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Commentary

Leveraging patient experience measures as surrogate outcomes to evaluate health care interventions

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Abstract
Patient experience quality measure scores are widely accepted as outcomes in health services research. For some patients and in some settings, such as hospice care, they can be the most important outcomes. While these measures are widely used, the potential to use them as surrogate outcomes in a clinical trial sense has gone under-recognized. The purpose of this commentary is to discuss the use of patient experience measures as potential surrogate outcomes in evaluating the effect of a health care intervention.

Keywords
Surrogate outcome, intervention effect, quality measures, patient experience

Introduction

Decades ago, there was relatively little attention paid to the human experience in health care settings. Today, nearly every health care encounter brings a request to evaluate that experience afterwards. Patient experience quality measures are now used in most health care settings including hospitals, outpatient encounters, home health, hospice, and nursing homes.

While some still argue against measuring, comparing, and paying incentives based on patient experience quality measures, a wealth of evidence supports the importance of a patient's experience when receiving care. For example, patients who have better experiences, who say their doctors and nurses listened to them and treated them with courtesy and respect, are more likely to follow advice, get recommended follow-up care, and fill their prescriptions.[1-4]

Patient experience quality measure scores are widely accepted as outcomes in health services research. For some patients and in some settings, such as hospice care, they can be the most important outcomes. While these measures are widely used, the potential to use them as surrogate outcomes in a clinical trial sense has gone under-recognized. The purpose of this article is to discuss the use of patient experience measures as potential surrogate outcomes in evaluating the effect of a health care intervention.

Key Factors for Consideration

Difficulties with Evaluating an Intervention

To evaluate the effectiveness of a health care intervention, it is essential to have a well-designed study and a clearly defined outcome. Examples of health care interventions include changes to health care delivery models, implementation of new processes of care or institutional programs, and establishment of strategic partnerships between teams, businesses, or organizations. Such interventions often aim to improve health outcomes by reducing mortality, morbidity, and health inequity.

However, these outcomes are often difficult to measure. In some cases, the outcome may require long-term follow-up. For example, depending on the patient population, outcomes such as death or disease onset may take years or decades. In addition, obtaining person-level outcomes is often resource-intensive, requiring medical record abstraction, chart review, and/or human or machine learning processing of medical record provider notes. Furthermore, the effect of an intervention is often complex, multi-faceted, and may induce unintended consequences, all of which are difficult to measure with a single outcome.

These challenges can make it difficult to evaluate an intervention, often resulting in the need for a very large study sample size or long follow-up.

The Promise of Surrogate Markers

The identification and validation of surrogate markers has been an active area of research in Phase 1-3 clinical trials. Among statisticians, there is currently no agreement on a single optimal statistical method to validate a surrogate marker.[5] Prentice (1989) defined a criterion for a valid surrogate marker by requiring that a test for a treatment effect on the surrogate marker also be a valid test for a treatment effect on the primary outcome.[6] Motivated by this criterion, statistical methods have been developed to evaluate potential surrogates by estimating the proportion

of the treatment effect on the primary outcome that is captured by the treatment effect on the surrogate marker.[7-9]

The Food and Drug Administration (FDA) considers a biomarker to be a surrogate marker or outcome if it is "reasonably likely" to predict the effect of a treatment on the primary clinical outcome of interest.[10] The FDA's Accelerated Approval program allows for a path to drug approval based on a demonstrated effect of a treatment on a surrogate outcome. For example, in clinical trials examining treatments designed to prevent or delay diabetes, change in hemoglobin A1c is often used as a surrogate outcome for a Type 2 diabetes diagnosis and is formally listed in the FDA's table of surrogate outcomes.[11]

Though the phrase "surrogate marker" is typically relegated to Phase 1-3 clinical trials, the concept of using an earlier or easier to measure outcome as a surrogate for an unmeasurable or difficult to measure primary outcome is widespread in health services research. In some settings, patient experience quality measures may serve as useful surrogate outcomes for the purpose of evaluating an intervention effect. Patient experience quality measures have the potential to capture components of the intervention's effect that are difficult to capture with more traditional outcomes i.e., the complex, multi-faceted, and potentially unintended effects.

Measuring Patient Experience is Not Easy

But wait, aren't patient experience measures hard to obtain? To be sure, obtaining patient experience survey scores is generally *not* considered a quick, cheap, or easy process. However, in many health care settings, administration of patient experience surveys and score calculations are already being done. And in the case of Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, these surveys have gone through extensive testing and analysis to ensure that measure scores are reliable and valid.[12] Furthermore, the Centers for Medicare & Medicaid Services (CMS) has invested enormous resources in testing web-based administration of CAHPS surveys.[13-15] While testing results have demonstrated that web-only surveys are not feasible in terms of adequate representation and response rates, web-*first* survey administration improves response rates and provides the opportunity to obtain responses more quickly than traditional mail surveys. Compared to obtaining outcomes via medical record abstraction, chart review, or error-prone claims data, patient experience outcomes that are being measured anyway may indeed prove to be faster, easier, and less costly.

Conclusion

There exists an opportunity to leverage patient experience quality measures as outcomes in the evaluation of health care interventions, as both the outcomes of primary interest and/or as surrogate outcomes that may capture complex intervention effects. For the latter purpose, further work is needed to evaluate the validity of these outcomes as valid surrogates. Specifically, available statistical methods can be used to investigate the surrogacy of these quality measures via the proportion of the intervention effect that can be explained by the measures.

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