Evaluating the Clinical Utility of Multi-Cancer Early Detection Tests

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Multicancer Early Detection (MCED) tests screen for multiple types of cancer using a blood, breath, urine, saliva, or stool sample. MCED tests aim to detect cancer early, even before symptoms appear, which may lead to better treatment outcomes and patient survival rates.

MCED testing is rapidly evolving, and while direct evidence for clinical utility is currently limited, some health systems are offering MCED cancer screening as a complement to guideline-directed single cancer screening. Due to the potential impact on cancer's public health impact, there is an urgent need to generate additional evidence about the clinical utility of MCED tests.

Clinical Utility and the Limitations of Randomized Trials for Evaluation

"Clinical utility" refers to the impact of a diagnostic test on patient outcomes. Clinical utility is a function of the test's performance and is determined by the impact of a specific therapeutic or other management decisions made based on the test result

Randomized controlled trials (RCTs) with mortality endpoints are the gold standard for demonstrating clinical utility of cancer screening tests. RCTs help reduce biases to provide accurate assessments of the benefits and risks of cancer screening methods.

However, there are drawbacks to relying on longer-term RCTs:

RCTs with mortality endpoints for MCEDs may take decades and involve hundreds of thousands of patients, potentially yielding results that aren't applicable to rapidly evolving MCED tests.

Delaying the adoption of screening tools with the potential to save lives may come with substantial opportunity costs.

Clinical Utility Framework

MCEDs have the potential to reduce cancer morbidity and mortality, but it will take many years to definitively establish their benefits and risks. Coordination across healthcare and research entities is critical for establishing common protocols for gathering real world evidence, harmonizing outcome measures in clinical studies, and ensuring efficient interpretation of accumulated evidence. As mortality trials are planned and implemented, the MCED Consortium recommends a parallel, collaboratively pursued strategy for more rapid evidence development guided by these key principles:

Intermediate/Surrogate Outcome Measures

Develop and validate intermediate and surrogate endpoints that correlate with the effectiveness of MCED screening to support nearer-term assessments to inform clinical and policy decisions.

Real-World Data & Evidence

Employ strategies for ongoing learning from real-world data about test performance and associated outcomes to augment data from screening RCTs.

Modeling Frameworks

Develop strategies to leverage emerging study data to populate and validate models to predict benefits and risks of MCEDs.

Learn more

Visit **mced.info** to learn more about the MCED Consortium and its work. Read the full white paper: ***Evaluating the Clinical Utility of Multi-Cancer Early Detection (MCED) Tests: Envisioning a Path Forward***.