Implementation Science Workshop: Synthesis

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Implementation of Genomic Medicine Workshop 2015
November 19, 2015

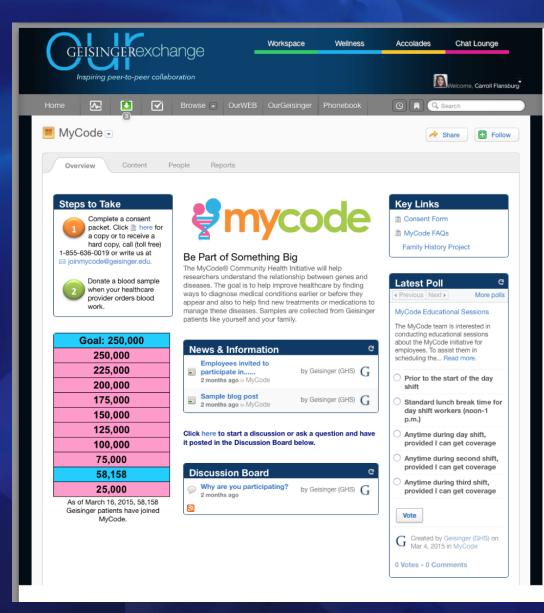
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Caveat

 The time is inadequate to do the presentations and discussions (and all that went into them) justice...

Filling Gaps Learned Through Community Engagement

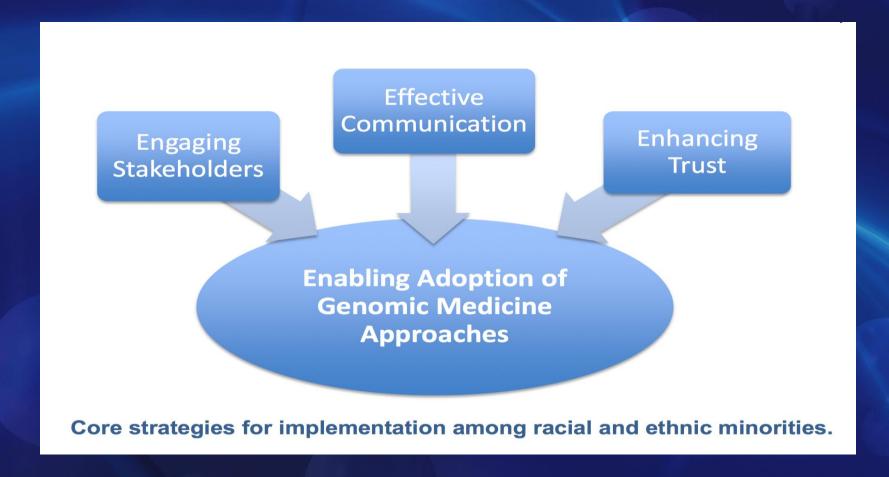


Employee Campaign

Two Goals

- All employees know basics of campaign and where to refer
- Employees have opportunity to participate

Lessons from recruitment



Research and Practice Overlap

Psychosocial and Environmental Markers of Trust in Trust in Biomedical Research Influencers **Biomedical Research** Cultural beliefs **Dimensions of Trust** ➤ Utilization of Research - Confidence in research results Educational attainment Honesty Range of Trust Participation in Research Socioeconomic status Communication - Willingness to volunteer for research Personal health status Confidentiality **High Trust** - Adherence to research protocols Personal experiences with health - Opting in or out of records or programs Safety Low Trust systems / research Groups' experience with: Fairness Mistrust Support - Support of family members or friends - Health systems Confidence Distrust who volunteer for research - Research past Competence - Research Present Fidelity **Engagement in Research** Participation as a research team member Experiences with discrimination System Trust - Acting as adviser or reviewer Historical research abuses - Participation in research prioritization Proposing or designing research



FROM PROJECTS TO AN ECOSYSTEM

Step 5

Establish clinical platform

Step 4

Post-competition engagement with regulatory and healthcare

Step 3

Panel guidelines: making the socioeconomic benefits cost

Step 2

Selecting clinically-oriented panel

Step 1

Designing implementation in the RFA



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Discussion Session One

- The "so what" question--IMPACT
- Engagement with patients, families, other stakeholders (PCOR)
- Fit with population needs
- Understanding/fit of local context
- Importance of Leadership
- Financing strategies
- Literacy among multiple groups
- Generalizability vs Specialization

A Challenge from Multiple Perspectives . . .



Implementation of EAPathways: Conclusions

- Patient-centered
 - Treat close to home (minimize travel inconveniences)
 - Pathways are to help generalists, not specialists
 - Strategy, Transparency, Inclusiveness, Disclosure
 - Consistency of diagnosis/treatment/follow-up/molecular testing etc.
- Integration of Research Efforts
 - Direct Notification/Communication
 - Specimen Collection
- Quality of delivery of care and cost containment measured

cfDNA for Prenatal Testing

What has contributed to very rapid uptake?

- o Valid, legitimate evidence?
 - All industry sponsored, not true cohorts
 - As presented, evidence is compelling**
- Clinician/staff knowledge/skill
 - History of Down syndrome screening**
 - Deceptively simple**
- Supportive professional norms
 - Long history of DS screening**
 - Traditional screening continues to be recommended
- External expectations
 - Competitive industry, attractive \$6b market**

Outpacing planful efforts...

- cfDNA has had a tremendously rapid uptake
 Very limited clinical data was available prior to implementation
- Some complexities of test are only coming to light subsequent to clinical introduction
- Test options are rapidly expanding with even less validation

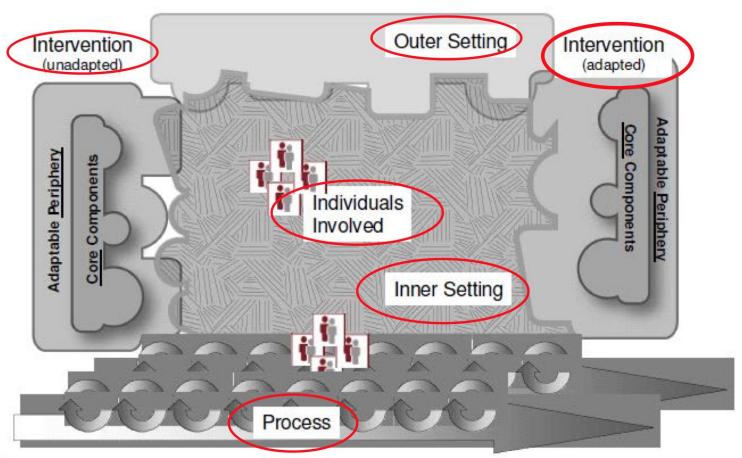
Is Genomics Any Different?

- Answer is probably yes and no, depending
- Some may be
 - Return of results to patients & family members
 - Interpretation of genomic specific data
 - Reimbursement
- Others likely not
 - Changing physician, health system workflow
 - Decision support
 - Reimbursement
 - Evidence base





CFIR





Damschroder et al., 2009/Reproduced from Beidas 2013



Genomic Specific Challenges?

- Unknown effects of genetic variants/novel variants (EVIDENCE)
- Return of results Counseling (DISSEMINATION)
- Integrating and formatting genetic test results in EMR (INTEGRATION)
- Timing and utility of EMR alerts (WORKFLOW)
- Reimbursement for testing (FINANCING)

Discussion Session Two

- Type III error—poor implementation
- Need to bring stakeholders to the table
 - E.g. Make sure that heathcare industry, payers, employers are aware
- Balance between genomic-specific and general implementation issues
- Most innovations are not selfimplementing, those that are may not do so optimally

Goal: Increase availability of cancer- related genetic information to the Michigan public and decrease barriers to risk-appropriate services

- □ *Implementation Objective 1*: By 2011, expand public knowledge about the impact of genetics on cancer risk and management (breast, ovarian, and colorectal cancers)
- Implementation Objective 2: By 2015, expand provider knowledge about the impact of genetics
- □ *Implementation Objective 3:* By 2015, improve genetic health care financing and access to testing and support

services

MULTI-LEVEL & MULTIDISCIPLINARY PARTNERS

National Health Partners:

CDC DCPC

NCCN Experts ASHG/Jackson Laboratory

LSSN

Kintalk.org/UCSF

Local Health Partners:

BCBSM

Priority Health

Other health plans

WSU Genetic Counseling Program

Grand Valley State University
Local cancer registrars

Providers of individuals at risk or with HBOC/LS:

Primary Care Providers Workshop Participants

Providers who care for cancer patients and cancer survivors Providers who care for family members of cancer patients

Michigan residents at risk for or with HBOC/LS

State Health Partners:

MDHHS Cancer Genomics
MDHHS Cancer Prevention & Control
Michigan Cancer Surveillance
Program & Vital Records
Michigan Medicaid
MiBRFS

Michigan Cancer Consortium Michigan Association of Health Plans Michigan Cancer Genetics Alliance

Clinical Practices:

BRCA Clinical Network
Health systems/clinical practices
that diagnose cancer
Health systems that perform
universal/routine LS screening
Health systems/practices that
collect family history

Family members at risk for HBOC/LS

Taplin et al, Multilevel Intervention Clinical-Public Health Collaboration, 2011

DIAGNOSIS AS A PIECE OF A LARGER SYSTEM...









Diagnostic odyssey

500,000 Canadian children

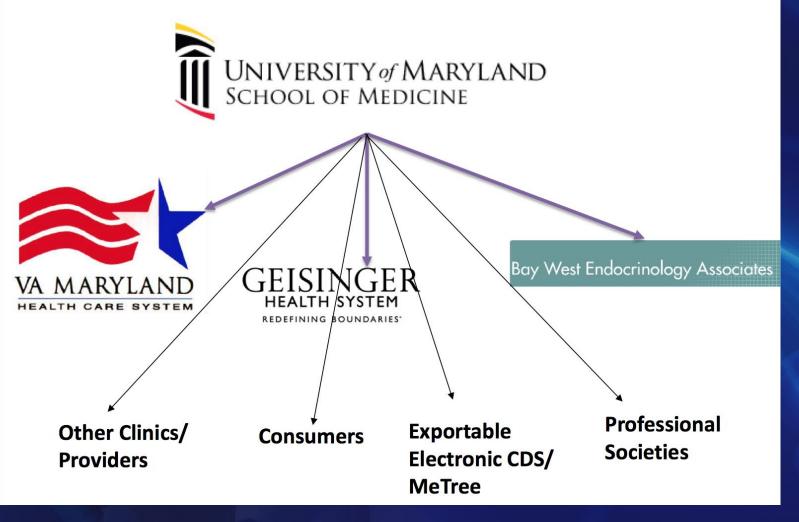
- 40% wrong diagnosis
- 50% no diagnosis
- 25% wait 5 to 30 years

Unmet medical need: Diagnosis is care

Personalizing Diabetes Care Challenges (Generalizable?)

- Lack of provider/consumer/payer awareness
- Clinical overlap
- Notion that "rare means never"
- Life-changing vs. life-saving
- Expense/complexity of testing
- Limited professional society guidance

Dissemination of the PDMP



How do we scale this up? (Payer Advisory Panel)?

Discussion Session Three

- Can't have complete unique ways of implementing every test
- Common "teachable" framework for scalability—can we add metrics?
- Payment for things not actionable?—what if it is in the future? What about cost to insurer?
- Need for data to reflect what's actually happening (single test vs. panel)
- Obligation/standards for full and accurate info for patients, according to preferences?
- Implementation Science can help

Selected Next Steps (1)

- For Discovery Science—integrating IS
 - Capturing experience of how clinicians, families and systems are using the findings?
 - Hybrid effectiveness/implementation studies—existing funding opps
 - Planning for implementation—incorporating existing measures (SIRC/GEM-IS)
 - Understanding/enhancing demand, literacy, equity

Next Steps (2)

- Within existing implementation efforts
 - Case inventory of "exceptional implementers", rapid uptake, also learn from un-successes (©)
 - Learning from/replicating Nimble, adaptive systems
 - Identifying optimal level of implementation for underused and overused testing
 - Clarifying short, med, long-term outcomes of success
 - Common report forms to patients, families
 National Cancer Institute

Next Steps (3)

- Leveraging existing systems
 - Learning community of states—who can do what MI, other states are doing?
 - Scaling up local implementation studies (e.g. MODY)
 - Using large networks around diagnosis to expand into appropriate Tx, follow-up (e.g. GenomeCanada)
 - Learning from efforts to communicate/educate/interpret existing tests within systems

