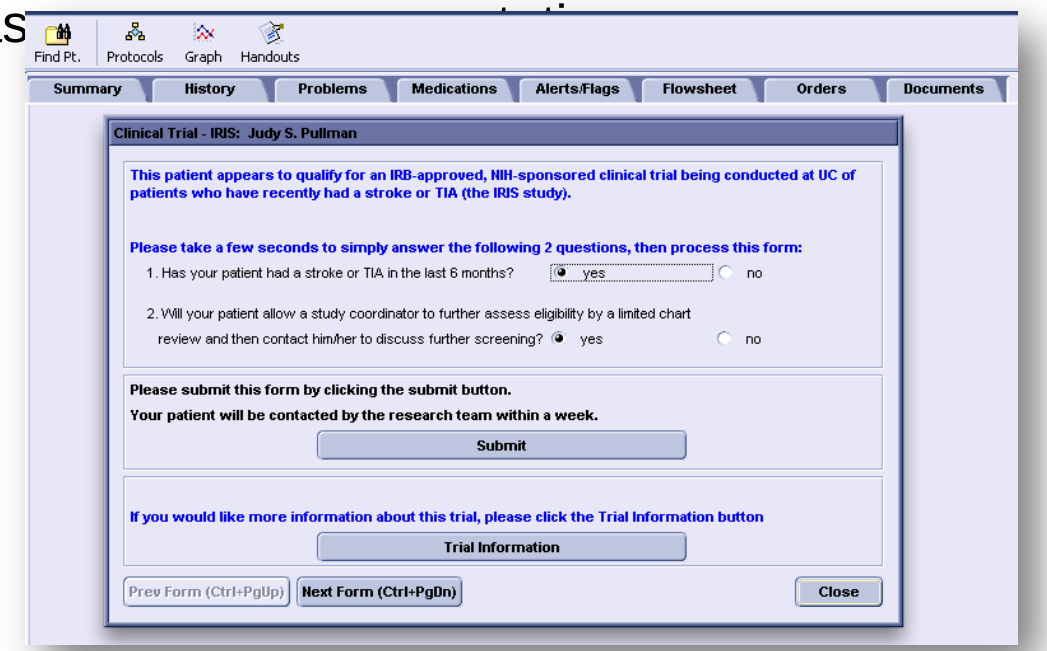
Realizing EGM: Informatics
Clinical Trial Alert

- 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

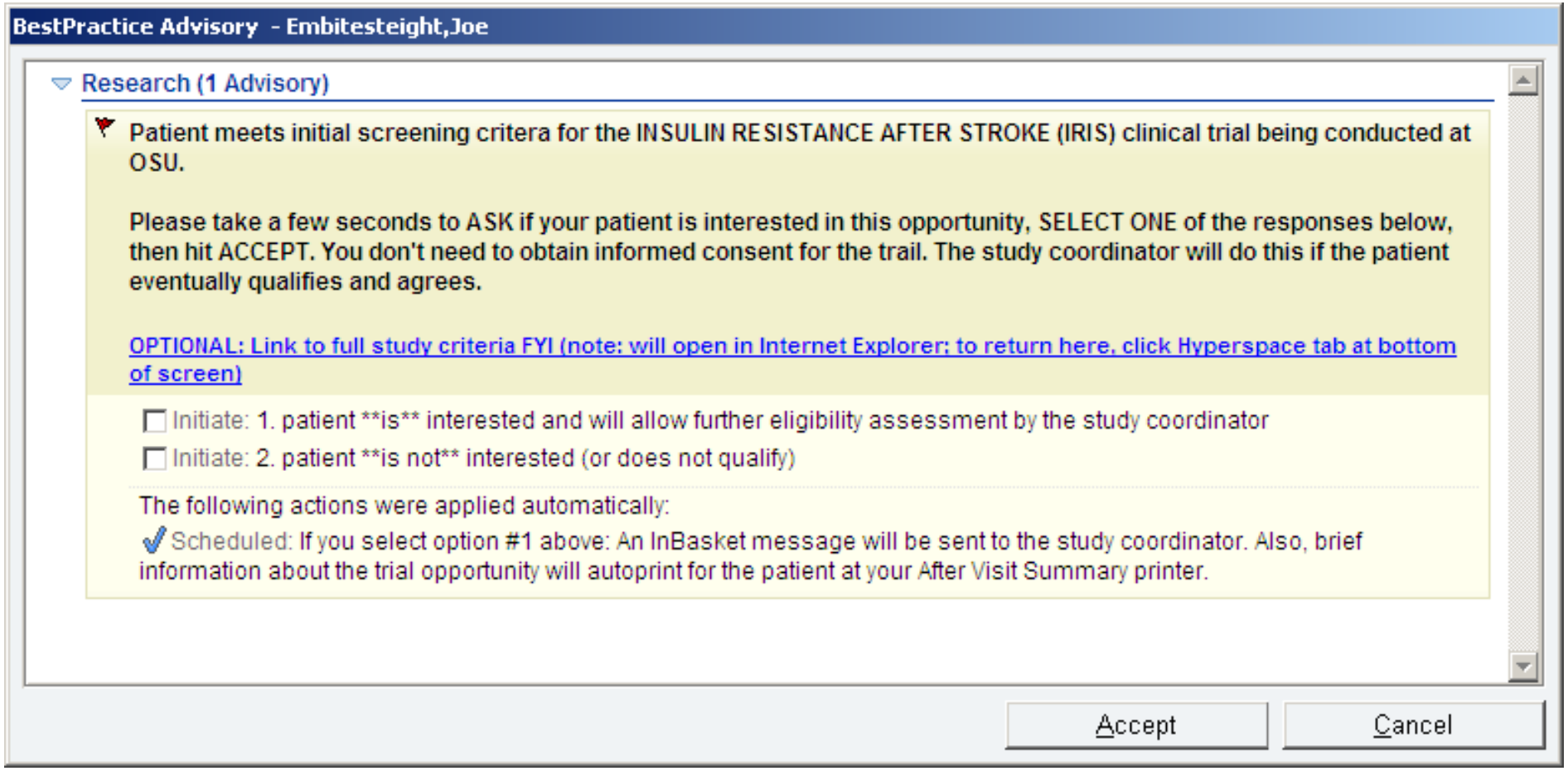
Realizing EGM: Informatics
Clinical Trial Alert RCT

- Addressed key generalizability questions; rigorous design
  - Applied to different diseas
    - **I**nsulin **R**esistance **I**n **S**troke (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



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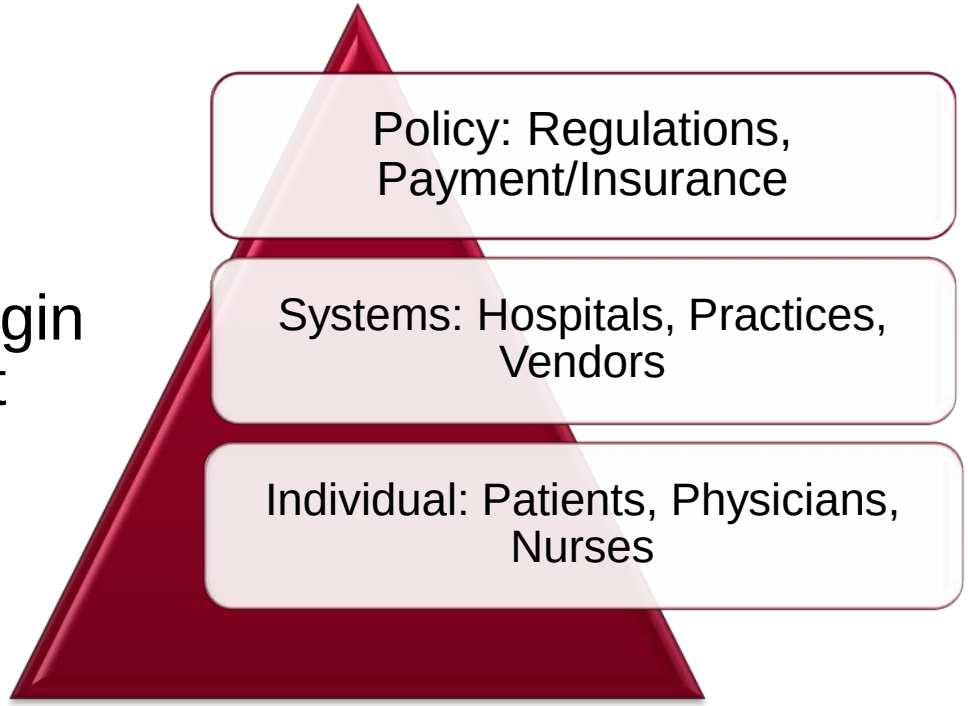
Advancing EGM: Socio-organizational issues & EGM

- 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…

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Extra slides

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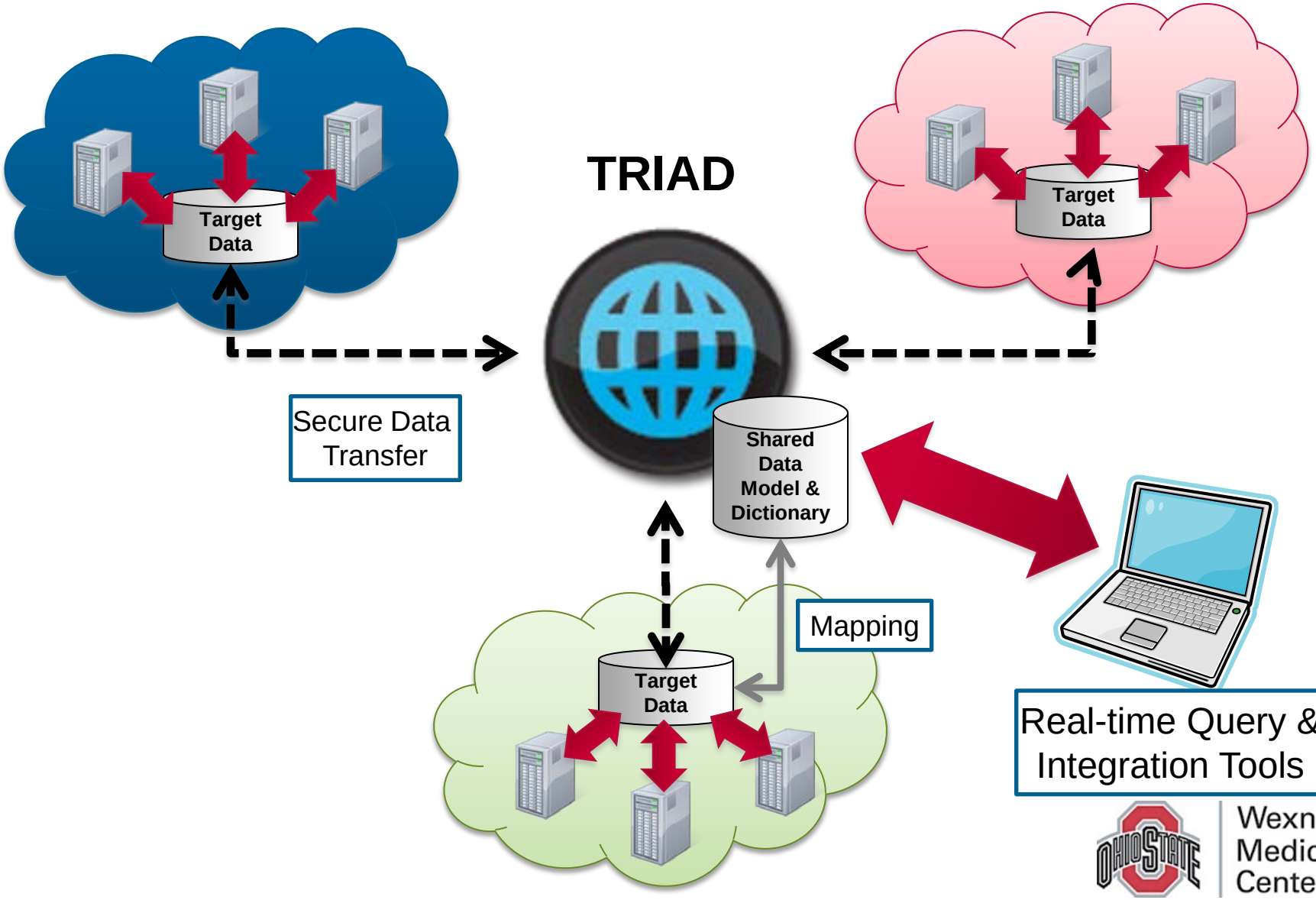
Realizing EGM: Informatics
Leveraging EHRs: Federated Data



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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
    - (Embi PJ et al. BMC Medical Inform & Dec Making. 2008)
- Others have since also studied CTA approach, such as…
    - Rollman RB. JGIM. 2008
    - Grundmeier RW. Proc AMIA. 2007
- Ongoing studies using RCT approach…

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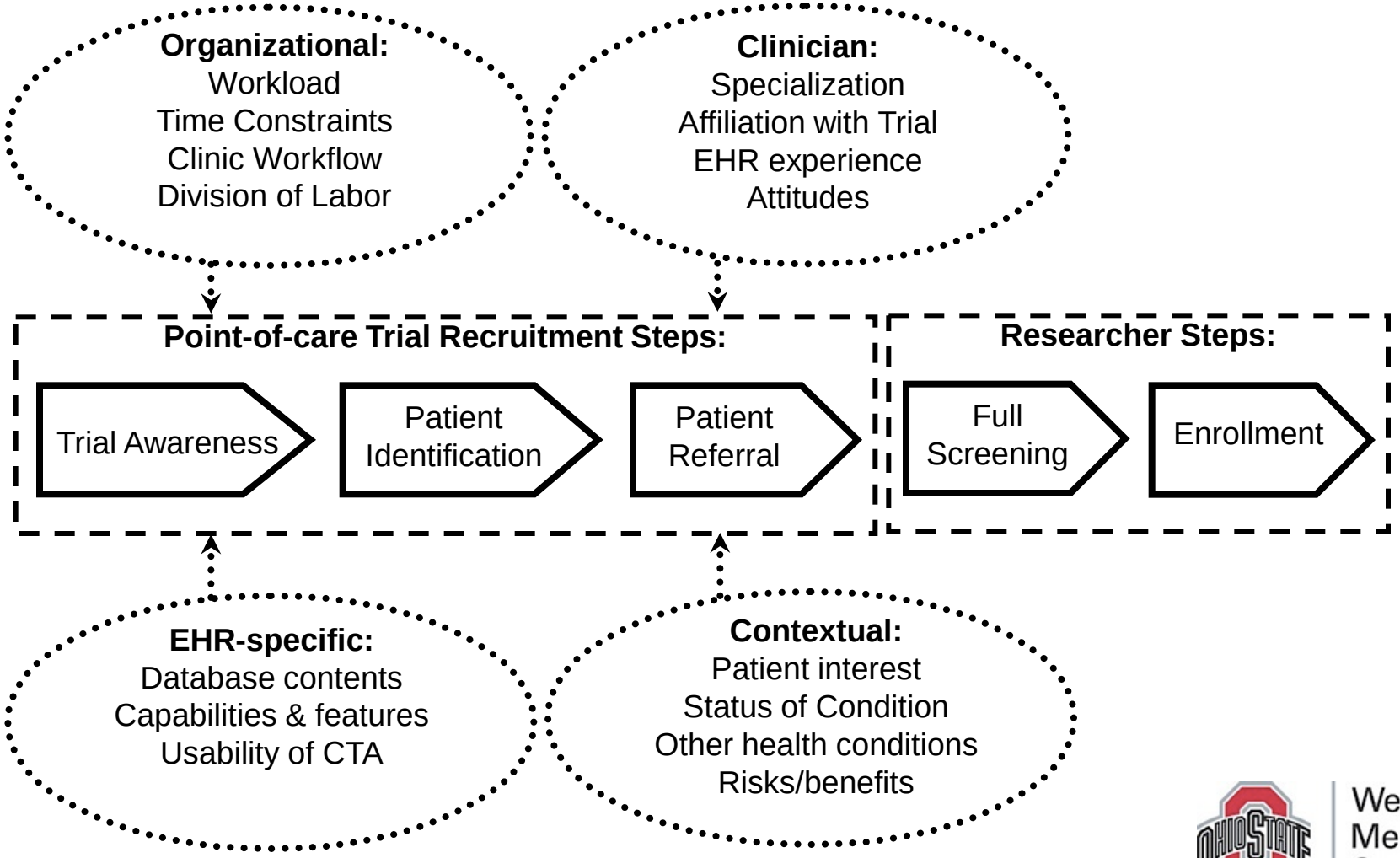
Realizing EGM:
Factors that Influence CTA-facilitate Recruitment at the Point-of-Care: Emerging Conceptual Model



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