The Intersection between Precision Medicine and Implementation Science

Precision Medicine and Population Health (PMPH) Interest Group
Session Logistics

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Session Logistics

● Introduction
  ● Dr. Muin Khoury (@DrKhouryCDC)
    Director, Office of Public Health Genomics, CDC
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● Presentations
  ● Dr. David Chambers (@NCIDAChambers)
    Deputy Director for Implementation Science, Division of Cancer Control & Population Sciences
  
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    Professor of Medicine, Pathology, and Biomedical Engineering, Duke University

● Questions
The Intersection between Precision Medicine and Implementation Science

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Session Outline

- A Brief Orientation to Implementation Science
- Considering Implementation Science within Precision Medicine?
- Challenging Existing Assumptions
It takes 17 years to turn 14 percent of original research to the benefit of patient care.

Original research

Submission

Negative results

Dickersin, 1987

variable

Reviews, guidelines, textbook

Poynard, 1985

Inconsistent indexing

Poynard, 1985

Implementation

9.3 years

“PUBLICATION PATHWAY”
We assume… “If you build it…”
Beyond The Test Itself…

- Even if genetic testing can identify optimal treatment for a specific illness or reduce risk for health problems, if:
  - Only half of insurers choose to provide them
  - Half of those systems choose to train clinicians to prescribe it
  - Half of the clinicians at those systems prescribe it
  - Half of their patients get tested:

(Assuming perfect access/testing/follow-up)

Impact: $0.5 \times 0.5 \times 0.5 \times 0.5 = 6\%$ benefit
Key Terms

- **Implementation Science** is the study of methods to promote the integration of research findings and evidence into healthcare policy and practice.

- **Dissemination research** is the scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to understand how best to spread and sustain knowledge and the associated evidence-based interventions.

- **Implementation research** is the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health.
Dissemination Research focuses on the process through:

- How the “evidence” is created?
- Packaging
- Transmitting
- Receiving
- Turning Information into Action
Studying Implementation

What?
- QIs
- ESTs

How?
- Implementation Strategies

Implementation Outcomes
- Feasibility
- Fidelity
- Penetration
- Acceptability
- Sustainability
- Uptake
- Costs

Service Outcomes
- Efficiency
- Safety
- Effectiveness
- Equity
- Patient-centeredness
- Timeliness

Health Outcomes
- Satisfaction
- Function
- Health status/symptoms

*IOM Standards of Care

Implementation Research Methods

Proctor et al, 2009, *APMH&MHSR*
Dissemination and Implementation (D&I) Research--

- Theories, empirical findings, and methods from a variety of fields:
  - information science, clinical decision-making, organizational and management theory, economics, individual and systems-level behavioral change, public health, business and public administration, statistics, anthropology, learning theory, engineering, and marketing.

- Collaboration with stakeholders from multiple practice settings, consumers of services and their families/social networks.

- Rigorous and relevant methodological approaches (e.g. observational, experimental, quasi-experimental, and simulation modeling)

- Studies of dissemination or implementation strategies should build knowledge both on the overall effectiveness of the strategies, as well as "how and why" they work (e.g. mechs, moderators, mediators)
Current Funding Announcements

- NIH: PAR-16-237; 13-238;13-236 (R03, R01, R21)
- NCI leads (16 ICs total, including FIC, NIMH, NHLBI, NHGRI, as well as OBSSR)
- Organizes the D&I research agenda across NIH
- >150 grants funded through NIH since 2006
- 2010 CSR standing review committee
- Modal Grant—Randomized trial of an implementation strategy for an effective intervention (where we’ve been)
Example: Lynch Syndrome

Sample IS Challenges:

- ID of Lynch Syndrome within CRC pop
- Family member scale-up
- Implementing screening/monitoring/
Example Two: BRCA1/2

Sample IS Challenges:

- ID of BRCA1/2 at pop level
- Family member scale-up
- Implementing screening/monitoring/pre-emptive Tx

Chances of Developing Breast Cancer by Age 70

- 6 in 10
- Mutated BRCA1
- 4 in 10
- Mutated BRCA2
- 1 in 10
- Normal BRCA

People now have the option of knowing if they are more likely to develop breast cancers.

Source:
See the references section of http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA
Example Three: PMI

Sample IS Challenges

- How does clinical practice incorporate PMI findings?
- How do you implement evidence that will be evolving?
- How do you train and support the workforce?
- What services will be covered/paid for?
Traditional Assumptions

- Evidence and Evidence-based practices are static
- System is static
- Implementation proceeds one practice or test at a time
- Consumers/Patients are homogeneous
- Choosing to not implement is irrational

How well do these relate to the implementation of precision medicine?
Choosing not to implement is irrational... (Does it fit?)

- QUESTIONS ABOUT “ACTIONABILITY”
- WHAT IS REIMBURSED?
- IS COUNSELING AVAILABLE?
- ARE EXISTING TESTS OPTIMAL?
- IS THERE A DEMAND FOR THE KNOWLEDGE?
Sustainability or Evolution?

- If precision medicine continues to evolve, should existing interventions be sustained in the same form that we’ve created them?
- How does the system cope with a dynamic field that is constantly changing?
- Where do we go from here?
A Dynamic Approach to Sustainability…

Enter the learning health care system…

Hope for the future…
Guiding Principles for IS & PM…

- First, context matters and is multilevel.
- Second, it’s not just whether a practice works, but whether that practice can be delivered in many real-world settings.
- Third, there are effective strategies to implement evidence-based practices.
- Fourth, implementation science is a team sport. Partnerships needed with a range of stakeholders, including patients, clinicians, administrators, researchers, and policy makers.
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