RE-AIM Framework to Evaluate Genomic Medicine Implementation

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Implementation science

- The study of methods to promote the integration of research findings and evidence into healthcare policy and practice

- *What works for who, when, and under what conditions*

  - Description
  - Application to genomic medicine evaluation
  - Application to program planning
  - Summary and comments

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**RE-AIM**

*Improving Public Health Relevance and Population Health Impact*
“All models are wrong …Some are useful”
-- George E.P. Box
RE-AIM Framework

- Provides specific and standard ways of measuring key factors important for public health impact and broad application
- To facilitate translation of research into practice in the “real world”
- Encourages attention on dimensions to improve adoption and sustainability (individual and org factors)
- Equally emphasizes internal and external validity and representativeness
- Originally = evaluation tool, now has been used for planning as well

- Reach – to the target population
- Effectiveness/Efficacy
- Adoption – by target settings/staff
- Implementation – consistency, costs
- Maintenance – of program and effects over time

www.re-aim.org
Other Important Points about RE-AIM

- Focus on the SETTING in which the program/intervention is delivered
- The STAFF delivering the program/intervention (and what THEY do, rather than what the individual participant does)
- Emphasizes potential for delivery in “real world”
- Encourages multi-level thinking and evaluation
- Concerned with costs (to implement/deliver program)
- Concerned with adaptations made to the program by individuals and within settings
<table>
<thead>
<tr>
<th>RE-AIM Construct</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reach</td>
<td>The absolute number, proportion, and <strong>representativeness</strong> of <strong>individuals</strong> who participate in the program</td>
</tr>
<tr>
<td>Effectiveness (or Efficacy)</td>
<td>Impact of the program on outcomes, including <strong>negative effects</strong>, QOL, economic outcomes</td>
</tr>
<tr>
<td>Adoption</td>
<td>The absolute number, proportion, and <strong>representativeness</strong> of <strong>settings/staff</strong> who initiate/participate in the program</td>
</tr>
<tr>
<td>Implementation (setting level)</td>
<td>How closely staff follow the program as intended (fidelity), what <strong>adaptations</strong> are made and <strong>costs</strong></td>
</tr>
<tr>
<td>Maintenance (setting and patient level)</td>
<td><strong>Setting level</strong>: extent to which program is integrated into routine practice and <strong>sustained</strong> <strong>Individual level</strong>: long term (6 months or more) effects of the program on outcomes</td>
</tr>
</tbody>
</table>
Operationalizing RE-AIM
Genomic medicine program evaluation
• Established 2007
• Inclusion criteria:
  • Any Geisinger Health System patient (PA and NJ)
  • Recruited through primary care and specialty clinics
• Consenting:
  • Blood sample and clinical data provided for genomic research
  • Broad consent for research use of samples and data and recontact for future research studies
  • Specifically addresses possibility of returning research results from genomic studies
• Sample provided with normal clinical blood draw
  • Additional blood taken specifically for biobank
# Reach - MyCode Participation

<table>
<thead>
<tr>
<th>Standard</th>
<th>Reach – MyCode Participation</th>
<th>Calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target population</td>
<td>Any Geisinger patient</td>
<td>Over 900,000</td>
</tr>
<tr>
<td>Exclusions</td>
<td>None</td>
<td>N/A</td>
</tr>
<tr>
<td>Total approached</td>
<td>Patients approached by consenter</td>
<td>85% consent rate</td>
</tr>
<tr>
<td>Total Consented</td>
<td>Patients completing consent</td>
<td>216,320</td>
</tr>
<tr>
<td>Total Samples</td>
<td>Patients who provide sample</td>
<td>140,519</td>
</tr>
<tr>
<td>Representativeness</td>
<td>Consented vs. population</td>
<td>Age, conditions</td>
</tr>
</tbody>
</table>

- All Geisinger patients are eligible for MyCode
- Approximately 85% of patients offered MyCode consent to MyCode
- 65% of those consented have actually participated (provided a sample for sequencing)
- MyCode participants tend to be older and more likely to have a condition than the general Geisinger population

[www.re-aim.org](http://www.re-aim.org)

Carey, David J. et al Genetics in medicine 18.9 (2016): 906–913
# Effectiveness – MyCode screening and GSC

<table>
<thead>
<tr>
<th>Outcomes to Measure</th>
<th>Genomic Screening and Counseling (GSC) Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure of effects on health behaviors, including:</td>
<td>Effectiveness of screening:</td>
</tr>
<tr>
<td>• Positive effects</td>
<td>• Prevalence of P/LP in population w/ and w/o FHx</td>
</tr>
<tr>
<td>• Negative effects</td>
<td>Effectiveness of GSC:</td>
</tr>
<tr>
<td>• unanticipated consequences</td>
<td>• Diagnosis of latent condition</td>
</tr>
<tr>
<td>• QOL</td>
<td>• Changes to medical management</td>
</tr>
<tr>
<td>• Economic outcomes</td>
<td>• Misunderstandings, inappropriate procedures</td>
</tr>
<tr>
<td></td>
<td>• Costs to healthcare system due to additional tests</td>
</tr>
</tbody>
</table>
Adoption – of GSC Processes

Geisinger Measures

• Utilization of GOALS courses to learn about condition
• Proportion of non-genetics providers contacting GSC to assist with patient results and management
• Qualitative and Quantitative differences between Geisinger and non-Geisinger providers in GSC process
### Implementation – of MyCode and GSC

<table>
<thead>
<tr>
<th>MyCode Implementation</th>
<th>GSC Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• How consistently did consenters present MyCode</td>
<td>• How well was the GSC protocol implemented</td>
</tr>
<tr>
<td>• What is the cost to implement (resource/personnel)</td>
<td>• What was the cost to implement the GSC protocol (testing, resource/personnel, cost per case detected)</td>
</tr>
<tr>
<td>• What (if any) changes had to be made over time to maintain/improve fidelity to consenting protocol</td>
<td>• What (if any) changes had to be made over time to maintain/improve fidelity to GSC protocol</td>
</tr>
</tbody>
</table>
Maintenance

**Definition**

- **Individual level:** long term effects of program on outcomes after 6 months or more
- **Setting level:** extent to which the program/policy becomes institutionalized or part of routine organizational practice

**GSC Application**

- What is the impact on longer term patient outcomes after receiving a result (e.g. 12 months, 24 months)
- How feasible and sustainable are different GSC protocols
Operationalizing RE-AIM
Genomic medicine program PLANNING and evaluation
<table>
<thead>
<tr>
<th>RE-AIM Dimension</th>
<th>Pragmatic Priorities to Consider/Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reach</td>
<td>WHO is/was intended to benefit, WHO actually participates or is exposed to the program</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>WHAT is/was the most important benefit you are trying to achieve? WHAT is the likelihood of negative outcomes?</td>
</tr>
<tr>
<td>Adoption</td>
<td>WHERE is/was the program applied and WHO applied it?</td>
</tr>
<tr>
<td>Implementation</td>
<td>HOW consistently is/was the program delivered by staff? HOW will it/was it adapted? HOW much did it cost, and WHY did you get the results you did?</td>
</tr>
<tr>
<td>Maintenance</td>
<td>WHEN will it/has it been sustained (setting); HOW LONG have the results/benefit been sustained by patients (individual level)?</td>
</tr>
</tbody>
</table>

RE-AIM Planning – Population Health Sequencing

- **WHO** – GHP members only (Reach)
- **WHAT** – sequence and return results of ACMG 59 (Effectiveness)
- **WHERE** – at 2 clinics only (Adoption)
- **HOW** – during routine visit and using MyCode GSC infrastructure for returns (Implementation)
- **WHEN** – review and consider sustainability and scale up potential (Maintenance)
Iterative and temporal application of the RE-AIM framework

Pragmatic Use of RE-AIM for Planning and Evaluation

Adaptions Made to Date to PHS

• Eligible patients not identified → Give list to front desk staff

• Not enough eligible patient visits in desired window to reach recruitment goals → expand eligibility criteria (also fixes issues with identification)
Pragmatic RE-AIM Questions for Evaluation

• What percentage and types of patients are REACHED?
• For whom is it EFFECTIVE at improving outcomes and with what unanticipated consequences?
• In what percentage and types of settings and staff is the program ADOPTED?
• How consistently are different program parts IMPLEMENTED and at what cost to the different parties?
• How well are the program components and their effects MAINTAINED over time?

## RE-AIM Pragmatic Evaluation*

<table>
<thead>
<tr>
<th>RE-AIM Domain</th>
<th>Pragmatic Evaluation PHS</th>
<th>Possible Data for evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reach</td>
<td>Total eligible patients, patients actually approached, patients tested (or declined)</td>
<td>Representativeness of those tested/declined</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>Number and type of results</td>
<td>Diagnosed conditions Pt/provider medical management plan Cost to the system</td>
</tr>
<tr>
<td>Adoption</td>
<td>Actual clinics that participate, staff that offer (don’t offer)</td>
<td>Representativeness of pilot clinics, representativeness of pilot clinicians/staff</td>
</tr>
<tr>
<td>Implementation</td>
<td>Staff fidelity to planned program protocol, adaptations/iterations to program protocol</td>
<td>Cost to implement (personnel, training)</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Is it sustainable and how</td>
<td>What do clinicians and patients do with the information over time</td>
</tr>
</tbody>
</table>

* For impact of adaptations measured over time and for overall pilot outcomes
Summary Points on Pragmatic use of RE-AIM for Genomic Medicine Implementation

• Focus on “real world” enables utilization of data and outcomes available in the clinical setting
• Allows iterative evaluation of adaptations and improvements over time
• Pragmatic questions are useful for clinicians, innovators, and champions who may not “do research”
• Accepted framework applies scientific rigor for research and researchers
Summary Points on RE-AIM as a Framework

• Each dimension provides opportunity for intervention
• RE-AIM can be used in observational, efficacy, effectiveness, and implementation science projects
• All dimensions can be addressed in a project (but not all need be intervened upon)
• Methods available to combine and summarize RE-AIM outcomes
• RE-AIM is an outcomes framework that can be used for planning and evaluation

Adapted from Glasgow 2018 re-aim.org
Resources

• http://re-aim.org/
• https://cancercontrol.cancer.gov/IS/
• https://societyforimplementationresearchcollaboration.org/
• http://www.nature.com/articles/gim2017144
• https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3592983/
• http://dissemination-implementation.org/index.aspx
Questions?

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