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Breakout Group #4
"Fostering physician-investigator careers outside the laboratory: Clinical, implementation, use of electronic medical records, and 'Big Data' "

Melvin Blanchard, MD, FACP
Mark Geraci, MD

Outline

- **Case for more and faster research results outside the lab**
- **Opportunities and challenges for investigators**
  - Clinical research
  - EHR based research
  - "Big Data"
  - Implementation science
- **Discussions questions**

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Case for More & Faster Research Results

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- The "Art of Medicine" contributes to practice variation
  - Noted since 1970s and gave rise to EBM
  - <50% of all medical treatments based on evidence
  - Driving the cost of healthcare
- IOM: 90% of practice will be based on evidence in 2020
- Therefore, research to define which clinical approaches work and which do not work must be done
  - T2 research must increase

- IOM (Institute of Medicine). 2008. *Evidence-based medicine and the changing nature of health care: 2007 IOM annual meeting summary.* Washington, DC: The National Academies Press.
- IOM (Institute of Medicine). 2010. *Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary.* Washington, DC: The National Academies Press.
- Health Affairs 2005;24:9

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- **IOM**
  - "Ideal in health care characterized by utilization of efficient and reliable methods for the development, dissemination, and application of evidence."

- **Evidence is derived through four main methods:**
  - (1) systematic reviews of the literature
  - (2) decision modeling on the basis of literature reviews
  - (3) **analyses of administrative claims data or EHR data**
  - (4) **experimental or observational prospective studies**

IOM (Institute of Medicine). 2008. *Evidence-based medicine and the changing nature of health care: 2007 IOM annual meeting summary.* Washington, DC: The National Academies Press.

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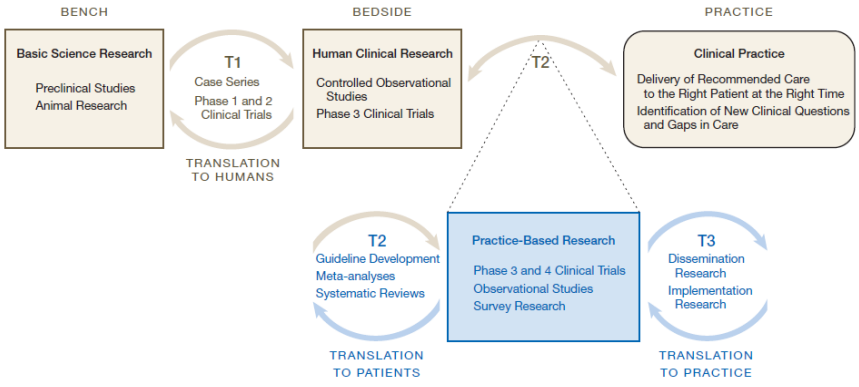
Figure. "Blue Highways" on the NIH Roadmap



JAMA 2007;292:403-407

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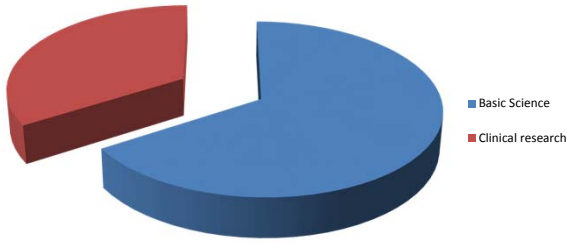
NIH Expenditure



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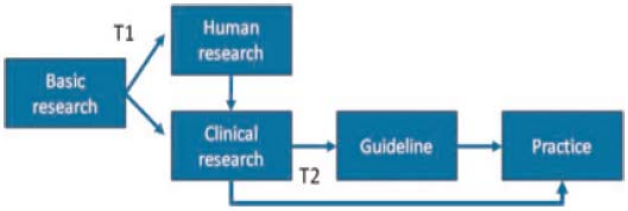
Cycle of evidence development

17 years from Research ➔ Benefit



T1: Conversion from bench to potential clinical product (bench to bedside)

T2: From promising intervention to healthcare practice (research to practice)

J R Soc Med 2011;104:510-520

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- We have to:
  - Increase generation of evidence for care and systems for effectively delivering care
  - Increase speed of evidence generation

- **Importance of T2 research**
- **Fostering investigators outside the lab:**
  - Clinical research
  - Implementation science
  - Use of EHR for research data
  - Use of "Big Data"

Opportunities and Challenges for Investigators

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Opportunities with Clinical research

- Clinical research:
  - Defines the clinical approaches that work and those that do not?

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Challenges for Clinical Investigators

- Funding and protected time
- Lack of support infrastructure
- Inadequate research training
  - inadequate mentorship and coaching
- Establishing clinical trial and material transfer agreements with sponsors and medical centers
- Obtaining IRB approvals, subject recruitment, complex consent forms and regulatory paperwork
- Data collection challenges

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Opportunities for research with EHR and Big Data

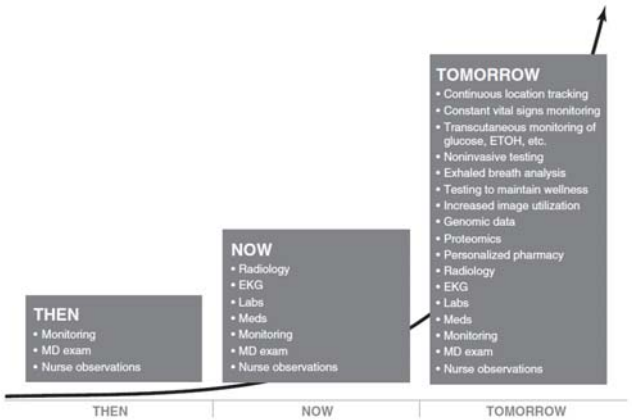

FIGURE 5-1 Data advances in medicine.

IOM

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Benefits of using EHR data

- Instant access to comprehensive data
- Ability to study longitudinally rather than narrow period
- Access to large sample size – 1,000,000s of patients vs 1,000s
- Opportunity to reconfigure studies
- Ability to evaluate population health and correlate with sociodemographic factors

Challenges using EHR data

- Data quality
  - Accuracy, completeness, comprehensiveness
- Paper records
- Unstructured data
- Inadequate IT support

Opportunity for research with "Big Data"

- Imagine walking into room of a patient with uncontrolled DM despite two drugs and the EMR recommend the next most effective drug specific patient:
  - *"Judging from her track record and characteristics, there is an 80% chance that this patient's a1c is likely to drop from 9.3 to 6.8 in 3 months if prescribed drug Z."*

Capability of "Big Data"

- Facilitates delivery of care that is:
  - Predictive
  - Personalized
    - Tailoring each decision in care to specific individuals
  - Preventive
  - Participatory

"Big Data"

- Routine operation of healthcare generate
  - ~2 exabytes of data per year
- Analytics could help offer:
  - right treatment to right patient at right time

Orders of magnitude for data		
Value	Measure	
1000	kB	kilobyte
1000^2	MB	megabyte
1000^3	GB	gigabyte
1000^4	TB	terabyte
1000^5	PB	petabyte
1000^6	**EB**	**exabyte**
1000^7	ZB	zetabyte
1000^8	YB	yottabyte

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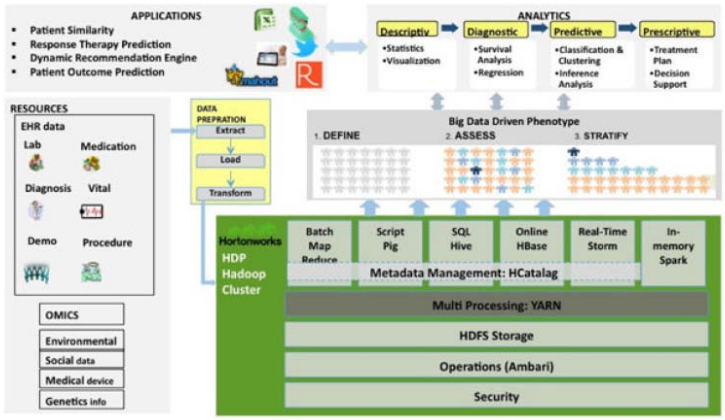

Figure 1.
Mayo's Big Data Architecture

Proc IEEE Int Conf Big Data. 2014 October ; 2014: 790–795.

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Challenges with "Big Data"

- **Variety**
  - Heterogenous, structured, unstructured, unlinked
  - Images, text, discrete, audio
- **Quality**
  - Semantics and ontology
  - GIGO
- **Volume**
  - 50x increase in 2020 c/w 2012
  - 25,000 Petabytes in 2020
- **Velocity**
  - Rapid changes in healthcare
- **Unlinked**
  - datasets (insurance claims, pharmacy records, HER data, social media, wearables, environmental data)
- **Other data allowed?**
  - 23 and Me; QOL, Pacemaker

Challenges for Investigators using "Big Data"

- Infrastructure for massive data storage and processing
- IRB/Ethics issues
  - Which patients need consent and which do not
- Data sharing and governance
- Experimental design and hypothesis generation
- Building multidisciplinary teams

Opportunities in Implementation Research

- Implementation Science
  - Transforms what we **know** into what we **do**
  - Takes guidelines and implement into routine use

- $200B on DM
  - 25 lipid drugs
  - 218 antihypertensives
  - 134 hypoglycemic agents
  - 526,687 articles about DM in PubMed

12%

DM with goal lipids, BP, glycemia

Challenges in Implementation Research

- As a young science, there are few mentors
- Requires multiple skills and multiple disciplines
  - Implementation scientists, economists, educators for staff training, behavioral psychology, communications expert for dissemination, Medicine, Statistician,…
- Funding
- Quality of science and reputation among colleagues
- No equivalent of “core labs” for stability of enterprise

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Discussions & Questions

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Questions

1. What are the core competencies for research in these areas (implementation, EHR, "Big Data") and how do we train investigators (who are already faculty)?

2. For implementation, EHR and "Big Data" research, a large number of disciplines are required. How do we assess contribution (amount and significance) so investigators are rewarded?

3. What cultural change is needed to ensure respect for the softer sciences such as implementation, EHR and "Big Data" research?

Questions

4. What infrastructure is needed to sustainably support investigators in academic medical centers for successful research?

5. What curricular changes are needed in medical school and residency to prepare trainees for research in these areas?

Thank you!

Melvin Blanchard, MD
mblancha@dom.wustl.edu

Mark Geraci, MD
MGeraci@IU.edu

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1. What are the core competencies for research in these areas (clinical, implementation, EHR, "Big Data") and how do we train investigators (who are already faculty)?

- *In training plan, consider what investigators, professional societies, funders, research institutions should do*

Competence	Clinical Research	EHR	Big Data	Implementation	Training plan

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2. For clinical implementation, EHR and "Big Data" research, a large number of disciplines are required. How do we assess contribution (amount and significance) so investigators are rewarded?

- Tenure and promotion committees consider number of grants, publications, national expertise. Does this undervalue some contribution s of investigators in these areas? What else can be considered?

Research area	Method for assessing contribution
Clinical research	
EHR	
Big Data	
Dissemination Science	

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3. What cultural change is needed to ensure respect for the softer sciences such as implementation, EHR and "Big Data" research?

- How to we help institutions realize that all research questions are important and that the methodology for conducting research may differ and should not necessarily determine value of the research.

Cultural changes
Adoption of guidelines such as CONSORT and ISPOR for implementation, EHR and Big Data research

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4. What infrastructure is needed to sustainably support investigators in academic medical centers for successful research?

- *eg. Formal training programs for investigators, equivalent of "core labs" for researchers in these areas.*

Research area	Infrastructure changes needed
Clinical research	
EHR based research	
Big Data	
Implementation science	

5. What curricular changes are needed in medical school and residency to prepare trainees for research in these areas?

- eg. *Given the importance of research in these areas, should research and design methodology, data management, data interpretation be more emphasized in medical school*

Curricular changes

Who will Do what by When

Who	Do What	When

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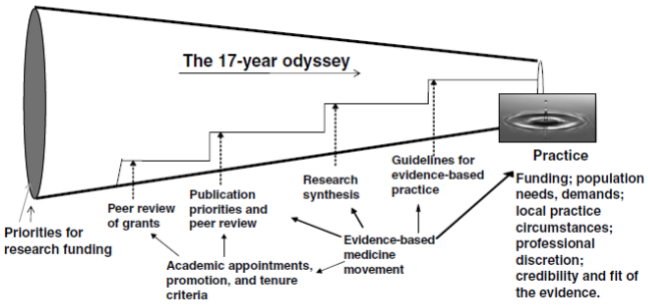
TABLE 2-3 Performance of Selected Major Academic Medical Centers on Measures of Adherence to Biologically Targeted Treatments and the Intensity of Care Delivery

	UCLA Medical Center	Johns Hopkins Hospital	Massachusetts General Hospital	Cleveland Clinic Foundation	Mayo Clinic (St. Mary's Hospital)
Provision of discrete, biologically targeted evidence-based interventions					
Composite quality score on measures of inpatient technical quality	81.5	84.3	85.9	89.2	90.4
Spending and care delivery for patients with serious chronic illness during last 6 months of life					
Medicare spending	50,522	43,363	40,181	28,077	26,330
Physician visits	52.1	29.8	42.2	32.2	23.9
Hospital days	19.2	17.1	17.7	14.6	12.9
Intensive care days	11.4	4.3	2.8	3.5	3.9
% admitted to hospice	26.1	31.5	19.6	34.2	25.5
% seeing 10 or more physicians	57.7	44.3	54.6	46.8	43.0

NOTES: Hospitals were selected for inclusion because they were ranked as the top five academic medical centers on the *U.S. News and World Report's* 2007 "Honor Roll." Utilization data are for 1999-2003. Composite quality score was calculated from CMS data for 2005, which are from the Dartmouth Atlas of Health Care.


The 17-year odyssey
Practice
Guidelines for evidence-based practice
Research synthesis
Publication priorities and peer review
Peer review of grants
Priorities for research funding
Funding; population needs, demands; local practice circumstances; professional discretion; credibility and fit of the evidence.
Evidence-based medicine movement
Academic appointments, promotion, and tenure criteria