Engaging Diverse Communities in Precision Medicine: Why and How?

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Vanderbilt Institute for Clinical and Translational Research (VICTR)

Tennessee Public Health Association – September 15, 2016
Overview

- What is Precision Medicine?
- The Precision Medicine Initiative (PMI)
- Why is precision medicine relevant to public health?
- Approaches to inclusivity and diversity
A Precision Medicine discovery and implementation view of the world

Survey instruments
Genomics
Images
mHealth
Metabolomics
Proteomics
Geospatial, food deserts
Poverty
Health records
“We are on the leading edge of a true revolution in medicine, one that promises to transform the traditional “one size fits all” approach into a much more powerful strategy that considers each individual as unique and as having special characteristics that should guide an approach to staying healthy”
“Personalized medicine” refers to the tailoring of medical treatment to the individual characteristics of each patient. It does not literally mean the creation of drugs or medical devices that are unique to a patient, but rather the ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment.” PCAST, 2008
Perspective

Preparing for Precision Medicine

Reza Mirnezami, M.R.C.S., Jeremy Nicholson, Ph.D., and Ara Darzi, M.D.

Moving toward precision medicine

Editorial

Clinical Pharmacology & Therapeutics 94, 169-172 (August 2013) | doi:10.1038/clpt.2013.101

Genomic Medicine, Precision Medicine, Personalized Medicine: What’s in a Name?

D M Roden and R F Tyndale

This issue of Clinical Pharmacology & Therapeutics is devoted to genomic medicine, and a reader may reasonably ask what we mean when we use those words. In the initial issue of the journal
What is precision medicine?

Precision medicine is an *emerging approach* for disease prevention and treatment that takes into account people’s variation in genes, environment, and lifestyle.
Precision Medicine

Concept is not new

• Consider prescription eyeglasses, blood transfusions...
• Prospects for broader application raised by recent advances in basic research, technology development, genomics, proteomics, metabolomics, EHRs, Big Data, mHealth, etc.

Why now

• Advances in data science and bioinformatics
• Better technologies for biomedical analysis
• New technologies for genomics
• Human-genome sequencing continues to get cheaper and faster
• Availability of new data – microbiome, diagnostics, and sensor data
Precision Medicine Initiative (PMI)
A New Initiative on Precision Medicine

Francis S. Collins, M.D., Ph.D., and Harold Varmus, M.D.

Comments open through March 4, 2015

“Tonight, I'm launching a new Precision Medicine Initiative to bring us closer to curing diseases like cancer and diabetes — and to give all of us access to the personalized information we need to keep ourselves and our families healthier.”

— President Barack Obama, State of the Union Address, January 20, 2015
Precision Medicine Initiative (PMI)  
Mission Statement

To enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized treatments.
Precision Medicine Initiative

Science Priorities:
- Cancer clinical trials – expand on successes in cancer precision medicine
- Large Research Cohort – 1 million or more Americans sharing their research & health data to advance precision medicine for all diseases
- Standards and resource development

Policy Priorities
- Streamline regulatory review of genomic technologies
- Ensure adequate privacy safeguards are in place
Science Priorities: National Research Cohort

- At least 1 million U.S. volunteers
- Participants will be:
  - Centrally involved in design, implementation
  - Able to share genomic data, lifestyle information, biological samples – all linked to their electronic health records
  - Can choose how, when to participate in research studies
- Will forge new model for scientific research that emphasizes:
  - Engaged participants
  - Open, responsible data sharing with privacy protections
Precision Public Health for the Era of Precision Medicine

Muin J. Khoury, MD, PhD, 1,2 Michael F. Iademarco, MD, MPH, 1,3 William T. Riley, PhD 2

The Precision Medicine Initiative 1 promises a new healthcare era. A proposed 1 million-person cohort could create a deeper understanding of disease causation. Improvements in quality of sequencing, reduction in price, and advances in "omic" fields and biotechnology promise a new era, variably labeled personalized or precision medicine. Although genomics is one driver of precision health care, other factors may be as important (e.g., health information technology).

Both excitement and skepticism met the announcement. 2 Public health experts are concerned about the disproportionate emphasis on genes, drugs, and disease, while neglecting strategies to address social determinants of health. A health priority by focus In 2014, Certally proven U.S. 3 Data 1 potentially p risk factors physical act. Could th medicine us health "beyo medicine is right patient be simply vi the right ps methods for behaviors, a ment of poj and targeted drive toward much more.

A Public Health Perspective on a National Precision Medicine Cohort Balancing Long-term Knowledge Generation With Early Health Benefit

Precision Lifestyle Medicine
A New Frontier in the Science of Behavior Change and Population Health

Jun Ma, MD, PhD, 1,2,3 Lisa G. Rosas, MPH, PhD, 2,3 Nan Lv, PhD 2

Despite marked strides in population health and increased life expectancy in the U.S. over the past two decades, chronic disease and disability dominate the U.S. health burden, 1 leading to poor quality of life, high healthcare use and costs, functional impairment, psychological distress, and premature death. An estimated one in seven U.S. adults has at least two of five major chronic conditions: cardiovascular disease, cancer, chronic obstructive pulmonary disease, diabetes, and arthritis. 2 These chronic conditions are highly related to unhealthy lifestyle factors, particularly smoking, physical inactivity, poor diet quality, and worsening or stagnant rates of obesity. The continuing erosion of these lifestyle factors 3 foretells increasing incidence, prevalence, and co-occurrence of lifestyle-related chronic new accountable care paradigm and critical to achieving the Triple Aim. Precision lifestyle medicine is fundamental to the success of these efforts to prevent and control costly chronic conditions, improve the health of populations, and eliminate health disparities.

The precision medicine movement, propelled by a recent presidential initiative and an NIH-sponsored national research cohort, heralds targeted and proactive treatments for precisely characterized disease phenotypes and endotypes to achieve optimal health for individual patients, made possible, in part, by advances in translational clinical research and biomedical technologies. Khoury and Evans 4 proposed the term precision prevention, which highlights opportunities to reap the benefits of precision medicine—increased effectiveness and efficiency.
### Using molecular technologies to counter infections in patients and populations

<table>
<thead>
<tr>
<th>Application</th>
<th>Patient care</th>
<th>Public health</th>
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<tbody>
<tr>
<td>Pathogen identification</td>
<td>Rapid diagnosis</td>
<td>Outbreak detection</td>
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<tr>
<td>Antibiotic selection</td>
<td>Proper treatment</td>
<td>Effective antibiotic use guidelines</td>
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<tr>
<td>Vaccines</td>
<td>Better protection</td>
<td>Reduced burden of disease</td>
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</table>
Precision Medicine and Public Health

• Improving Early Detection of Pathogens and Infectious Disease Outbreaks
• Modernizing Public Health Surveillance, Epidemiology and Information Systems
• Targeting Health Interventions to Improve Health and Prevent Disease

March 2, 2015; Muin J Khoury, Director, Office of Public Health Genomics, CDC
Benefits & Challenges to Engagement

**Benefits**
- Stakeholders bring a lived experience knowledge
- Stakeholders’ knowledge is practical & complements the researchers’ scientific knowledge
- Can enhance the quality & relevance of clinical research

**Challenges**
- A new concept for many researchers
- Skills typically developed in rigorous career training do not translate to identifying, recruiting & convening stakeholders
- Becoming proficient requires training and hands-on experience; may take years
The Continuum of Community (Stakeholder) Engagement in Research

Patient/Community-Driven Research: Stakeholders serve as Principal Investigator (PI) or Co-PI and are leading the research.

Research Team Members: Stakeholders are integral members of the research team and participate in key activities.

Advisory and Governance: Stakeholders serve on boards, councils, and committees that provide oversight and/or guidance.

Focus groups, semi-structured interviews, nominal groups techniques, Community Engagement Studios: Stakeholders serve specific, time-limited roles.

Surveys, online polling, listening sessions: Broader community of stakeholders provides brief input.

Ongoing Involvement

Short-Term Involvement

Number of Stakeholders

Wilkins CH et al. 2015
Community Engagement Studios

- Structured process
- Project-specific input
- Use in any phase of translational research
- Stakeholders selected based on project
- Experienced team identifies stakeholders
- Reduces burden to researcher

Community Engagement Studios:
- consultative method of stakeholder engagement
- 90-minute facilitated roundtable

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<tr>
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<th>Community Engagement Studios</th>
<th>Focus Groups</th>
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<tr>
<td>Purpose</td>
<td>Obtain feedback/guidance to inform research at any stage</td>
<td>Qualitative research</td>
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<tr>
<td>Approach</td>
<td>A dialogue; bi-directional discussion</td>
<td>Uni-directional</td>
</tr>
<tr>
<td>Participants</td>
<td>Serve as consultants; experts based on “lived experience”</td>
<td>Research participants</td>
</tr>
<tr>
<td>Participants determined</td>
<td>In consultation with community engaged research team</td>
<td>Research team</td>
</tr>
<tr>
<td>Facilitator</td>
<td>A trained community member; balances power</td>
<td>Usually research team</td>
</tr>
<tr>
<td>Pre-meeting activities</td>
<td>Consultation with CE Studio team; coaching for research team; orientation for community experts</td>
<td>Usually none</td>
</tr>
<tr>
<td>Compensation</td>
<td>Consultant fee equivalent to local volunteer compensation rate</td>
<td>Incentives determined by health research team</td>
</tr>
<tr>
<td>Other distinctions</td>
<td>Written and oral comments; may request additional information; may question research approach; may peruse unanticipated topics; may contact after CE studio; paperwork as advisor</td>
<td>IRB approved questions/script; Informed consent obtained; qualitative analysis; no contact after focus group; themes identified and connected with participants</td>
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Clinical trial recruitment before and after a Community Engagement Studio

African American Women Needed for Research Study

This study will look at how muscles absorb glucose (sugar) and how the body regulates your blood pressure.

You may qualify if you:
1. Are an African American, and
2. Have high blood pressure or borderline high blood pressure,
3. Are overweight, and
4. Are between the ages of 18-60 years, and
5. Have high triglycerides, high cholesterol, or high blood sugar, and
6. Do not smoke.

This study will require a screening visit, four clinic visits, two study days, study medications, and blood and urine collections.

Participants will be compensated for their time.

If you would like to learn more about this study, contact
Ginnet Farley
ginnet.farley@vanderbilt.edu
Vanderbilt University

African American Women Needed for Research Study

You can help with this important clinical study that will test if a drug improves blood sugar levels and blood pressure.

This study is conducted at Vanderbilt University Medical Center.

Requires a screening visit, study medication, 3 study days, and blood and urine collection.

Participants will be compensated.

For more information PLEASE CALL 615-689-1033 (Davalynn Johnson)
Davalynn.a.johnson@vanderbilt.edu


Wilkins CH et al; 2015, Developing a measure of trust that includes dimensions more common among racial and ethnic minorities.

Subjective numeracy scale: McNaughton et al Medical Decision Making 2015;35:932-6

Ber, Duke, Boyer, Sherden, Fair, Wilkins 2015
Engagement in the Preparatory/Prototyping Initiative (Pi)
Precision Medicine Initiative Direct Volunteers Pilot

Broad engagement necessary for PMI Cohort success
CE studios, CAB, A/B testing, HCI review, community partners

Traditional participant engagement for trial enrollment and retention

- Public awareness/education
- Public input into PMI design
- Consent/enrollment
- Data collections
- Specimen collections
- Bidirectional flow of information
- Ongoing Engagement

Participant provided (all participants)
Initial exam trials (focused studies)
Mobile-provided data (some)
Prevalent activity monitors (some)
EHR data uploads (some)

Vanderbilt’s Preparatory/Prototyping Initiative PMI Direct Volunteers Pilot - Feb 2016
Optimizing tools and design in PMI through Engagement Studios

17 priority populations identified to test

Planned Community Engagement Studios:

- Website
- Enrollment
- Informed consent
- Return of Value

Other engagement strategies:

- User testing
- Community Advisory Board
- Cognitive Interviews

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<th>Priority Populations</th>
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<tr>
<td>General Population</td>
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<tr>
<td>Parent/Child Dyads</td>
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<tr>
<td>Older Adults (65+)</td>
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<td>Those living in rural areas</td>
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<tr>
<td>Sexual &amp; Gender Minorities</td>
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<tr>
<td>Chinese Americans</td>
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<tr>
<td>Native Americans</td>
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<tr>
<td>Latinos</td>
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<tr>
<td>African Americans</td>
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<tr>
<td>Individuals with limited English proficiency</td>
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<tr>
<td>Individuals with limited educational attainment/literacy</td>
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<tr>
<td>Individuals with 3 or more chronic health conditions</td>
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<td>Individuals with no ability to access the internet</td>
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<tr>
<td>Individuals who are blind or limited vision</td>
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<tr>
<td>Individuals who are deaf or hard of hearing</td>
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<tr>
<td>Individuals with limited technical proficiency</td>
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<tr>
<td>Individuals with limited use of upper extremities</td>
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PMI Community Engagement Studios
(4/29/16 – 8/12/16)

- 49 Community Engagement Studios
- 424 community members consulted
- Avg 8.7 community members/studio
- 42% (178) self-identified as a racial/ethnic minority
- 8% (34) self-identified as a sexual or gender minority
PMI Pilot Community Engagement Studio Participants
(as of August 12, 2016)
Partners for Community Engagement Studios

Community Centers
– MLK Center (Bronzeville, Chicago)
– Mountain Community Parent Resource Ctr, White Oak
– Nashville Opportunities Industrialization Center
– Progreso Community Center (Nashville)

Community Health Centers
– CHIPS Health and Wellness Center (St. Louis)
– Matthew Walker Comprehensive Health Center (Nashville)
– Pueblo Del Sol Community Center (Los Angeles)

Churches and Faith Organizations
– Christ Universal Temple (Chicago)
– Mt. Pisgah Missionary Baptist Church (Chicago)
– Nashville Korean United Methodist Church
– San Lucas United Church of Christ (Chicago)
– Holman Methodist Church (Los Angeles)

Advocacy Organizations
– Alzheimer’s Association, St. Louis Chapter
– Chinese Mutual Aid Association (Chicago)
– Fifty-Forward (Nashville)
– Hearing Loss Association of America (Nashville)
– Middle Tennessee Council of the Blind
– Nashville CARES
– SunServe, Inc. (Ft. Lauderdale)

Other Partners
– Community Campus Partnerships for Health (CCPH)
– Lowell Elementary School (Chicago)
– Office of Commissioner Stanley Moore (Chicago)
– National Association of Hispanic Nurses, Los Angeles

Academic Institutions
– University of Miami Miller School of Medicine
– Univ of South Dakota School of Medicine/Sanford
– Cedars Sinai Medical Center
– Univ of Rochester, National Center for Deaf Health Res
Vanderbilt-Miami-Meharry Center of Excellence in Precision Medicine & Population Health Organizational Chart

Center of Excellence in Precision Medicine and Population Health

Oversight and Advisory:
Steering Committee, Consortium Advisory Board, Ethics Advisory Board

Executive Committee:
Wilkins, Cox, Weiss, Lima

Operations Committee

Evaluation Team

Project Managers

Biospecimen and Clinical Data Core

Consortium Core

Implementation Core

Training and Mentoring Core

Disparity Driver Analysis
Pl: Rao/Kobetz

Genetic Risk of Disparity
Pl: Cox

Person-Specific Obesity Tx
Pl: Griffith
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