

Nicole Dowling Co-Chair, Workshop Planning Committee

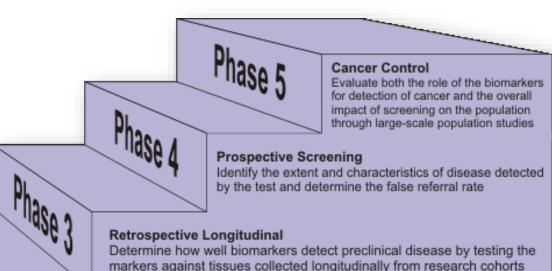
## **Revisiting the Workshop Goals**

- Describe the key principles of cancer screening.
- Review the evidence base for cancer screening, including key gaps and methodologic and statistical challenges in assessing the benefits and risk of cancer screening.
- Highlight opportunities to improve the evidence base for cancer screening, including the potential to leverage new research approaches and learning health systems.
- Consider the challenges and opportunities to developing new cancer screening tests, as well as the
  potential for new approaches to mitigate risk, improve patient outcomes, and deliver more personalized
  approaches to cancer screening.
- Examine opportunities to improve shared decision making in cancer screening decision-making, including strategies to better tailor population-based screening guidelines and improve risk stratification.
- Identify opportunities to reduce disparities in cancer outcomes by facilitating patient access to high-quality cancer screening and follow-up care.

- Cancer screening is a series of tests with some uncertainties and some risk.
- Finding cancer is not a measure of successful cancer screening. Reduction in mortality is the only true proof of effective screening—increased survival is not a legitimate measure of success outside a RCT.
- We need to hold preventive services to a high bar before recommending them. Many people will
  not experience the benefits of screening, but all will be exposed to the harms.
- Overdiagnosis—a complex biological challenge and clinical dilemma—is arguably the largest harm
  of cancer screening, and difficult to communicate and to address in clinical practice. Need
  education, terminology changes, prevention/deimplementation research, and research on the
  underlying biology of tumors and microenvironment
- The quality of cancer screening and follow-up care is critical to ensuring the effectiveness of cancer screening and improving patient outcomes, but there has not been enough emphasis on equitable access to quality care.

- There are many claims about the benefits of novel cancer screening tests, but a majority do not get implemented. A major challenge is the validation of novel screening tests due to bias in research design.
- The usefulness of a cancer screening test relies on test performance, as well as the benefit and harms of screening, but these are very challenging to measure.
- The primary methodological and statistical challenge is accurately quantifying population-relevant benefits and harms.
  - Which benefits? Which harms? What time horizon? Whose perspective(s)?
  - Understanding optimal vs. realistic expectations for cancer screening in practice.
  - Better data on the natural history of disease.
  - Challenge/inability to apply population-based overdiagnosis data on individual screening decisions.
- How can (or should) health economics be leveraged to improve cancer screening program design, implementation, and evaluation?
- Importance of contextual factors and improving decision making for beyond average populations?
   (considerations of age, comorbidities, subpopulations with different distributions of disease biology and competing mortality).

- State of the science of biomarker research: ~4-5k papers on biomarkers of early detection each year, but very few, if any, receive regulatory approval
- Challenges of cancer screening biomarker development include: failure to use rigorous biomarker science, limited understanding of the biology of early disease, selective reporting, lack of collaboration, inadequate incentives for validation work.
- Follow biomarker development pathway
- Novel technologies/approaches for cancer screening offer promise and challenges



Studies to determine the capacity of biomarkers to distinguish between people with

Source: Pepe et al, J. Natl. Cancer Inst. 93, 1054-1061, 2001

Clinical Assay and Validation

cancer and those without

Exploratory studies to identify useful biomarkers

Preclinical Exploratory

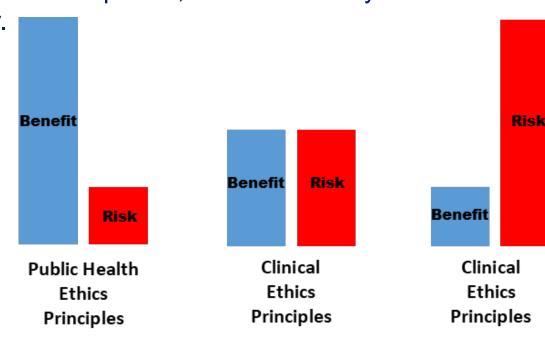
- Many barriers to high-quality cancer screening and follow up care, including patient, clinician, and organizational factors:
  - no access to services in community, unaffordability of care, competing health concerns, mistrust of health care system, lack of social support, transportation barriers, scheduling difficulties, unconscious bias, fatalism/fear, insufficient follow-up, poor communication.
- Lack of timely follow up of abnormal screening tests diminishes the impact of cancer screening on patient outcomes.

• Inequities in access to high-quality cancer screening and follow up care, as illustrated by cervical

cancer screening in the context of the Rio Grande Valley.

 No easy solutions to address the challenge of patient access, but engagement with federally qualified health centers is critical.

 Tension between public health and clinical ethics principles in cancer screening.



- What defines a high-quality decision-making process?
  - Patient engagement, recognition of the decision to be made, awareness of the alternatives, awareness of pros and cons of each option, awareness of the uncertainties in the decision, consideration of patient preferences/values, ability to carry out the decision
- Shared decision making (SDM): ensuring that patients are informed about and included in the healthcare decisions which are made together with their clinicians (can span spectrum of SDM from paternalism to consumerism)
  - Clinicians bring expertise as well as their values; Patients bring their values and experiences.
  - SDM and decision aids can augment engagement in cancer screening decision making.
  - There are challenges to incorporate SDM to diverse groups.
- When there are competing priorities in a busy primary care visit, how realistic is it to incorporate SDM and decision aids?
- Improve uptake and implementation of shared decision making through:
  - Clinician and patient training; changes in clinician attitudes
  - Integration into practice/clinical workflow, use of technology
  - Aligning incentives, and removing barriers to participation
  - Engage stakeholders to collaborate in the generation of evidence

# Opportunities to Advance Progress in Cancer Screening

- Address barriers in access to high-quality cancer screening and follow-up care.
- New screening and testing technologies require ongoing assessment and careful introduction to avoid bias in use and expectations of improved value.
- Consider opportunities to improve rigor of cancer screening research:
  - Address systems issues to ensure incentives to improve the strength of science
  - Arrange/engage appropriate expertise and leadership in cancer research planning
  - Invest in infrastructure to enable discovery and validation research
- Improve knowledge of the natural history of disease
- Test risk-based screening approaches to better tailor individual decision making
- Pair cancer screening with risk reduction interventions