

MEASURES MANAGEMENT SYSTEM

The Business Case: What It Is, Why It Helps, and How to Get Started

What is a business case for a clinical quality measure?

In measure development, a business case documents all potential impacts of a quality measure. This should include a description of anticipated financial outcomes, but also potential impacts to health care organizations and patients. There is a wide range of potential positive and negative impacts associated with implementing a measure, including:

- Health outcomes such as morbidity and mortality, quality of life, length of stay, and readmissions.
- Organizational outcomes such as workplace safety, employee turnover, and impacts on clinician time.
- Financial outcomes such as costs reduced by minimizing medical errors, including costs associated with liability and litigation.

The Centers for Medicare & Medicaid Services (CMS) use this information to determine whether to invest resources in the development or continued use of a measure. To facilitate that decision-making, measure developers provide CMS with cost and resource information demonstrating that the measure represents a good balance of cost, benefits, and risks. The business case highlights the healthcare system's capacity to implement the measure. For example, an electronic clinical quality measure that relies on data elements that are not likely to be discretely captured in electronic health record (EHR) systems may be burdensome to calculate and report. These types of feasibility challenges can affect how CMS perceives a given measure in terms of viability for implementation in one of its programs.

Information that must be detailed in the business case includes:

- The purpose of the measure, why it's important, and how it aligns with CMS priorities
- Information about the strength of the evidence supporting the measure
- The financial costs, benefits, and savings associated with the measure
- Details about the measure's feasibility, specifically the likelihood that a health care organization would be able to implement the measure without undue burden
- Improved health outcomes and health care experiences for patients and families

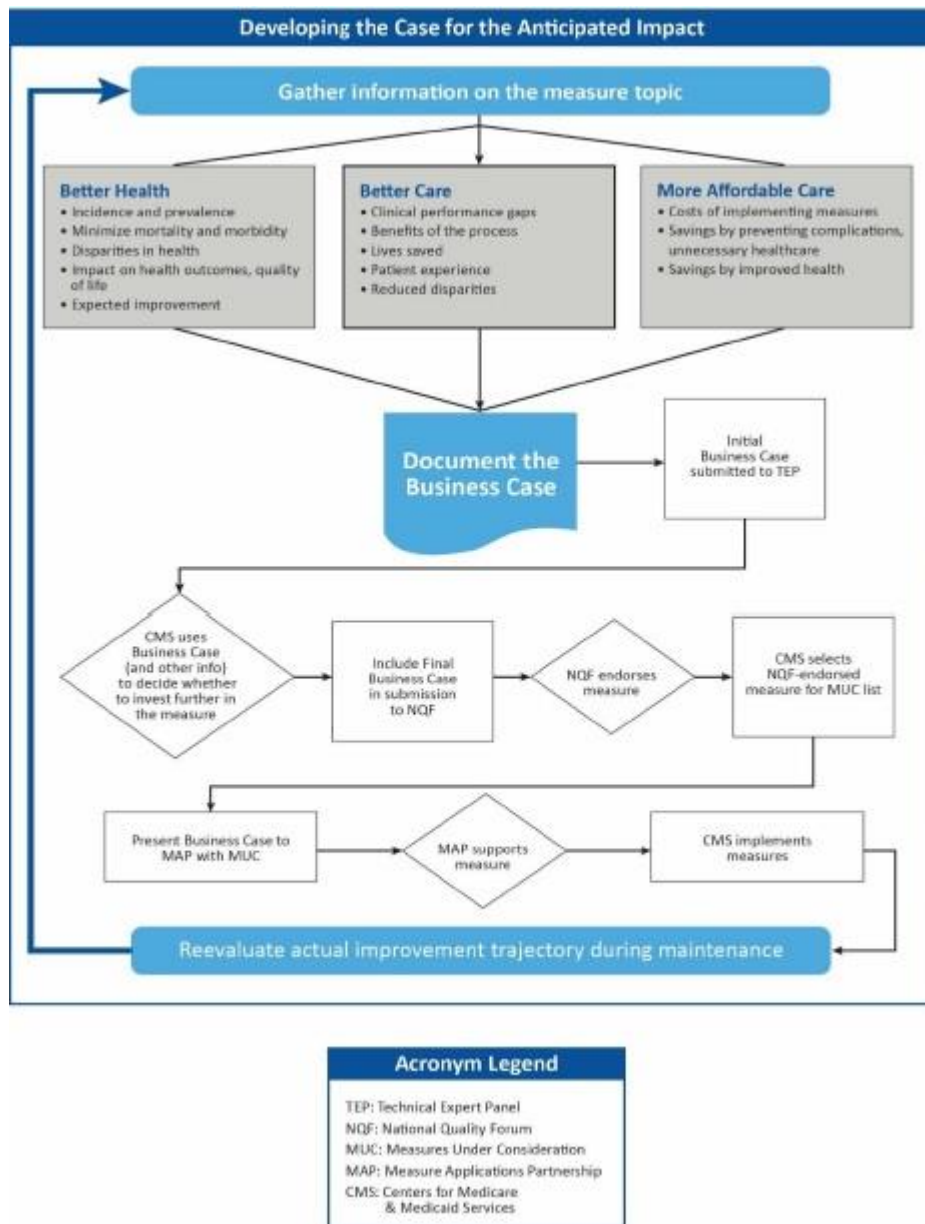
Benefits from improvements gained through measures that could be presented in the business case include:

- Better care through improvement in the quality of care provided and positive influence on patients' perception of their care
- Better health through reduction in mortality and morbidity and improvements in quality of life
- More affordable care through cost savings

Figure 1 below diagrams the business case inputs and the role of the business case throughout the Measure Lifecycle.

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Figure 1. Inputs and Uses for the Business Case



What evidence should be incorporated into the business case?

The claims documented in the business case must be supported by thorough evidence. Measure developers may cite clinical practice guidelines or other clinical evidence, such as randomized controlled trials (RCTs), to justify their measure. When using such evidence in the business case, measure developers should consider the strength of the evidence. For example, measure developers should review and describe the types of studies that support the clinical practice guidelines cited in the business case. RCTs are typically considered to be the strongest type of evidence, and a larger quantity of RCTs (five or more) or other studies suggests consistency in results and increases the confidence in the evidence.

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Another factor to consider is whether a given study provides direct or indirect evidence. Direct evidence refers to studies that draw conclusions that immediately relate to the measure. Indirect evidence, on the other hand, requires that an inference be made between the evidence and the conclusion drawn from it. Take for example a diabetes measure related to annual neurological exams of the foot and ankle. A clinical study that shows improved outcomes (i.e., fewer foot amputations) for Type II diabetes patients who receive annual lower extremity neurological exams would provide direct evidence for that process measure because it directly illustrates the value of the process being measured. A study showing that diabetic patients with neuropathy are more likely to develop foot ulcers may be considered an example of indirect evidence because it requires the reader to infer that (1) screening for neuropathy will reduce the incidence of foot ulcers and (2) reducing the incidence of foot ulcers will lead to fewer amputations. For each study referenced in the business case, measure developers should describe study factors, such as the study design and potential flaws, whether the evidence is direct or indirect in relation to the measure, and overall precision in measurement to ensure transparency about the strength of the evidence used to support the measure.

In addition to presenting information about the strength of clinical evidence, a business case must also clearly describe the benefits and risks associated with a measure. A cost model is the most common method for presenting this type of evidence due to its quantitative nature. A cost model is used to estimate the measure's impact on health care costs based on information from multiple sources. However, any approach that provides testable results and high-quality evidence can be used to characterize the potential benefits of a measure.

What are the benefits of a business case?

A business case provides a framework for measure developers and CMS to accurately assess the importance and viability of measures they are developing. Because CMS factors this information into their decisions about whether to develop, implement, and eventually use a measure in their programs, a well-researched business case increases the likelihood that measures in these programs are based on sound evidence and unlikely to cause undue reporting burden among providers.

Furthermore, the business case ensures measures address the evaluation criteria used by CMS and the National Quality Forum (NQF) including: the importance to measure and report on the topic, scientific acceptability of measure properties, feasibility, usability and use, and harmonization. In fact, many of the fields in the business case template align with fields in the NQF submission form. As such, investing resources to develop a strong business case early in development can serve as the foundation for later steps in the measure development process. For example, the information can be directly plugged into NQF submission forms, and the business case can be provided to the Measure Applications Partnership (MAP) committee during Pre-Rulemaking to aid in their decision-making about whether to recommend a measure for use in a CMS program.

Where can measure developers learn how to write a business case?

The [MMS Blueprint](#) offers instructions and a template in the Forms and Templates section. This can serve as a helpful guide to organize the relevant details of the measure. CMS has closely aligned this form with the National Quality Forum's (NQF) [Measure Submission Form](#) to help streamline the endorsement process. NQF has also provided [Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement](#) that contains guidance on what to consider in the development of a measure business case.

For complete information on the topic of Business Case Development, please refer to [the MMS Blueprint \(Section 3 Chapter 11 in v. 14\)](#).