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# Implementing Universal Lynch Syndrome Screening

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**Geisinger Health System**

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**May 29-31, 2019**

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# Presentation Overview

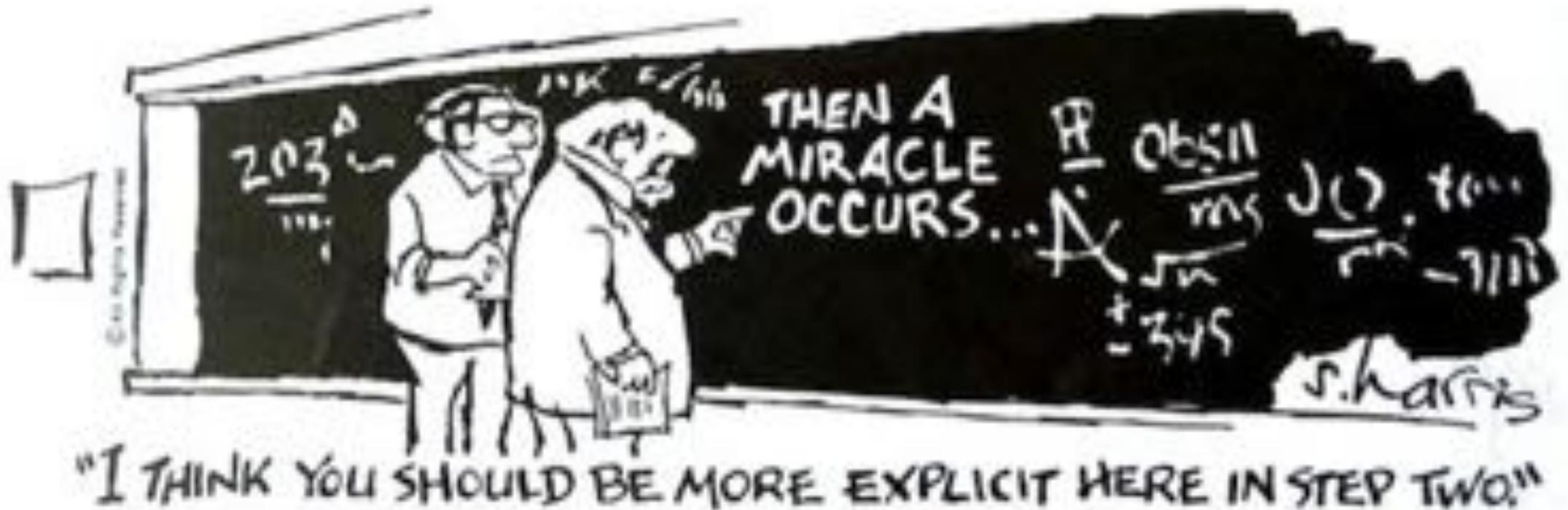
- **Overall goal:** *Implementation Science frameworks/thinking in precision health will help us learn more efficiently and effectively about identification of hereditary conditions to improve health of individuals and populations.*
- Example – Implementing universal Lynch syndrome screening across multiple healthcare systems
  - Multi-level, multi-disciplinary, complex, ever-changing organizations, evolving evidence
  - Frameworks/IS thinking will be used to generate useful guidance to influence implementation, sustainability, and adaptation/ evolution

# 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/clinical practice audience to understand how best to spread and sustain knowledge and the EBI
- **Implementation research** is the scientific study of the use of strategies to adopt and integrate EBIs into clinical and community settings to improve outcomes and benefit population health
- **Pragmatic research** is the use of real-world tests in real-world populations and situations

# 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/in what contexts*



# Other Issues for Precision Health

- Evidence is growing rapidly
- Guidelines changing / expanding
- Testing changing / expanding
- Costs decreasing
- Organizations are constantly changing / growing / merging

***In general how do we facilitate implementation of programs when evidence and environments are constantly changing?***

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# Sustainability or Evolution?

Slide credit: David Chambers, NCI



- AS PRECISION MEDICINE CONTINUES TO EVOLVE, SHOULD EXISTING PROGRAMS 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 TO HELP IMPLEMENT AND EVOLVE IN LIGHT OF EVER-GROWING EVIDENCE?

# Lynch Syndrome screening

A precision health example for implementation science

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# Lynch Syndrome

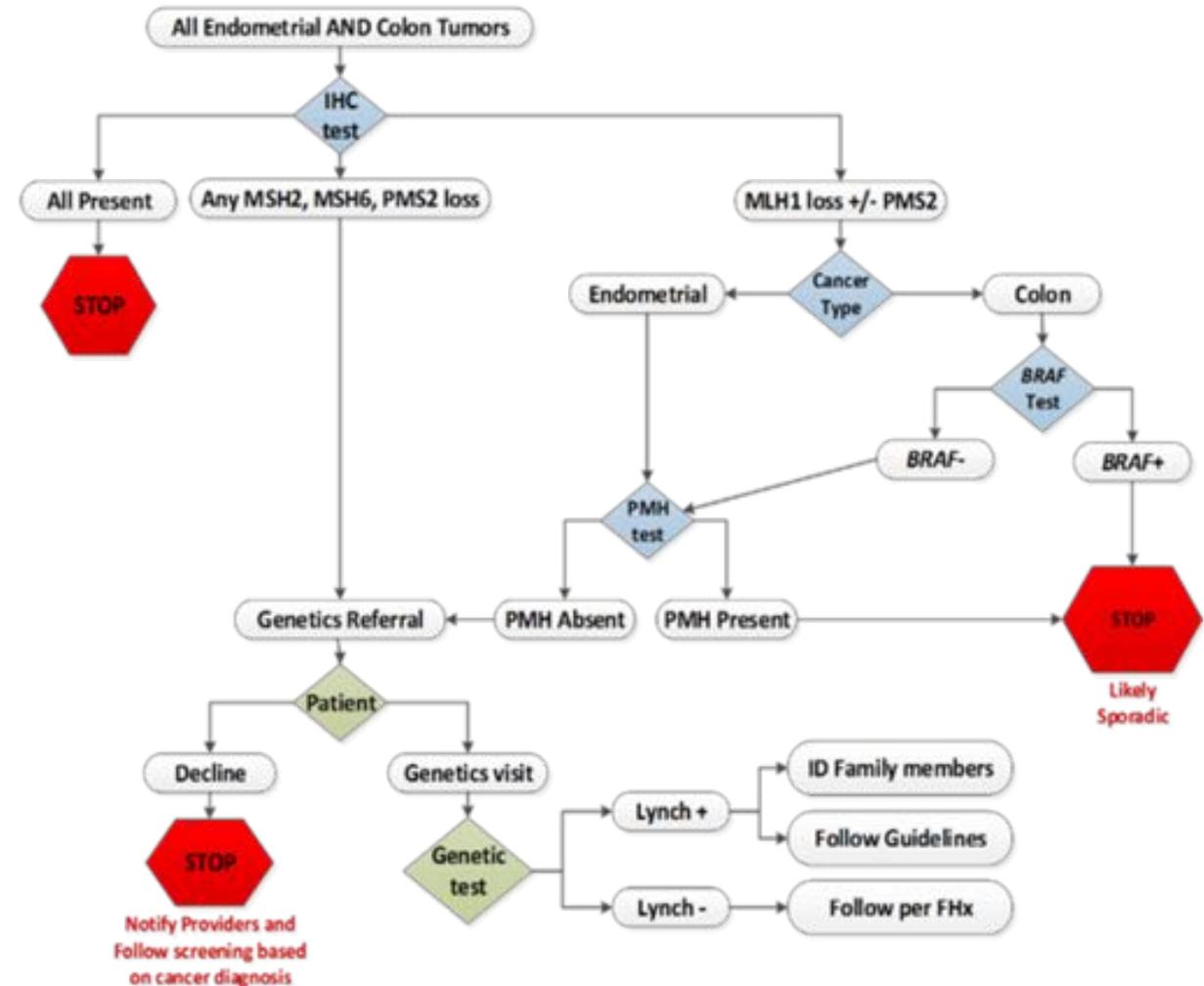
- Hereditary cancer risk syndrome
- 2-5% of all colon cancers
- Germline mutations in MLH1, MSH2, MSH6, PMS2
- Females have 30-60% risk for endometrial cancer
- Substantially increased risk for CRC (54-74% males/ 35-52% females)
- Up to 10% lifetime risk for other cancers: gastric, ovarian, prostate, sebaceous gland, and breast
- **First degree family members are at 50% risk to inherit high-risk allele**

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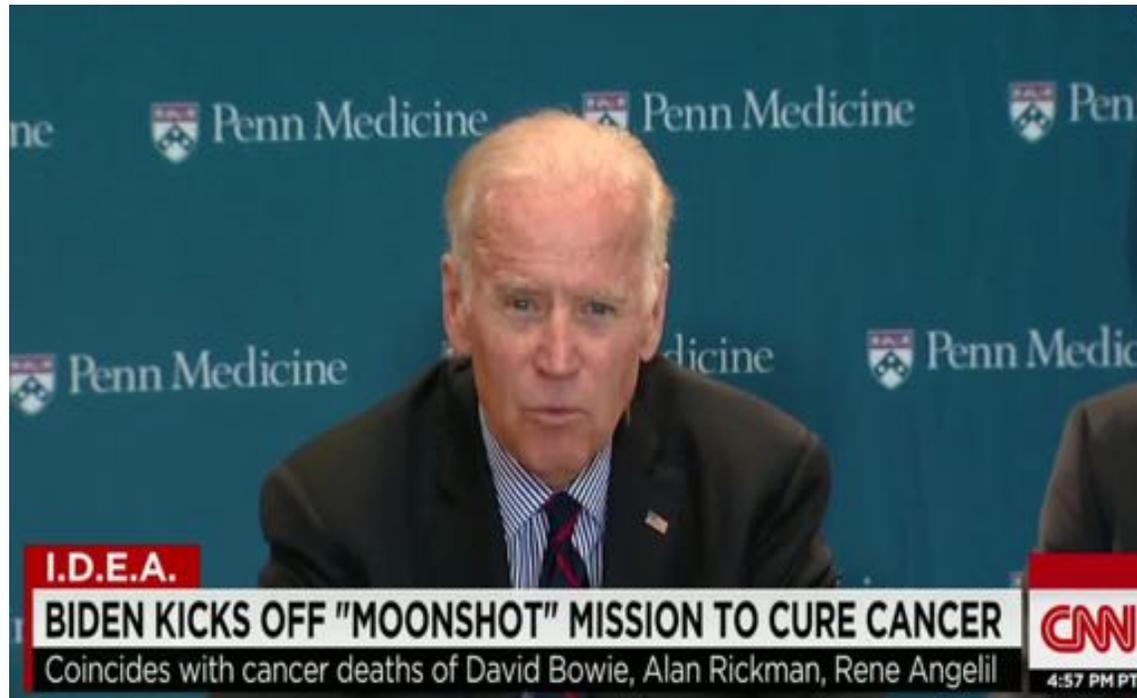
# Universal Lynch syndrome Screening

- EGAPP working group CRC – 2009
- SGO guideline added EC – 2014
- Cost-effective
- Tier 1 evidence to reduce cancer-related morbidity and mortality
- Either MSI/IHC testing as first line
- Implementation is slow and variable

Figure 1. Suggested Optimal LS Screening Program Protocol



# 2016 - Cancer moonshot / Blue Ribbon Panel



<http://www.cnn.com/2016/11/30/politics/joe-biden-cancer-moonshot-congress/>

- Precision Prevention and Early Detection Working Group
- Recommendation: Lynch syndrome demonstration Project
- Identify CRC/EC patients with LS
- Identify at-risk family members



*“Study of innovative implementation strategies to improve access to, engagement in, and quality of genetic counseling, early detection, screening and follow-up will improve health outcomes for families with LS”*

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# Project Goals

- To utilize CFIR and other tools from implementation science to describe, explain, and compare decision making and other variations in LS screening implementation across multiple healthcare systems.
- To create an organization-level toolkit for implementing, maintaining and improving LS screening through considering contextual issues, organizational costs, and impact on patients identified
- To understand and facilitate ULS implementation as a use-case for implementing genomic medicine

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Rahm et al. BMC Health Services Research (2018) 18:824  
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BMC Health Services Research

STUDY PROTOCOL

Open Access



Implementing universal Lynch syndrome screening (IMPULSS): protocol for a multi-site study to identify strategies to implement, adapt, and sustain genomic medicine programs in different organizational contexts

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## Abstract

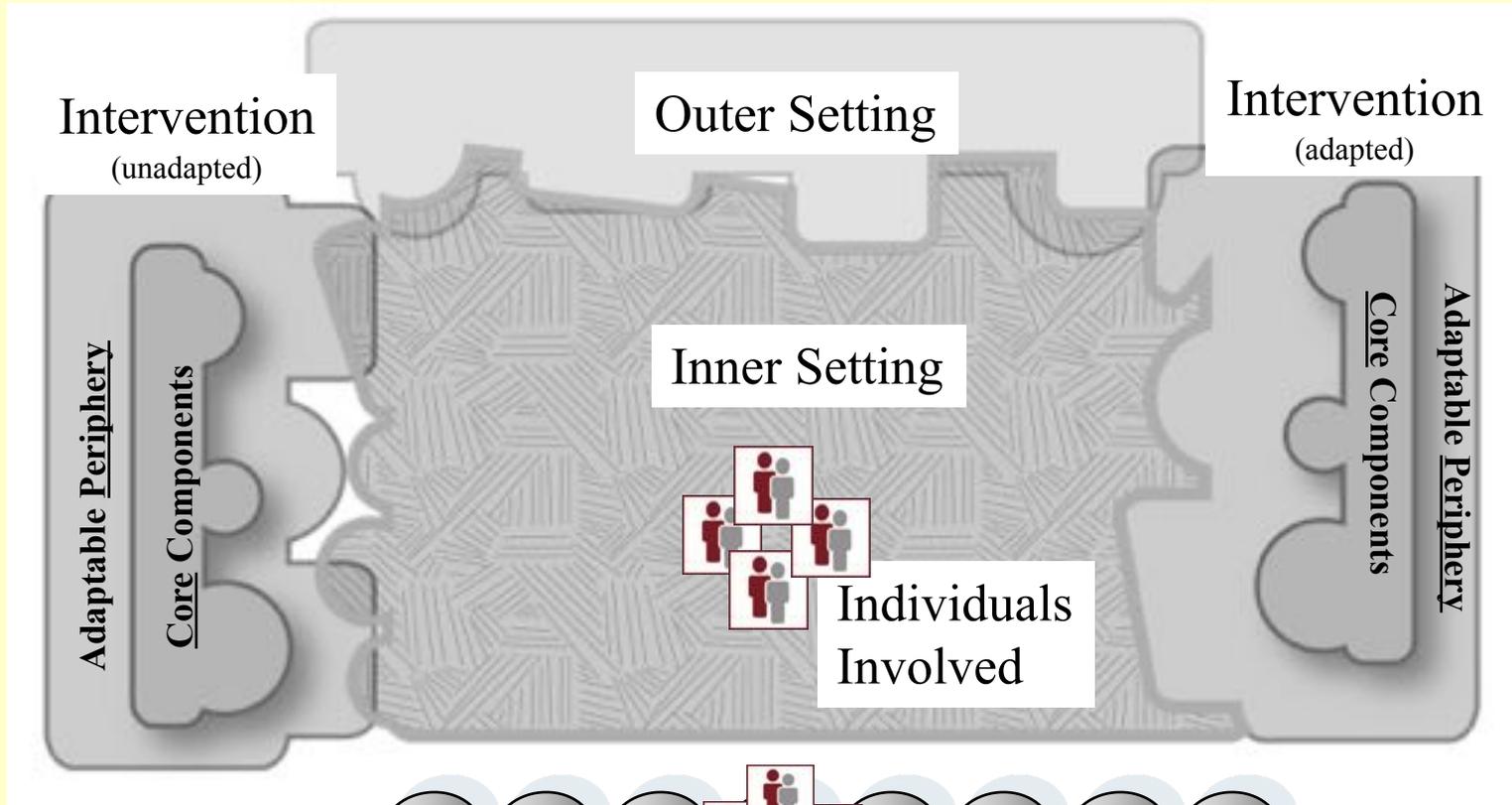
**Background:** Systematic screening of all colorectal tumors for Lynch Syndrome (LS) has been recommended since 2009. Currently, implementation of LS screening in healthcare systems remains variable, likely because LS screening involves the complex coordination of multiple departments and individuals across the healthcare system. Our specific aims are to (1) describe variation in LS screening implementation across multiple healthcare systems; (2) identify conditions associated with both practice variation and optimal implementation; (3) determine the relative effectiveness, efficiency, and costs of different LS screening protocols by healthcare system; and (4) develop and test in a real-world setting an organizational toolkit for LS screening program implementation and improvement. This toolkit will promote effective implementation of LS screening in various complex health systems.

**Methods:** This study includes eight healthcare systems with 22 clinical sites at varied stages of implementing LS screening programs. Guided by the Consolidated Framework for Implementation Research (CFIR), we will conduct in-depth semi-structured interviews with patients and organizational stakeholders and perform economic evaluation of site-specific implementation costs. These processes will result in a comprehensive cross-case analysis of different organizational contexts. We will utilize qualitative data analysis and configurational comparative methodology to identify facilitators and barriers at the organizational level that are minimally sufficient and necessary for optimal LS screening implementation.

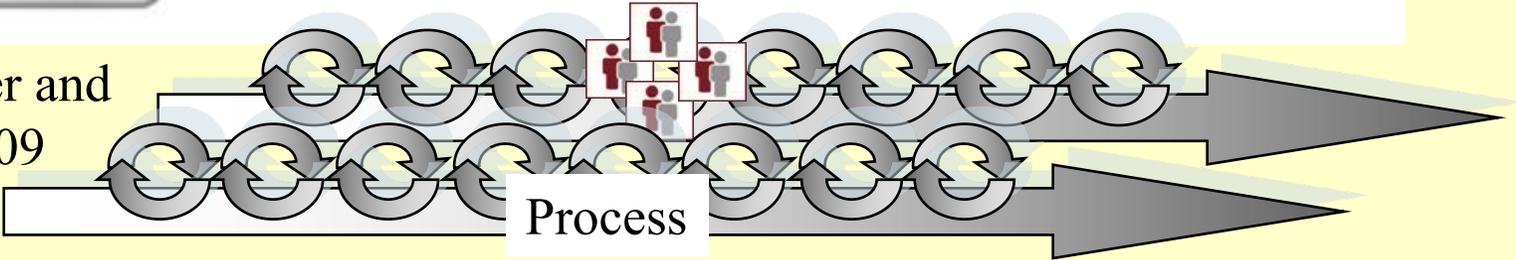
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# Study Aims

- **Aim 1:** Describe variation in LS screening, implementation, and contextual conditions across healthcare systems
- **Aim 2:** Explain practice variation and identify influential contextual conditions and minimally sufficient and necessary combinations for optimal LS screening implementation
- **Aim 3:** Determine relative costs of different LS screening protocols using decision analytic models and determine relative costs for healthcare systems from local data
- **Aim 4:** Develop and disseminate an organizational toolkit to facilitate LS screening implementation and optimization



Damschroder and  
Damush, 2009



Process

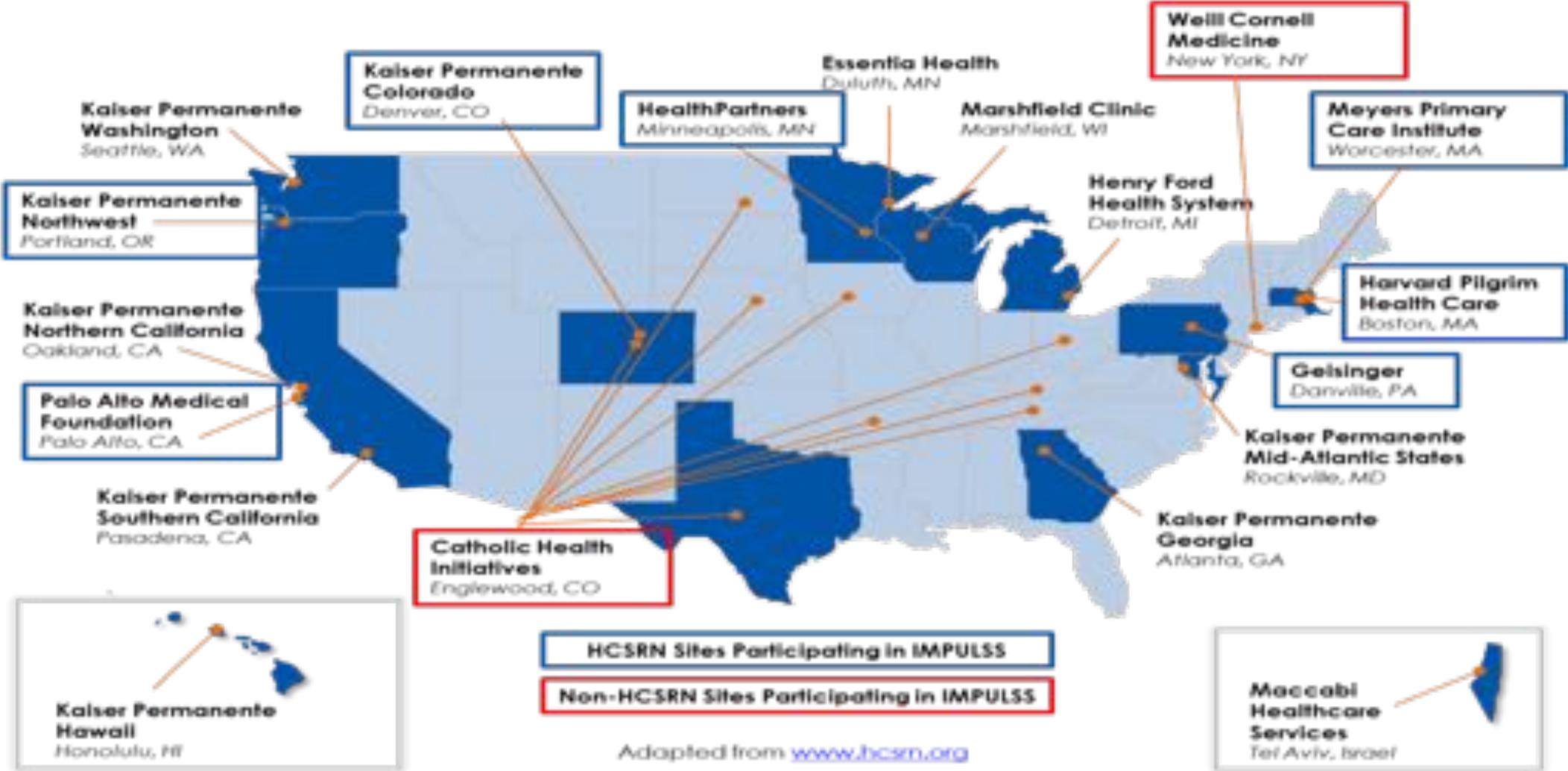
# Guiding Framework

Consolidated Framework for Implementation Research (CFIR)

# LS Screening in IMPULSS Healthcare Systems

Healthcare System	System Type	HCSRN Participant	LS Screening Implementation
Geisinger	Member and FFS	Yes	All CRC and EC
Sutter Health Palo Alto Medical Foundation	Member and FFS	Yes	No Program
Kaiser Permanente Colorado	Member only	Yes	No Program
Kaiser Permanente Northwest	Member only	Yes	All CRC and EC
Meyers Primary Care	Member and FFS	Yes	All CRC
HealthPartners	Member and FFS	Yes	All CRC and EC
Harvard Pilgrim	Member and FFS	Yes	No program
Northwell Health	FFS only	No	All CRC and EC
Catholic Health Initiatives	Member and FFS	No	Variable depending on Hospital location

Figure 1. Map of HCSRN with IMPULSS Study Sites Highlighted



# Site Case Report Creation

CFIR Constructs by Domain Specific to LS Screening to be Assessed in Stakeholder Interviews

CFIR Domain	CFIR Constructs Specific to LS Screening
Intervention Characteristics	Adaptability of LS screening to local context
	Perceived difficulty implementing LS screening
	Cost to the organization associated with screening
Outer Setting	Patient needs and resources
	Competitive pressure to implement screening
	Impact of external policies on organization
Inner Setting	Organization structure
	Perceived organizational priority to implement
	Implementation climate in organization
Characteristics of Individuals	LS knowledge and beliefs, perceptions of evidence
	Individual readiness to implement screening
	Self-efficacy to complete actions in screening
Implementation Process	Planning process to implement LS screening
	Champions, opinion leaders, and other stakeholders
	Tracking and feedback processes for LS screening

- **Create a case-report of each system with patient, stakeholder, and organizational-level information important to LS screening and program implementation over time**
- Qualitative interviews: newly diagnosed CRC patients
- Qualitative interviews: patients with positive screens through LS screening programs (From sites with LS screening only)
- Qualitative interviews: organizational stakeholders at all sites
- **“Change tracking” across sites over study period**

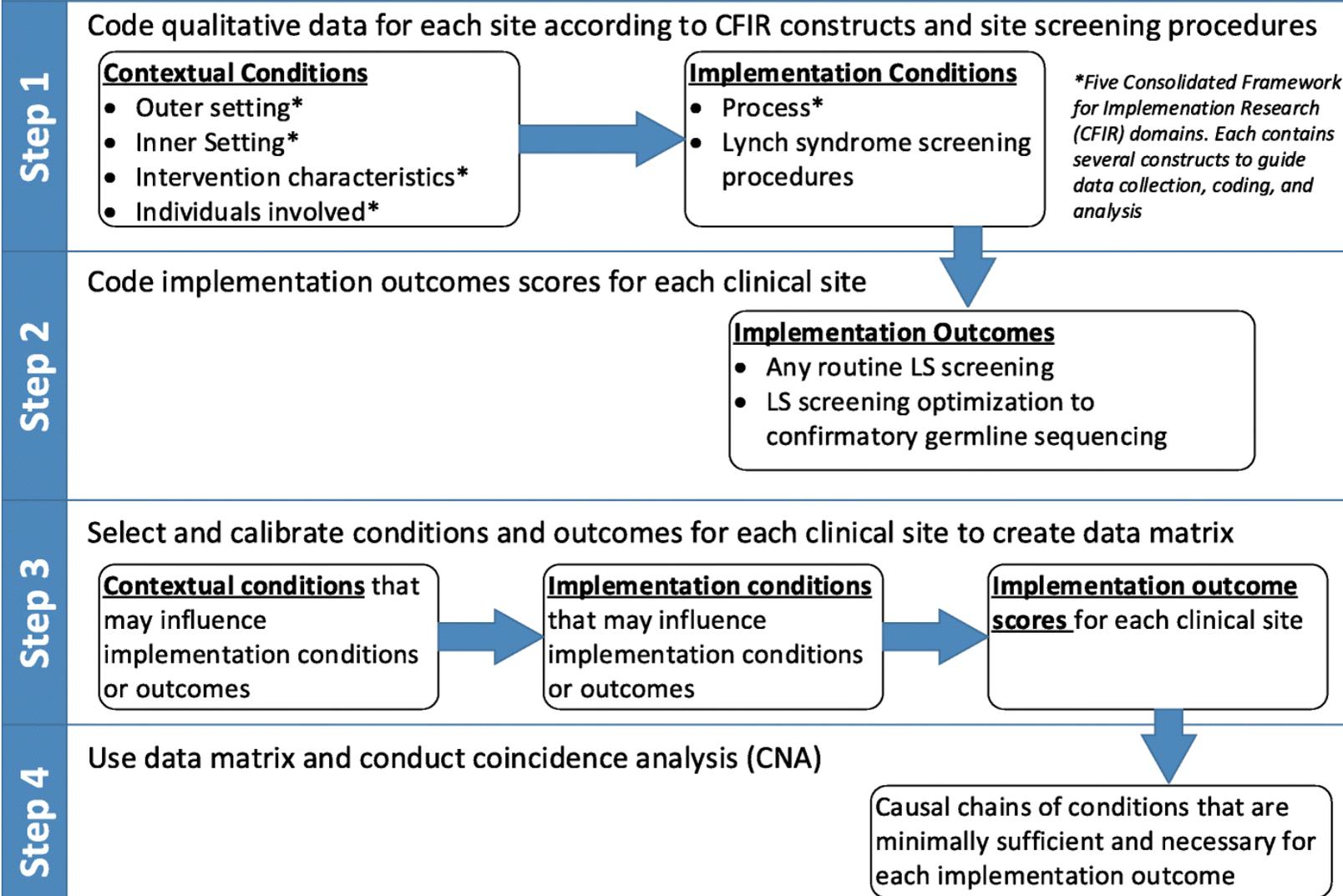


# Change as DATA – Change Tracking Over Time

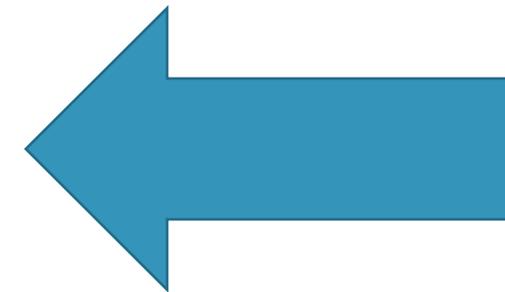


- Complete pathology turnover in one organization
- Merger of health plan and research arms into more integrated system
- De-Merging of health system and research arms into more separate organizations
- Merger of one large health system with another, resulting in the loss of their research unit all together and total restructuring of leadership
- One site that thought it had ULS, may not have ULS in all sites
- From proposal to funding one site implemented full program
- One site improved program to add EC screening after first year

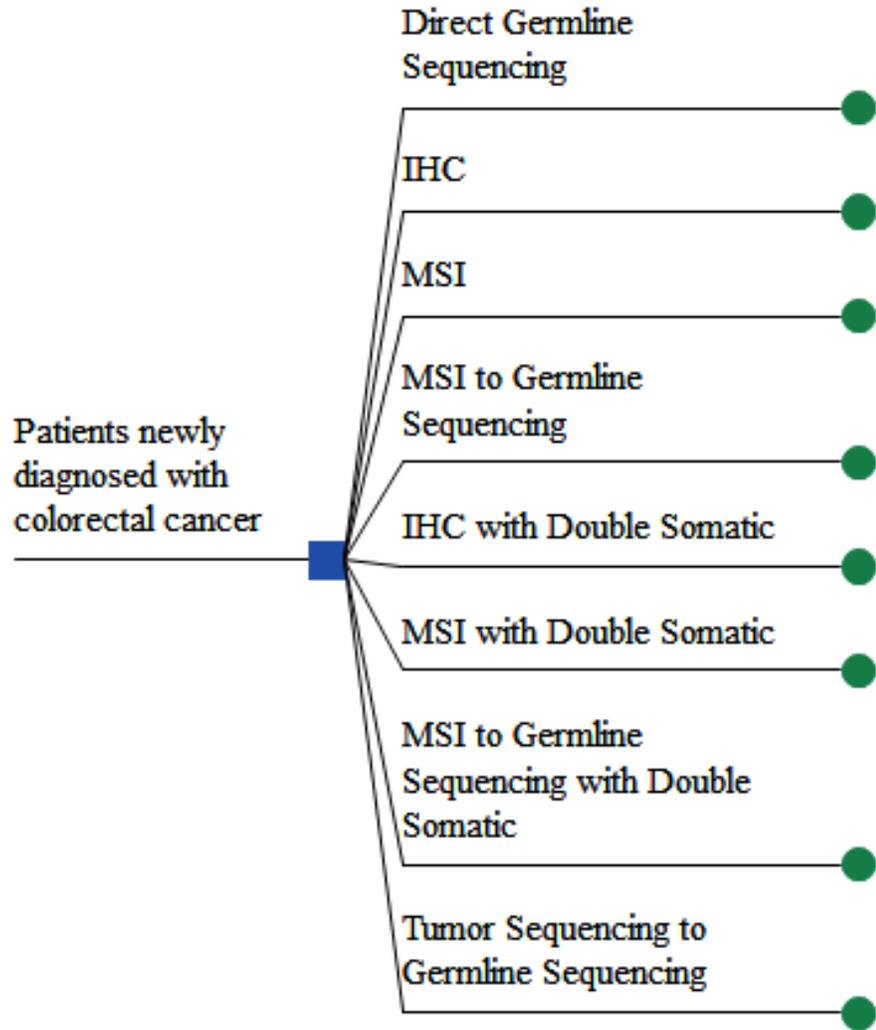
# Steps for Configurational Comparative Methods



# Qualitative Comparative Methods



# Costs - Updated Decision Model – Decision Tree



- Updated economic evaluation model based on up-to-date evidence and guidelines
- From local decision makers' perspective using local data vs. societal perspective
- Aims for guiding and accelerating implementation of ULS
- Focus on identifying LS cases, not treatment indication
- Focus on proband

# Developing A Precision Health “Toolkit”

- Tools to facilitate implementation, sustainability, improvement/adaptation
- Tools to make decisions based on actual organizational costs and data
- Tools to make decisions based on organizational resources and values
- Tools to evaluate and sustain programs
- Tools to facilitate evaluation and adaptation as evidence changes, as costs change, as new tests and guidelines are available



# Closing Thoughts

## Implementation Science....

- Embraces change and context
- Has processes for collecting evidence while implementing
- Focuses on multi-level context and complexity
- Promotes real-world feasibility and functionality
- Is a multi-disciplinary team sport

*“Implementation science, with its focus on identification of all major contributions to improvement of healthcare, from individual factors up to policy and public health interventions, can serve as a framework for considering the future of precision health.”*

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