

Hawaii Department of Human Services, Med-QUEST Division
2005-2006 PIP Validation Tool
for <QUEST Plan Name>

ACTIVITIES	EVALUATION ELEMENTS	SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation VI. Accurate/ Complete Data Collection	The data collection techniques provide for the following:		Data collection must ensure that the data collected on the PIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement.
—	1. Clearly defined data elements to be collected.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	
—	2. Clearly identified sources of data.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	
—	3. A clearly defined and systematic process for collecting data that includes how baseline and remeasurement data will be collected.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	
—	4. A timeline for the collection of baseline and remeasurement data.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	
—	5. Qualified staff and personnel to collect manual data.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	
C*	6. A manual data collection tool that ensures consistent and accurate collection of data according to indicator specifications.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	
—	7. A manual data collection tool that supports inter-rater reliability.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	
—	8. Clear and concise written instructions for completing the manual data collection tool.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	
—	9. An overview of the study in written instructions.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	

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ACTIVITIES	EVALUATION ELEMENTS	SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation VI. Accurate/ Complete Data Collection	The data collection techniques provide for the following: 10. Automated data collection algorithms that show steps in the production of indicators. 11. An estimated degree of automated data completeness between:	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A <input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A 100%-80% 79%-50% <50% (or not provided)	Data collection must ensure that the data collected on the PIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement.
Totals for Activity VI	1**	Met Partially Met Not Met N/A	

* "C" in this column denotes a *critical* evaluation element.

** This number tallies the total number of *critical* evaluation elements for this review activity.

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ACTIVITIES	EVALUATION ELEMENTS	SCORING	COMMENTS	
Performance Improvement Project/Health Care Study Evaluation				
VII. Appropriate Improvement Strategies	Planned/implemented strategies for improvement are:		Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing system-wide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or beneficiary level.	
		—		<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A 1. Related to causes/barriers identified through data analysis and QI processes.
		—		<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A 2. System changes that are likely to induce permanent change.
		—		<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A 3. Revised if original interventions are not successful.
		—		<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A 4. Standardized and monitored if interventions are successful.
Totals for Activity VII	0*	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A		

* This number tallies the total number of critical evaluation elements for this review activity.

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ACTIVITIES	EVALUATION ELEMENTS	SCORING	COMMENTS	
Performance Improvement Project/Health Care Study Evaluation				
VIII. Sufficient Data Analysis and Interpretation	The data analysis:		Describe the data analysis process on the selected clinical or nonclinical study indicators. Include the statistical analysis techniques utilized.	
		C ⁺		1. Is conducted according to the data analysis plan in the study design. <input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A
		C ⁺		2. Allows for generalization of the results to the study population if a sample was selected. <input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A
		—		3. Identifies factors that threaten internal or external validity of findings. <input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A
		—		4. Includes an interpretation of findings. <input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A
		—		5. Is presented in a way that provides accurate, clear, and easily understood information. <input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A
		—		6. Identifies initial measurement and remeasurement of study indicators. <input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A
		—		7. Identifies statistical differences between initial measurement and remeasurement. <input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A

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ACTIVITIES	EVALUATION ELEMENTS	SCORING	COMMENTS		
Performance Improvement Project/Health Care Study Evaluation					
VIII. Sufficient Data Analysis and Interpretation	The data analysis:		Describe the data analysis process on the selected clinical or nonclinical study indicators. Include the statistical analysis techniques utilized.		
		—		8. Identifies factors that affect ability to compare initial measurement with remeasurement.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A
		—		9. Includes the extent to which the study was successful.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A
Totals for Activity VIII	2**	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A			

* "C" in this column denotes a *critical* evaluation element.

** This number tallies the total number of *critical* evaluation elements for this review activity.

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ACTIVITIES	EVALUATION ELEMENTS	SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation IX. Real Improvement Achieved	There is evidence of "real" improvement based on the following:		
	1. Remeasurement methodology is the same as baseline methodology.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	Describe any meaningful change in performance observed during baseline measurement that was demonstrated. Discuss any random year-to-year variation, population changes, and sampling error that may have occurred during the remeasurement process.
	2. There is documented improvement in processes or outcomes of care.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	
	3. The improvement appears to be the result of intervention(s).	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	
	4. There is statistical evidence that observed improvement is true improvement.	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	
Totals for Activity IX	0*	<input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A	

* This number tallies the total number of critical evaluation elements for this review activity.

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ACTIVITIES	EVALUATION ELEMENTS	SCORING	COMMENTS
<p>Performance Improvement Project/Health Care Study Evaluation</p> <p>X. Sustained Improvement Achieved</p>	<p>There is evidence of sustained improvement based on the following:</p>	<p>Describe any demonstrated improvement through repeated measurements over comparable time periods. Discuss any random year-to-year variation, population changes, and sampling error that may have occurred during the remeasurement process.</p>	
<p>—</p>	<p>1. Repeated measurements over comparable time periods demonstrate sustained improvement, or the decline in improvement is not statistically significant.</p>	<p><input type="checkbox"/> Met <input type="checkbox"/> Partially Met <input type="checkbox"/> Not Met <input type="checkbox"/> N/A</p>	
<p>Totals for Activity X</p>	<p>0*</p>	<p>___ Met ___ Partially Met ___ Not Met ___ N/A</p>	

* This number tallies the total number of critical evaluation elements for this review activity.

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Table A-1—2005–2006 Performance Improvement Project Scores
for <PIP Topic>
for <QUEST-Abbr-Ftr>

Review Activity	Total Number of Evaluation Elements	Number of Evaluation Elements Met	Number of Evaluation Elements Partially Met	Number of Evaluation Elements Not Met	Number of Evaluation Elements N/A	Total Number of Critical Elements	Total Critical Elements Met
I. Appropriate Study Topic	6					1	
II. Clearly Defined, Answerable Study Question	2					1	
III. Clearly Defined Study Indicator(s)	7					3	
IV. Correctly Identified Study Population	3					2	
V. Valid Sampling Techniques	6					1	
VI. Accurate/Complete Data Collection	11					1	
VII. Appropriate Improvement Strategies	4					No Critical Elements	
VIII. Sufficient Data Analysis and Interpretation	9					2	
IX. Real Improvement Achieved	4					No Critical Elements	
X. Sustained Improvement Achieved	1					No Critical Elements	
Totals for All Activities	53					11	

Table A-2—2005–2006 Performance Improvement Project Overall Score
for <PIP Topic>
for <QUEST-Abbr-Ftr>

Percentage Score*	Validation Status

* Percentage score is calculated by dividing the total Met by the sum of the total Met, Partially Met, and Not Met.
** One or more critical elements were <Partially Met/Not Met>.

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EVALUATION OF THE OVERALL VALIDITY AND RELIABILITY OF PIP/STUDY RESULTS

HSAG assessed the implications on the validity and reliability of the PIP findings and reviewed the study based on demonstrated confidence in the reported PIP findings. Identifying PIP design problems and determining when an accumulation of threats to validity and reliability reach a point at which PIP findings and are no longer credible are always judgment calls. (See CMS Protocol for Validating PIPs, Activity 3, page 21).

*Met = High confidence/Confidence in reported PIP results

**Partially Met = Low confidence in reported PIP results

***Not Met = Reported PIP results not credible

Summary of Aggregate Validation Findings

* Met

** Partially Met

*** Not Met

Summary statement of the validation findings:

Validation of Performance Improvement Projects (PIPs) PIP Tool Completion Instructions

The PIP form has been developed by Health Services Advisory Group, Inc. (HSAG) to flow logically through the Balanced Budget Act (BBA) requirements for submission of a PIP. Below is each PIP form activity, which includes the criteria used by the HSAG review team to complete the validation process.

Performance Improvement Project (PIP)

Activity I: Select the Study Topic(s)

A. Activity One: Choose the Selected Study Topic. Topics selected for study should reflect the Medicaid enrollment in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of the disease. Topics could also address the need for a specific service. The goal of the project should be to improve processes and outcomes of health care. The topic may be specified by the State Medicaid agency or on the basis of Medicaid consumer input.

Study Topic: Make sure that the responses address all evaluation elements below:

HSAG Evaluation Elements

1. Reflects high-volume or high-risk conditions (or was selected by the State).
2. Is selected following collection and analysis of data (or was selected by the State).
3. Addresses a broad spectrum of care and services (or was selected by the State).
4. Includes all eligible populations that meet the study criteria.
5. Does not exclude recipients with special health care needs.
6. Has the potential to affect recipient health, functional status, or satisfaction.

Activity II: Clearly Defined, Answerable Study Question

B. Activity Two: The Study Question. Stating the question(s) helps maintain the focus of the PIP and sets the framework for data collection, analysis, and interpretation.

Study Question: Make sure that the responses address all evaluation elements below:

HSAG Evaluation Elements

1. States the problem to be studied in simple terms.
2. Is answerable/provable.

Performance Improvement Project (PIP)

Activity III: Clearly Defined Study Indicator(s)

C. Activity Three: Selected Study Indicators. A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received a flu shot in the last twelve months), or a status (e.g., a consumer's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.

Make sure that the responses address all evaluation elements below:

HSAG Evaluation Elements

1. The study indicator(s) is well defined, objective, and measurable.
2. The study indicator(s) is based on practice guidelines, with sources identified.
3. The study indicator(s) allows for the study question/hypothesis to be answered or proven.
4. The study indicator(s) measures changes (outcomes) in health or functional status, recipient satisfaction, or valid process alternatives.
5. The study indicator(s) has available data that can be collected on each indicator.
6. The study indicator(s) is nationally recognized measures such as HEDIS[®], when appropriate.
7. The study indicator(s) includes the basis on which each indicator was adopted, if internally developed.

HEDIS[®] is a registered trademark of the National Committee for Quality Assurance (NCQA).

Performance Improvement Project (PIP)

Activity IV: Correctly Identified Study Population

D. Activity 4: Identified Study Population. The selected topic should represent the entire Medicaid enrolled population with system-wide measurement and improvement efforts to which the PIP study indicators apply. Once the population is identified, a decision must be made whether to review data for the entire population or a sample of that population.

Identified Study Population: Make sure that the responses address all evaluation elements below:

HSAG Evaluation Elements

1. The method for identifying the eligible population is accurately and completely defined.
2. The method for identifying the eligible population includes requirements for the length of a recipient's enrollment in the managed care plan.
3. The method for identifying the eligible population captures all recipients to whom the study question applies.

Performance Improvement Project (PIP)

Activity V: Valid Sampling Techniques

E. Activity 5: Sampling Methods. If sampling is to be used to select members of the study, proper sampling techniques are necessary to provide valid and reliable information on the quality of care provided. The true prevalence or incidence rate for the event in the population may not be known for the first time a topic is studied.

Make sure that the responses address all evaluation elements below:

HSAG Evaluation Elements

1. Consider and specify the true or estimated frequency of occurrence (or the number of eligible consumers in the population).
2. Identify the sample size (or use the entire population).
3. Specify the confidence interval to be used (or use the entire population).
4. Specify the acceptable margin of error (or use the entire population).
5. Ensure a representative sample of the eligible population.
6. Ensure that the sampling techniques are in accordance with generally accepted principles of research design and statistical analysis.

Performance Improvement Project (PIP)

Activity VI: Accurate/Complete Data Collection

F. Activity 6: Data Collection Procedures. Data collection must ensure that the data collected on the PIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement.

Make sure that the responses address all evaluation elements below:

HSAG Evaluation Elements

1. The data collection techniques provide clearly defined data elements to be collected.
2. The data collection techniques clearly specified sources of data.
3. The data collection techniques provide for a clearly defined and systematic process for collecting data that includes how baseline and remeasurement data will be collected.
4. The data collection techniques provide for a timeline for the collection of baseline and remeasurement data.
5. The data collection techniques provide for qualified staff and personnel to collect manual data.
6. A manual data collection tool that ensures consistent and accurate collection of data according to indicator specifications.
7. A manual data collection tool that supports inter-rater reliability.
8. Clear and concise written instructions for completing the manual data collection tool.
9. An overview of the study in written instructions.
10. Automated data collection algorithms that show steps in the production of indicators.
11. An estimated degree of automated data completeness.

Performance Improvement Project (PIP)

Activity VII: Appropriate Improvement Strategies

G. Activity 7. Improvement Strategies. Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing system-wide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or beneficiary level.

Make sure that the responses address all evaluation elements below:

HSAG Evaluation Elements

1. Planned/implemented strategies for improvement are related to causes/barriers identified through data analysis and quality improvement (QI) processes.
2. Planned/implemented strategies for improvement are system changes that are likely to induce permanent change.
3. Planned/implemented strategies for improvement are revised if original interventions are not successful.
4. Planned/implemented strategies for improvement are standardized and monitored if interventions are successful.

Performance Improvement Project (PIP) Name: *Enter Title of PIP*

Activity VIII: Sufficient Data Analysis and Interpretation

H. Activity 8. Data analysis and interpretation of study results: Describe the data analysis process on the selected clinical or non-clinical study indicators. Include the statistical analysis techniques utilized.

Make sure that the responses address all evaluation elements below:

HSAG Evaluation Elements

1. The data analysis is conducted according to the data analysis plan in the study design.
2. The data analysis allows for generalization of the results to the study population if a sample was selected.
3. The data analysis identifies factors that threaten internal or external validity of findings.
4. The data analysis includes an interpretation of findings.
5. The data analysis is presented in a way that provides accurate, clear, and easily understood information.
6. The data analysis identifies initial measurement and remeasurement of study indicators.
7. The data analysis identifies statistical differences between initial measurement and remeasurement.
8. The data analysis identifies factors that affect the ability to compare initial measurement with remeasurement.
9. The data analysis includes the extent to which the study was successful.

Performance Improvement Project (PIP) Name: *Enter Title of PIP*

Activity IX: Real Improvement Achieved

1. Activity 9. Reported Improvement: Describe any meaningful change in performance observed during baseline measurement that was demonstrated.

Make sure that the responses address all evaluation elements below:

HSAG Evaluation Elements

1. Remeasurement methodology is the same as baseline methodology.
2. There is documented improvement in processes or outcomes of care.
3. The improvement appears to be the result of intervention(s).
4. There is statistical evidence that observed improvement is true improvement.

Performance Improvement Project (PIP) Name: *Enter Title of PIP*

Activity X: Sustained Improvement Achieved

J. Activity 10. Sustained improvement: Describe any demonstrated improvement through repeated measurements over comparable time periods. Discuss any random year-to-year variation, population changes, and sampling error that may have occurred during the remeasurement process.

Make sure that the responses address all evaluation elements below:

HSAG Evaluation Elements

1. Repeated measurements over comparable time periods demonstrate sustained improvement, or the decline in improvement, or the decline in improvement is not statistically significant.

Scoring Methodology Examples for Med-QUEST

The score for the QUEST Plan Name was calculated as the percentage of elements across all steps that received a *Met* status. The following five examples demonstrate how the scoring was applied.

Example Findings	Validation Status	Percent Score	Comments
Met = 43 All critical elements (CE) were <i>Met</i> Partially Met = 2 Not Met = 0 NA = 8	<i>Met</i>	43/45 95.6%	No further action is required.
Met = 52 One critical elements was <i>Not Met</i> Partially Met = 0 Not Met = 1 NA = 0	<i>Not Met</i>	51/52 0%	QUEST Plan Name should submit a revised PIP and any additional information necessary to resolve the unmet critical element.
Met = 43 One critical elements was <i>Partially Met</i> Partially Met = 1 Not Met = 1 NA = 8	<i>Partially Met</i>	43/45 95.6%	QUEST Plan Name should submit a revised PIP and any additional information necessary to resolve the <i>Partially Met</i> critical element and <i>Not Met</i> non-critical element.
Met = 38 All critical elements are <i>Met</i> Partially Met = 11 Not Met = 4 NA = 0	<i>Partially Met</i>	38/53 71.7%	QUEST Plan Name should submit a revised PIP and any additional information necessary to resolve the <i>Partially Met</i> and <i>Not Met</i> non-critical elements.
Met = 38 One critical element was <i>Partially Met</i> Partially Met = 11 Not Met = 4 NA = 0	<i>Partially Met</i>	38/53 71.7%	QUEST Plan Name should submit a revised PIP and any additional information necessary to resolve the <i>Partially Met</i> critical element, and <i>Partially Met</i> and <i>Not Met</i> non-critical elements.

Hawaii Department of Human Services, Med-QUEST Division
Key Steps for the Performance Improvement Project (PIP)
Data Analysis Plan

Key Steps	Due Date
Complete medical record (MR) review.	
Getting the Data Ready	
Perform quality checks on MR data (“clean the data”).	
Create clean database of abstracted MR data.	
Combine administrative data with MR database (optional).	
Eliminate duplicate information – Perform second cleaning.	
Create final database for analysis.	
Conducting the Analysis	
Create and test programming logic/queries for study indicators.	
Calculate rates for study indicators.	
Compare rates, if possible (e.g., internal goals, baseline results, regional and/or national statistics).	
Conduct in-depth analysis for study indicators (e.g., consider comparing rates by clinics or providers to determine if a targeted intervention for a specific clinic could improve rates) and/or other data that was captured for the study.	
PIP Activities VI and VIII	
Activity VI - Discuss how the final database was created, including how data accuracy was maintained (e.g., inter-rater reliability for MR review, the validation of data during steps in the process to create the final database, medical record abstraction tool and instructions, and a flow diagram of the process).	
Activity VI - Discuss data completeness (e.g., may include IBNR report for study period showing administrative claims/encounters were 95% complete for time period, and that MR review was conducted so that data completeness not an issue).	
Activity VI - Discuss the timeline for the baseline data collection, intervention and remeasurement.	
Activity VI - Discuss the staff qualifications for data collection (e.g., used only Registered Nurses to abstract data, conducted ongoing inter-rater reliability).	
Activity VIII - Discuss any factors that occurred that may have affected the validity of the results, and what steps were taken to minimize the issue (e.g., changes in practice guidelines, or an abstractor had poor inter-rater reliability and therefore was retrained or replaced in order to complete the project). If there were no issues, then simply state there were no issues.	

Hawaii Department of Human Services, Med-QUEST Division
 Key Steps for the Performance Improvement Project (PIP)
 Data Analysis Plan

<p>Activity VIII - Discuss statistical techniques used in the analysis, or that will be used following the remeasurement period (e.g., t-test, chi-square). Include how baseline results will be compared to remeasurement.</p>	
<p>Activity VIII - Interpret the findings and present them in a clear and easily understood manner. Include basic demographics, such as eligible population and final sample size, with a generalization of the results to the eligible population.</p>	
<p>Future Steps to Consider – PIP Activities VII through X</p>	
<p>Activity VII - Determine quality improvement strategies or interventions based on causes/barriers identified through the data analysis. The interventions should be system changes that are likely to induce permanent change.</p>	
<p>Activities VII & VIII - Follow analysis plan from baseline – include statistical testing results between baseline and remeasurement, with an interpretation of the findings (e.g., was the intervention successful, and if not how will the interventions be revised, or is more time needed to notice true change and why?)</p>	
<p>Activity IX – Discuss statistical improvement in rates between measurement periods.</p>	