Performance Improvement Project Validation
Revised 2008

Purpose of the Performance Improvement Project (PIP) Validation

All managed care organizations that serve Medicaid or Medicare enrollees must conduct two Performance Improvement Projects (PIPs) each year aimed at improving care outcomes. One of the PIPs must focus on improving clinical care, and the other on improving nonclinical services. To ensure that the PIPs are designed, conducted, and reported in a methodologically sound way, the PIPs are validated each year by external quality review.

The validation protocol presented here is based on version 1.0 of the protocol released in May 2002 by the Centers for Medicare & Medicaid Services: *Validating Performance Improvement Projects, Final Protocol*. The validation procedure consists of the following activities:

Part 1: Assessing the methodology for conducting the PIPs
Part 2: Evaluating the validity and reliability of PIP results

Assessing the methodology for conducting PIPs

Assessing the PIP methodology consists of the following 10 steps.

Step 1: Review the study topic
Step 2: Review the study question
Step 3: Review the study indicator(s)
Step 4: Review the identified study population and sampling methods
Step 5: Review the data collection procedures
Step 6: Assess the improvement strategy
Step 7: Review the data analysis and interpretation of study results
Step 8: Assess the likelihood that reported improvement is “real” improvement
Step 9: Assess whether the RSN has documented additional interventions or modifications
Step 10: Assess whether the RSN has sustained the documented improvement

Each step addresses the extent to which the PIP complies with a particular standard in the CMS protocol. The criteria for assessing compliance with each standard are listed below.

Step 1. Review the study topic

Criterion 1.1. The topic was based on relevant information.

The topic must reflect the demographics, prevalence of diagnoses, potential risks, or service needs of the RSN’s Medicaid population. Examples of other relevant information from which topic may be selected include

- utilization patterns that reflect deficiencies in service
- enrollee or provider input
- grievances or appeals that indicate underlying issues in care or services

Criterion 1.2. Topic was determined through a systematic selection and prioritization process.

The topic must aim to improve care and services for a large portion of the RSN's Medicaid population. Examples of evidence for a systematic selection and prioritization process include

- descriptions of data that support the topic selection
- documentation of opportunities for soliciting enrollee or provider input

Example—clinical: Developing an algorithm to standardize prescribing patterns for specific diagnoses

Example—nonclinical: Assessing and improving the accessibility of specific services; reducing disparities in services provided to minority enrollees as compared with non-minority enrollees; designing processes to improve care coordination

Step 2: Review the study question

Criterion 2.1. The RSN has clearly defined the questions the study is designed to answer. The questions are

- stated so they can be answered quantitatively or qualitatively by the PIP study
- stated so as to create a framework for data collection, analysis, and interpretation

Step 3: Review the selected study indicator(s)

Each project should use at least one quality indicator for tracking performance and improvement.

Criterion 3.1. Indicators are objective, measurable, clearly defined, unambiguous statements of an aspect of quality to be measured. The indicator statement clearly identifies

- who—the eligible population
- what—the care or service being evaluated
- when—the specific care or service time frame

The indicator description includes

- *definition of the denominator:* the eligible population, identifying inclusions and exclusions (criteria used to determine the eligible population, such as age, gender, and diagnosis and enrollment status)
- *definition of the numerator:* the outcome achieved or service rendered to the eligible population
- dates of service, procedure codes for administrative data, or acceptable medical record data
- the basis for adopting the indicators (e.g., that they are generally used in the industry—these are preferred; or if the RSN developed its own indicators either at the outset of the study or as a means of narrowing the focus for the study, a description of how the indicator was developed)
- justification (from the literature or expert consensus) for using process measures as proxies for outcome measures in clinical care studies

Criterion 3.2. Indicators are capable of measuring enrollee outcomes, enrollee satisfaction, or processes of care strongly associated with improved enrollee outcomes.

- Indicators for clinical care should include at least some measure of change in health status or functional status or process-of-care proxies for these outcomes.
- Process measures may be used as proxies for outcomes only if validity has been established in the literature or by expert consensus.

Step 4: Review the identified study population and sampling methods

Criterion 4.1. The study population is clearly defined so that all the RSN's Medicaid enrollees who are eligible for the study are included.

The study population

- represents the RSN's entire Medicaid population that fits the eligibility criteria described by the indicators
- is defined in terms of enrollment time frames

If the study population is an "at risk" subpopulation,

- the RSN has clearly defined the risk and the subpopulation
- the RSN has provided a rationale for selecting the subpopulation

The RSN may use a sample for the study. *If a sample is used,* the RSN must

- provide the rationale for using a sample
- explain the sampling methodology that produced a representative sample of sufficient size (see below)

Criterion 4.2. When the study includes the RSN's entire eligible population, the data collection approach captures all eligible enrollees.

Criterion 4.3. The RSN has described the method for determining the sample size.

If a clinical or service condition is being studied for first time, the true prevalence or incidence is not likely to be known. Large sample sizes would be needed to establish a valid baseline. The sampling methodology rationale should include

- rationale for the size of the sample based on the RSN's eligible population
- the frequency of the occurrence being studied
- the confidence interval and acceptable margin of error

Criterion 4.4. The sampling methodology is valid and protects against bias.

The description establishing validity and bias protection should include

- a description of the sampling type (e.g., probability or nonprobability; stratified random or convenience)
- the rationale for selecting the sampling type

Criterion 4.5. The sample is large enough to allow calculation of statistically meaningful measures.

Step 5: Review the data collection procedures

The data collection process for the PIP must ensure that the data collected on the indicator(s) are valid and reliable. Validity indicates the accuracy of the information. Reliability indicates the repeatability or reproducibility of a measurement.

Criterion 5.1. The study design clearly specifies the data to be collected.

- Data elements are defined unambiguously
- Descriptive terms (e.g., "high," "medium," "low") are defined numerically

Criterion 5.2. The data sources are clearly identified.

- Example data sources: medical records, encounter and claim systems, or surveys
- Time frames for collection of baseline and remeasurement data are specified

Criterion 5.3. The study design describes a systematic method of collecting valid and reliable data on the entire RSN population to which the indicator(s) apply.

- *For administrative data* (claims or encounter data), the data are complete and include all data submitted by providers. For automated data collection, the RSN has provided the data specifications and algorithms used to collect the data.
- *For medical record abstraction* or review of other primary sources, the RSN has documented the steps taken to ensure that the data were consistently extracted and recorded.

Criterion 5.4. *For manual data collection,* the data collection instrument provides for consistent, accurate data that are appropriate for the study indicators and that can be used over the study time period.

- The data abstraction process is documented, including a data collection instrument with clear guidelines and definitions.
- Reviewer training is documented, including guidelines, definitions, instructions on how to use the instrument, and instructions on how to handle situations not covered in the documentation.
- Methods of ensuring inter-rater reliability are provided.

Criterion 5.5. The study design prospectively specifies a data analysis plan that includes

- whether qualitative or quantitative data or both were collected
- whether data were collected on the entire population or a sample
- whether measures were to be compared to previous results or similar studies. If comparing measures between two or more studies, the appropriate statistical test has been identified.
- whether the PIP was to compare to the performance of different sites/clinics. If comparing the performance of two or more entities, the statistical design and analytical considerations need to reflect the comparisons.

Criterion 5.6. *For manual data collection,* the study design includes the rationale for the data abstraction and the staff qualifications.

- The documentation indicates that staff received training on the use of the data collection instrument.
- The documentation indicates the inter-rater reliability of the data collection instrument.

Step 6: Assess the improvement strategy

An improvement strategy is defined as an intervention(s) designed to change behavior at an institutional, practitioner, or enrollee level. The effectiveness of the intervention(s) is determined by measuring a change in performance based on the quality indicator(s).

Criterion 6.1. The RSN reported on at least one intervention undertaken to address causes/barriers identified through the quality improvement process. Interventions were

- systemic—i.e., designed to affect a wide range of participants through long-term system change
- timed to effect change after the baseline measurement and prior to remeasurement
- effective in improving the indicator for the population(s) studied
- reasonably expected to result in measured improvement
- free of major confounding variables that were likely to affect outcomes

Step 7: Review data analysis and interpretation of study results

The RSN calculated its performance in the indicators by adhering to appropriate statistical analysis techniques as defined in a data analysis plan.

Criterion 7.1. The analysis of the findings adhered to a data analysis plan that used an appropriate statistical methodology.

Criterion 7.2. The study results, including numerical results and findings, were presented in a manner that provided accurate, clear, and easily understood information.

Criterion 7.3. The analysis identified baseline and remeasurement data, the statistical significance of the results, any factors that influenced comparability, and any factors that threatened the validity of the data.

Criterion 7.4. The analysis was based on continuous quality improvement and focused on delivery system processes.

- The interpretation of the success of the PIPs included lessons learned and identified barriers to success or presented a hypothesis about less-than-optimal performance
- Follow-up activities addressed the barriers identified

Step 8: Assess the likelihood that reported improvement is "real" improvement

The reported improvement represents "real" change and is not due to a short-term event unrelated to the intervention or to chance.

Criterion 8.1. The RSN used the same methodology for measuring the baseline as for conducting remeasurement, or the RSN has described a change in measurement methodology and explained why it is comparable.

Criterion 8.2. The analysis discussion includes documentation of

- quantitative improvement in processes related to the study question
- improvements in associated outcomes of care

Criterion 8.3. The analysis discussion describes clearly how the interventions relate to the improvement in performance.

Criterion 8.4. The analysis includes an appropriate calculation of statistical significance, with a discussion of the test used to calculate significance. (There is no required level of significance.)

Step 9: Assess whether the RSN has documented additional interventions or modifications

Changes in the fundamental processes of health care delivery result in sustained improvements. The RSN has documented sustained improvement by remeasuring performance on the initial study indicators at regular intervals. (*Note:* Interventions may be modified between remeasurement periods to address barriers or to take advantage of study findings.)

Criterion 9.1. The RSN has documented ongoing or additional interventions or modifications that are based on earlier data analyses.

Step 10: Assess whether the RSN has sustained the documented improvement

Criterion 10.1. Sustained improvement was demonstrated by additional remeasurements conducted over comparable time periods.