Caring

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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"All models are wrong …Some are useful"

-- George E.P. Box

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RE-AIM Framework

www.re-aim.org

- 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

- **R**each – to the target population
- **E**ffectiveness/Efficacy
- **A**doption – by target settings/staff
- **I**mplementation – consistency, costs
- **M**aintenance – of program and effects over time

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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

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Definitions (traditional/academic)

RE-AIM Construct	Definition
Reach	The absolute number, proportion, and **representativeness** of **individuals** who participate in the program
Effectiveness (or Efficacy)	Impact of the program on outcomes, including **negative effects**, QOL, economic outcomes
Adoption	The absolute number, proportion, and **representativeness** of **settings/staff** who initiate/participate in the program
Implementation (setting level)	How closely staff follow the program as intended (fidelity), what **adaptations** are made and **costs**
Maintenance (setting and patient level)	**Setting level:** extent to which program is integrated into routine practice and **sustained** **Individual level:** long term (6 months or more) effects of the program on outcomes

Operationalizing RE-AIM

Genomic medicine program evaluation

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Carey, David J. et al Genetics in medicine 18.9 (2016): 906–913
Schwartz MLB et al. Am J Hum Genet. 2018 Jul 30

MyCode Community Health Initiative

- 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

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

- 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

Carey, David J. et al Genetics in medicine 18.9 (2016): 906–913

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Effectiveness – MyCode screening and GSC

Outcomes to Measure

Measure of effects on health behaviors, including:

- *Positive effects*
- *Negative effects*
- *unanticipated consequences*
- *QOL*
- *Economic outcomes*

Genomic Screening and Counseling (GSC) Application

Effectiveness of screening:

- Prevalence of P/LP in population w/ and w/o FHx

Effectiveness of GSC:

- Diagnosis of latent condition
- Changes to medical management
- Misunderstandings, inappropriate procedures
- Costs to healthcare system due to additional tests

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Adoption – of GSC Processes

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- 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

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Implementation – of MyCode and GSC

MyCode Implementation

- How consistently did consenters present MyCode
- What is the cost to implement (resource/personnel)
- What (if any) changes had to be made over time to maintain/improve fidelity to consenting protocol

GSC Implementation

- How well was the GSC protocol implemented
- What was the cost to implement the GSC protocol (testing, resource/personnel, cost per case detected)
- What (if any) changes had to be made over time to maintain/improve fidelity to GSC protocol

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Maintenance

Definition	GSC Application
• ***Individual level**: long term effects of program on outcomes after 6 months or more*	• What is the impact on longer term patient outcomes after receiving a result (e.g. 12 months, 24 months)
• ***Setting level:** extent to which the program/policy becomes institutionalized or part of routine organizational practice*	• How feasible and sustainable are different GSC protocols

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Operationalizing RE-AIM

Genomic medicine program PLANNING and evaluation

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Pragmatic Use of RE-AIM

RE-AIM Dimension	Pragmatic Priorities to Consider/Answer
Reach	WHO is/was intended to benefit, WHO actually participates or is exposed to the program
Effectiveness	WHAT is/was the most important benefit you are trying to achieve? WHAT is the likelihood of negative outcomes?
Adoption	WHERE is/was the program applied and WHO applied it?
Implementation	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?
Maintenance	WHEN will it/has it been sustained (setting); HOW LONG have the results/benefit been sustained by patients (individual level)?

Glasgow R & Estabrooks P. Pragmatic application of RE-AIM for health care initiatives in community and clinical settings. Prev Chron Dis (2018)

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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)

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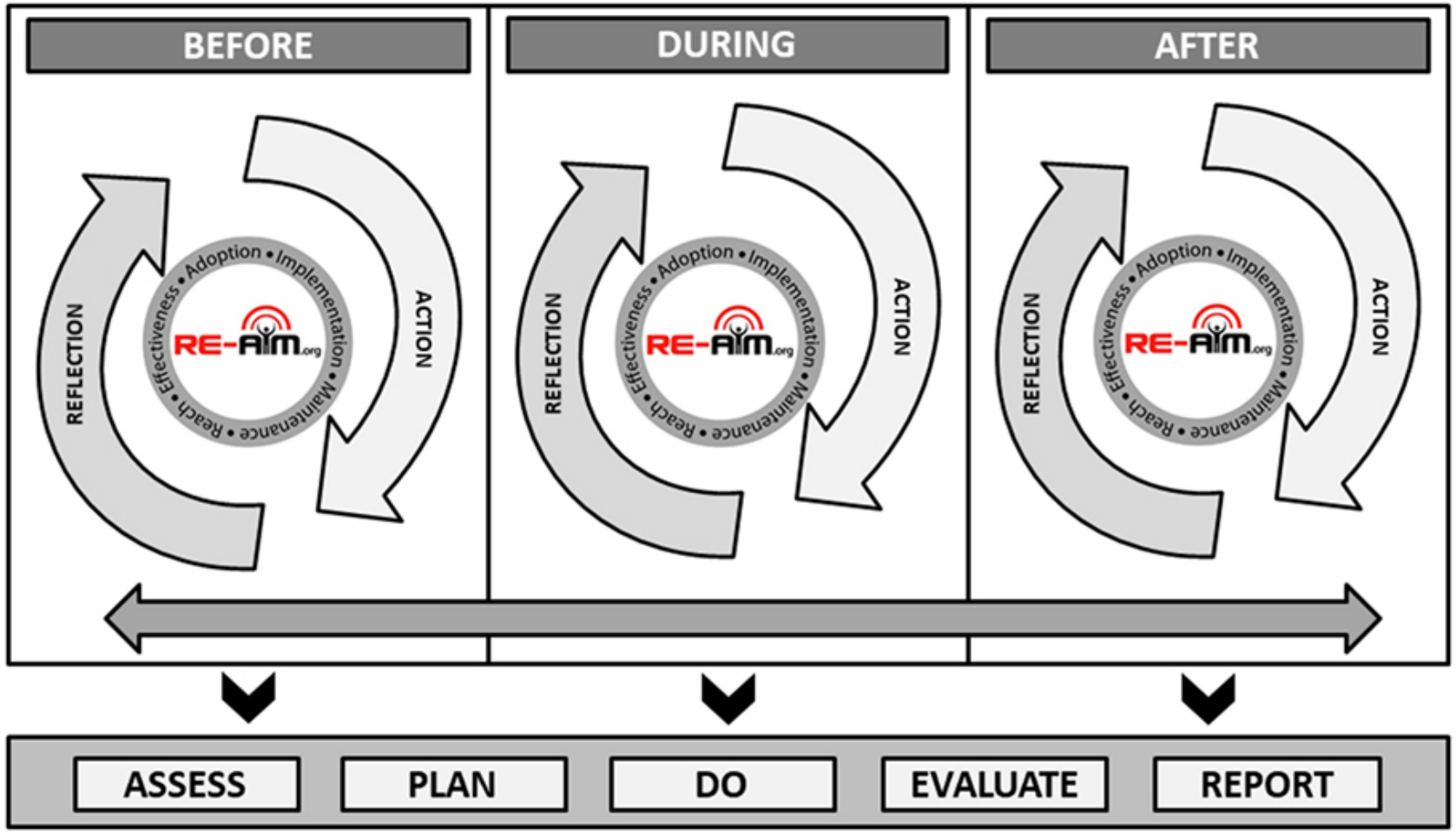
https://www.frontiersin.org/articles/10.3389/fpubh.2018.00071/full

Pragmatic Use of RE-AIM for Planning and Evaluation

Iterative and temporal application of the RE-AIM framework



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)

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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?

Gaglio B, Glasgow RE. Evaluation approaches…In: Brownson R, Colditz G, Procter E, (Eds). *Dissemination and implantation research in health: Translating science to practice*. New York: Oxford University Press; 2012. Pages 327-56

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RE-AIM Pragmatic Evaluation*

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

* For impact of adaptations measured over time and for overall pilot outcomes

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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

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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

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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

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Questions?

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