Equity considerations for clinical practice guidelines around genomic testing

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Examining Clinical Guidelines for the Adoption of Genomic Testing: A workshop

Session III: Guidelines for Genomic Testing Today

October 29, 2024

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Disclosures

- PI on AHRQ contracts for systematic reviews and technical assistance to support the US Preventive Services Task Force
- Royalties from UpToDate topic on Clinical Practice Guidelines

JUNE 26, 2024

Summit on Addressing Racial and Ethnic Health Equity in Systematic Reviews and Evidence-based Guidelines

AHRQ Agency for Healthcare Research and Quality

rwjf robert wood johnson foundation

Global Evidence Summit

Workshop: Incorporating Health Equity in Guideline Development

Thursday, Sep 12, 2024
11:00 - 12:30
Hall D3

Acknowledgments

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Equity vs. Equality vs. Disparities

- Health disparities
  - Differences in health are among groupings defined socially, economically, demographically, and/or geographically
  - Differences in health are clinically meaningful
- Health inequity
  - Health disparities + differences in health are avoidable and remediable
- **Health equity is a fundamental human right**
- Health equality (e.g., equal access) is necessary but not sufficient for health equity
- Health equity in guidelines generally refer to the elimination of differences in:
  - Social drivers of health (aka social determinants of health) and clinical risk factors
  - Provision and receipt of health care services
  - Disease incidence and related patient health outcomes (morbidity and mortality)

Equity considerations must be built into the guideline process

Example: Health equity framework for the entire USPSTF recommendation process

Phase	Actions (and rationale)	Checklist items
Topic nomination, selection & prioritization	2	8
Work plan (protocol)	7	23
Evidence review	13	30
Decision analyses	Not yet addressed	
Evidence deliberation	4	15
Recommendation statement	2	15
Dissemination & implementation of recommendations	3	9 (checklist items around implementation not yet developed)

At each phase, practical approach of

- **what** needs to happen (or at a minimum should be considered),
- **why** it should happen, and
- **how** to implement it

Build in equity relevant perspective early in the process

Subject matter expertise	Representation and expertise in review teams and guideline • Members from underrepresented and disproportionately affected groups • Equity training
	Involvement of non-clinical subject matter expertise relevant to equity (e.g., implementation science, health policy, sociology, medical ethics)
Interest-holder engagement	Engagement of patients or public from affected groups in review and guideline process (i.e., anyone with interest in the 'outcome' of process) • Engagement early in the process • Address barriers to involvement, balancing conflicting input, compensation, power dynamics
	Engagement in weighing importance of outcomes, interventions, values, preferences, and other information relevant to implementation

Prioritize and develop equity focused topics and questions

Identifying and selecting topics	Use of health equity criterion to select and prioritize topics
Developing equity focused questions	Understanding upstream drivers of health inequities as well as equity sensitive populations, outcomes, and settings • Use of PROGRESS-Plus to identify equity sensitive populations • Use of logic (conceptual) models to explore drivers of inequities and their inter-relationship
	Understanding implementation considerations affecting health inequities • Mediators and moderators of test accuracy or effectiveness/harms in different populations and settings • Barriers and facilitators, e.g., availability, feasibility, acceptability, cost

Understanding effects in different populations

Applicability of findings	Understanding applicability of included evidence and extrapolation of evidence to disproportionately affected groups (e.g., by race/ethnicity) • Extrapolation of findings of diagnostic or prognostic test accuracy (and relative effects) unless compelling reason to question applicability (e.g., biological or physiologic differences) • Understanding representativeness (e.g., by ancestry) and encoded biases in data (e.g., missing data) • Challenges of apply ancestry to individuals (rather than by population)
Estimating absolute effects	Understanding differences in **absolute effects** of benefits and harms across relevant equity sensitive populations • Estimate absolute effects using relative effects in included studies applied to baseline risk by specific population (e.g., formal or informal decision analyses, health improvement distribution index)

From evidence to decision

Integration of a broader set of questions	Questions addressing upstream and implementation, for example: • How and where inequities arise in access to current testing, care, and outcomes for affected populations • How the evidence used to support the testing may be biased or not account for equity sensitive groups or their interests • How inequities may arise in the use of testing for patients and families/caregivers • How implementation of testing may address, create or reinforce health system inequities
Implementation considerations	• Implementation considerations not limited to availability/resources, feasibility, cost, quality, and patient acceptability • Sensitive to potential societal considerations as health interventions do not take place in isolation • Inclusion of guidance on strategies to improve receipt of recommended care when implementation considerations alone are not sufficient to assure equitable receipt of recommended care

Identify what is not known or is still needed

Evidence, practice, and policy gaps	Identification of equity specific evidence gaps that might lead to actionable recommendations to address health inequities
	Articulation of equity relevant clinical practice and policy gaps • Questions and evidence on social and health care drivers of health equity may point to specific gaps clinical care, as well as health care, social, and public policy gaps • Judicious use of 'good practice statements' to highlight clinical practice gaps

Key Takeaways

- Assuring health care equality is necessary but not sufficient for addressing health equity
- Guideline groups have a responsibility that *at a minimum* guidance/recommendations do not perpetuate or exacerbate observed inequities
- Building in equity considerations into guidelines requires intentionality and resources
  - But this can happen incrementally
- Equity considerations should be built into the entire guideline or evidence-based decision-making process, and start at the planning phase
- Developing actionable recommendations to mitigate health inequities requires:
  - Ensuring a wider perspective- representation
  - Asking the ‘right’ questions and using fit for purpose methods to answer questions
  - Addressing upstream drivers of health and implementation of testing (and cascade of care downstream to testing)

Extra slides

Evidence considerations for genomic testing

Lin *et al. BMC Medical Informatics and Decision Making* 2012, **12**:117
http://www.biomedcentral.com/1472-6947/12/117

BMC
Medical Informatics & Decision Making

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Evaluating genomic tests from bench to bedside: a practical framework

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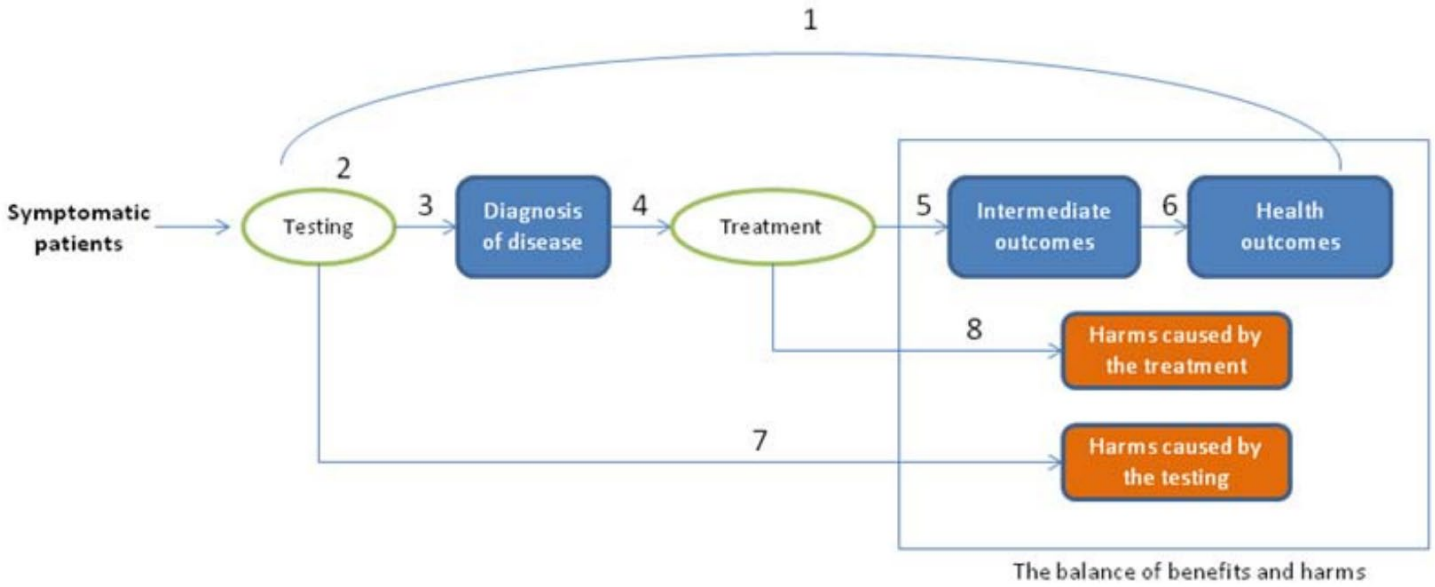
Abstract

The development of genomic tests is one of the most significant technological advances in medical testing in recent decades. As these tests become increasingly available, so does the need for a pragmatic framework to evaluate the evidence base and evidence gaps in order to facilitate informed decision-making. In this article we describe such a framework that can provide a common language and benchmarks for different stakeholders of genomic testing. Each stakeholder can use this framework to specify their respective thresholds for decision-making, depending on their perspective and particular needs. This framework is applicable across a broad range of test applications and can be helpful in the application and communication of a regulatory science for genomic

Evidence and evidentiary thresholds for decision-making

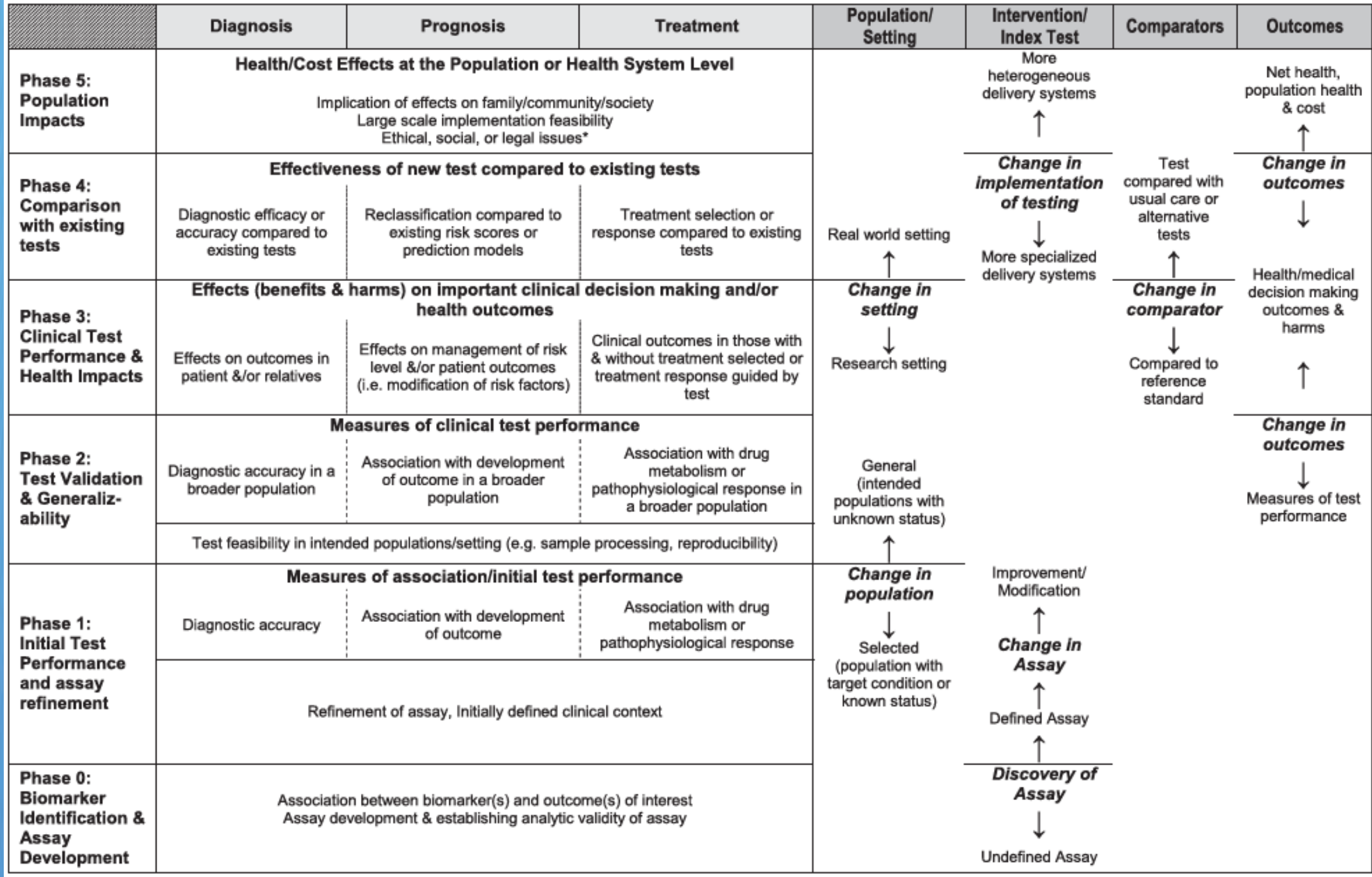
- Transparency of included/considered evid
  - Be specific
  - Use a common language/taxonomy
  - Always consider the 'chain' of evidence
    - medical testing itself does affect patient outcomes



- Evidentiary thresholds *** this will vary
  - Be flexible
    - But transparent about where the threshold is being drawn *and* factors external to evidence affecting decision making
  - Take into account decisional context
    - E.g., what is the harm of inaction, does genomic test replace existing test(s), life-course approach
  - Be mindful of 'possible' evidence (e.g., rare disease)

Evaluating genomic tests from bench to bedside: a practical framework

Figure 2: Framework for phased evaluation of new genetic tests in relation to proposed roles



* May be considered at earlier points as well