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
Case for More & Faster Research Results

• 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

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3. Health Affairs 2005;24:9
• **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


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**Figure.** “Blue Highways” on the NIH Roadmap

[Diagram showing the NIH Roadmap with pathways from Bench to Practice, including T1: Case Series, Phase 1 and 2 Clinical Trials, T2: Human Clinical Research, Controlled Observational Studies, Phase 3 Clinical Trials, and T3: Delivery of Recommended Care to the Right Patient at the Right Time, Identification of New Clinical Questions and Gaps in Care.]

JAMA 2007;292:403-407
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)
• 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

Opportunities with Clinical research

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

Opportunities for research with EHR and Big Data

FIGURE 5-1 Data advances in medicine.
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

<table>
<thead>
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<th>Value</th>
<th>Measure</th>
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<td>1000^2</td>
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<td>1000^7</td>
<td>ZB</td>
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<td>1000^8</td>
<td>YB</td>
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Figure 1. Mayo’s Big Data Architecture

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

Discussions & Questions
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?
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

<table>
<thead>
<tr>
<th>Competence</th>
<th>Clinical Research</th>
<th>EHR</th>
<th>Big Data</th>
<th>Implementation</th>
<th>Training plan</th>
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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 contributions of investigators in these areas? What else can be considered?

<table>
<thead>
<tr>
<th>Research area</th>
<th>Method for assessing contribution</th>
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<tbody>
<tr>
<td>Clinical research</td>
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<tr>
<td>EHR</td>
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<td>Big Data</td>
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<td>Dissemination Science</td>
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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 do 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.

<table>
<thead>
<tr>
<th>Cultural changes</th>
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<tr>
<td>Adoption of guidelines such as CONSORT and ISPOR for</td>
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<td>implementation, EHR and Big Data research</td>
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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.

<table>
<thead>
<tr>
<th>Research area</th>
<th>Infrastructure changes needed</th>
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<td>Clinical research</td>
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<td>EHR based research</td>
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<td>Big Data</td>
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<tr>
<td>Implementation science</td>
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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

<table>
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<th>Curricular changes</th>
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### Who will Do what by When

<table>
<thead>
<tr>
<th>Who</th>
<th>Do What</th>
<th>When</th>
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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**

<table>
<thead>
<tr>
<th>Measure of Adherence / Intensity of Care</th>
<th>UCLA Medical Center</th>
<th>Johns Hopkins Hospital</th>
<th>Massachusetts General Hospital</th>
<th>Cleveland Clinic Foundation</th>
<th>Mayo Clinic (St. Mary's Hospital)</th>
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<tbody>
<tr>
<td>Composite quality score on measures of care quality</td>
<td>81.5</td>
<td>84.3</td>
<td>85.9</td>
<td>89.2</td>
<td>90.4</td>
</tr>
<tr>
<td>Spending and care delivery for patients with serious chronic illness during last 6 months of life</td>
<td>30,522</td>
<td>43,361</td>
<td>40,181</td>
<td>28,077</td>
<td>26,330</td>
</tr>
<tr>
<td>Physician visits</td>
<td>52.1</td>
<td>29.8</td>
<td>42.2</td>
<td>32.2</td>
<td>23.9</td>
</tr>
<tr>
<td>Hospital days</td>
<td>19.2</td>
<td>17.1</td>
<td>17.7</td>
<td>14.6</td>
<td>12.9</td>
</tr>
<tr>
<td>Intensive care days</td>
<td>11.4</td>
<td>4.3</td>
<td>2.8</td>
<td>3.5</td>
<td>3.9</td>
</tr>
<tr>
<td>% admitted to hospice</td>
<td>26.3</td>
<td>31.5</td>
<td>19.6</td>
<td>34.2</td>
<td>23.5</td>
</tr>
<tr>
<td>% seeing 10 or more physicians</td>
<td>37.7</td>
<td>44.3</td>
<td>54.6</td>
<td>46.8</td>
<td>43.0</td>
</tr>
</tbody>
</table>

**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 "Mover 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.