
Introduction

Ned Calonge, MD, MPH
Incoming ACHDNC Chair
Associate Dean of Public Health Practice
Colorado School of Public Health

Background

- Trained in family medicine and preventive medicine; board certified in preventive medicine, earned an MPH in epidemiology
- Served as full-time faculty in family medicine at CU for 6 years (now 36 years total)
- Served as Chief of Preventive Medicine for Kaiser Permanente, Colorado for 10 years
- Served as Chief Medical Officer for the Colorado Department of Public Health and Environment for 10 years
- Served as President and CEO of The Colorado Trust, a health equity foundation, for 11 years
- Now Associate Dean for Public Health Practice at the Colorado School of Public Health

Evidence-base recommendations background

- Served on the US Preventive Services Task Force for 8 years, 7 as chair
- Served on CDC's Community Preventive Services Task Force for 11 years, 4 as chair, chaired the Methods Committee
- Served on the ACHDNC for 3 years, co-authored the original methods
- Served on CDC's EGAPP Working Group (genetic testing recs for 9 years, 4 as chair, co-authored the methods
- Served on two evidence-based medicine methods committee for CDC's Advisory Committee on Immunization Practices
- Served on the National Academies of Sciences, Engineering and Medicine consensus study on "An Evidence Framework for Genetic Testing
- Chaired the NASEM consensus study committee on Evidence-based public health preparedness and response, co-authored new mixed-methods evidence review and synthesis and evidence-to-decision framework to include qualitative and other evidence types
- Chaired the NASEM consensus study on Guidance on PFAS testing and follow-up, co-developed new methods to address clinical decision-making under significant scientific uncertainty for environmental exposures

Philosophy

- Decisions regarding screening decisions require the highest level of evidence, free from politics, special interests and advocacy
- We should only recommend screening tests where our certainty of a level of net benefit (benefits minus harms) is acceptable—that is, we have a small risk of being wrong

Advocacy

- Still, advocacy plays a vital role in EBM, perhaps especially in newborn screening
 - Essential to understand the impact of newborn conditions on the child and their family
 - Essential to remember these children are much more than just numbers
 - Essential to respect and consider the interest and values of those impacted
 - Essential to have political advocacy to support and advance implementation of newborn screening at the state and federal level

Criteria for a screening program (from Wilson and Jungner)

- The disease is important
- There is a recognizable pre-symptomatic stage long enough to allow for screening, diagnosis and treatment
- Reliable screening tests exist for the pre-symptomatic stage
- Treatment of the disease during the pre-symptomatic stage results in improvement in outcomes
- Sufficient resources exist for diagnosis and treatment in the population with positive screening tests

Harris/Sawaya/Moyer/Calonge Criteria

- If implemented under present conditions, would the screening program result in sufficient net benefit (benefits minus harms) to justify starting (or continuing) the program, given the level of resources required?

Potential harms of screening

- There are 5 things that can happen with a screening test, and 4 of them are bad:
 - » False negative test (false reassurance, delay in diagnosis of treatable condition)
 - » False positive test (unnecessary and potentially harmful diagnostic tests, treatment, and labeling)
 - » Over-diagnosis (true positive, but disease wouldn't progress and treatment unnecessary)
 - » No benefit from early detection (diversion of resources from effective services)
- Also, there may be harms intrinsic to the test itself

Principles for decision making under uncertainty

- **Proportionality:** Decisions should balance plausible harms and benefits proportionally
- **Justice:** Decisions should balance harms and benefits fairly across all individuals, promote health equity, and respect human rights
- **Autonomy:** Decisions should incorporate informed decision-making by individuals and respect their values
- **Feasibility:** Decisions should take account of resource availability, including follow-up services
- **Adaptability:** Decisions should respond to new information about harms, benefits, and other relevant considerations (e.g., health equity and feasibility)

Thank you!
