Health technology assessment evidence criteria: What types of evidence should be presented for products used to screen for disease in the United States?

Author: McGee, Nancy Mari


Abstract: New technologies can be tools of innovative change in healthcare. They can be associated with improved treatment options, quality of care for patients, and cost savings. Distinguishing valuable technologies from those that offer added costs with no improvements in outcomes is the art of technology assessment. A key function of that art involves selecting those patients, conditions, providers and settings in which a technology may offer improvements over current care. With recent scientific discoveries such as the mapping of the human genome, development of genetic marker tests, and the growing interest in stem cell technologies, innovation is far ahead of any type of assessment that is currently used to establish which technologies should be made accessible to patients.

Screening technologies are on the forefront of innovation and may have a dramatic impact on the care of patients in terms of identifying disease and appropriate treatment options at an early stage. As a result, screening technologies are of key interest to health technology assessment (HTA) agencies in the United States and abroad. Similarly, because screening technologies are developing quickly and are believed to have the potential to make a significant change in patient care, it is important to develop a robust level of HTA criteria to evaluate these new technologies and determine which technologies should be integrated into the practice of medicine and made accessible to patients.

Findings from this study indicate that while technology assessment organizations do have standard sets of criteria to evaluate products that are therapeutic, the assessment and level of evidence used to evaluate screening technologies are less clear. The objective of this research study is to evaluate existing technology assessment standards for screening technologies in order to establish a best practice that may be implemented by US technology assessment organizations to broaden the criteria used in assessments for screening products. The results of this study indicate that the best practices should include criteria to: support screening reliability, sensitivity and specificity; evaluate data to identify appropriate patient populations; reference to the natural course of the disease; consider ethical implications; and the impact of cost.

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