

What Is Clinical Utility and Why Should We Care?

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This issue of *Clinical Pharmacology & Therapeutics* addresses the complexities and challenges of defining and demonstrating clinical utility in the era of personalized medicine. "Utility" is a term that is ubiquitously used in fields ranging from economics to medicine. Broadly speaking, utility is a measure of the personal benefit that someone has from an intervention, outcome, product, or process. "Clinical utility" is a term that is widely used in medicine to describe the relevance and usefulness of an intervention in patient care. Despite general agreement that clinical utility assessments are multidimensional and may include economic, clinical, and/or humanistic domains, there is no consensus on its definition or how to robustly demonstrate it to the satisfaction of multiple stakeholders.

The individualization of a treatment or an intervention depends on the interplay among intrinsic (i.e., patient-specific) and extrinsic (i.e., environmental) factors.¹ In particular, the use of personal genetic or other biomarker information for the purpose of stratifying patient populations for different dosing and/or treatment strategies, enriching clinical trials,² or identifying patients at risk for adverse events has been postulated as a mechanism by which better health outcomes and lower health-care costs

could be achieved. Despite this promise, many feel that few personalized treatments or interventions have achieved widespread clinical adoption, i.e., have had their clinical utility demonstrated to the satisfaction of health-care providers, third-party payers, and other stakeholders.

Stakeholders in personalized medicine want to know whether genetic tests are valid and useful. The accuracy of a genetic test is evaluated by measuring its analytical and clinical validity. The usefulness of a genetic test is typically evaluated by its clinical utility in medical practice. The issue of clinical utility has been said to be of central importance to personalized medicine.³

The question of evidence generation to support clinical utility

Clinical utility is often test-, drug-, and context-dependent, and it is rarely easily quantified. In the context of a drug-test pair, clinical utility has historically been a composite measure of benefit, risk, and perceived value in medical decision making. Clinical utility is frequently a matter of judgment depending on a stakeholder's perspective of the supporting evidence.

The major questions in the current dialogue regarding the generation of evidence to demonstrate clinical utility are (1) what is the minimum threshold of

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