

Implementation of Genomic Emerging Tests: Building the Evidence Base for Appropriate and Efficient Implementation of Emerging Genomic Tests for Disease Management and Screening

Overview:

Payer coverage and economic value continue to be critical factors in determining whether genomic medicine (GM) is appropriately and efficiently implemented into clinical care and health policies. However, genomic tests are now emerging that present particularly difficult challenges for coverage and value determinations.

This study will provide unique insights by examining (a) multiple clinical scenarios that allow us to compare disease management to screening tests and to compare tests for the most common application of GM (cancer) with uses that have been less common but are increasing (e.g., coronary artery disease), and (b) both coverage and economic value so that we can understand how these are interrelated.

Objectives:

Our objective is to assess payer coverage decisions and the economic value of two types of emerging genomic tests for disease management and screening: cell-free DNA (cfDNA) and tests based on Polygenic Risk Score (PRS).

Aim 1: Examine which cfDNA and PRS tests are covered and why using (a) systematic evidence reviews of payer coverage policies and (b) structured interviews with payers on how they consider evidence and make coverage decisions.

Aim 2: Understand the economic value of cfDNA and PRS tests by taking a patient-centered approach, addressing key methodological challenges, and identifying gaps in evidence.

Aim 3: Compare evidence needs for payer coverage (Aim 1) and economic value assessment (Aim 2) across clinical scenarios and generalize our findings on evidence needs to other emerging clinical scenarios, considering patient access and stakeholder perspectives.



TRANSPERS

Launched in 2008, the Center for Translational and Policy Research on Precision Medicine (TRANSPERS) at the University of California, San Francisco is a first-of-its-kind research center dedicated to developing evidence-based information for patients, providers, industry, researchers and policymakers to objectively assess how precision medicine can be most beneficial and efficient in improving health outcomes. The TRANSPERS Center has been funded by grants from the National Institutes of Health (NIH) and several foundations.

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