

Clinical Quality Management Policy Clarification Notice

Policy Clarification Notice (PCN) #15-02

Related legislation: Title XXVI of the Public Health Service (PHS) Act §§ 2604(h)(5), 2618(b)(3)(E), 2664(g)(5), and 2671(f)(2)

Scope of Coverage: Ryan White HIV/AIDS Program (RWHAP) Parts A, B, C, and D

Purpose of PCN:

The purpose of this PCN is to clarify the Health Resources and Services Administration (HRSA) RWHAP expectations for clinical quality management (CQM) programs.

Background:

[Title XXVI of the Public Health Service Act](#) RWHAP Parts A – D¹ requires the establishment of a clinical quality management (CQM) program to:

- Assess the extent to which HIV health services provided to patients under the grant are consistent with the most recent Public Health Service guidelines, (otherwise known as the HHS guidelines) for the treatment of HIV disease and related opportunistic infections; and
- Develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to, and quality of HIV services.

¹ See §§ 2604(h)(5), 2618(b)(3)(E), 2664(g)(5), and 2671(f)(2) of the PHS Act.

The CQM requirement applies directly to Parts A – D recipients; it is the responsibility of the recipient to work directly with their subrecipients to implement, monitor and provide any needed data on the CQM program.

Health care's adaptation of continuous quality improvement and total quality management techniques from manufacturing began nearly 50 years ago with much momentum in the 1980s^{2,3,4}. Over the years since, a large body of evidence has emerged suggesting a robust and effective CQM program contribute to overall improvements in healthcare quality delivery. CQM is a major component in the National HIV/AIDS Strategy (NHAS),⁵ updated July 2015, for both optimizing health outcomes and ultimately reducing HIV incidence. Coordination of CQM program activities is encouraged across all RWHAP funded recipients and subrecipients within a service area or a service area to support a reduction in data burden and alignment of performance measurement and to maximize the impact of improved health outcomes.

Components of a CQM Program

A CQM program is the coordination of activities aimed at improving patient care, health outcomes, and patient satisfaction. To be effective, a CQM program requires:

- Specific aims based in health outcomes;
- Support by identified leadership;
- Accountability for CQM activities;
- Dedicated resources; and

² Donabedian A. Evaluating quality of medical care. *Milbank Q.* 1966;44:166–206.

³ Donabedian A. Exploration of quality assessment and monitoring. Vols 1, 2, 3. Ann Arbor, Michigan: Health Administration Press, 1980.

⁴ Berwick DM. Continuous improvement as an ideal in health care. *N Engl J Med* 1989;320: 53-6. 2

⁵ National HIV/AIDS Strategy. The White House. Accessed at <https://www.aids.gov/federal-resources/national-hiv-aids-strategy/overview/>

- Use of data and measurable outcomes to determine progress and make improvements to achieve the aims cited above.

CQM activities should be continuous and fit within and support the framework of grant administration functions. Recipients are strongly encouraged to use the NHAS to frame CQM activities and goals.

In order to develop a CQM program that improves patient care, health outcomes, and patient satisfaction, certain components are necessary. The three necessary components are infrastructure, performance measurement, and quality improvement, and each of these components have a distinct role in the overall CQM program. All are important to implement a comprehensive CQM program that is able to meet established goals.

Recipients may choose to have subcontracts for some or all of the CQM activities. Recipients may also work collaboratively with their stakeholders such as planning councils/planning bodies, governing bodies, and/or board of directors, as appropriate. Whatever mechanism is used, the recipient is ultimately responsible for ensuring that the CQM program meets HRSA's requirements for the RWHAP Parts.

A. Infrastructure

Appropriate and sufficient infrastructure is needed to make the CQM program a successful and sustainable endeavor. Infrastructure is needed to plan, implement, and evaluate CQM program activities. Utilization of RWHAP grant funds to establish an appropriate infrastructure for a CQM program is allowed. An ideal infrastructure consists of:

- Leadership: Leadership to guide, endorse, and champion the CQM program
- Committee: A CQM committee that develops the CQM program and corresponding activities

- Dedicated Staffing: Staff who are responsible for CQM duties and resources, as well as any contractors that may be funded to assist with CQM work
- Dedicated Resources: Resources for building capacity in order to carry out CQM activities (e.g., training on collecting performance measurement data)
- Quality Management Plan: A quality management plan describes all aspects of the CQM program including infrastructure, priorities, performance measures, quality improvement activities, action plan with a timeline and responsible parties, and evaluation of the CQM program
- Consumer Involvement: People living with HIV (PLWH) involvement that reflects the population that is being served and ensures that the needs of PLWH are being addressed by CQM activities
- Stakeholder Involvement: Stakeholder involvement (e.g., subrecipient, other recipients in region, planning body and/or its committees, consumers) that provides input on CQM activities to be undertaken
- Evaluation of CQM Program: Evaluating the effectiveness of the CQM program ensures that the CQM activities are making changes that positively affect outcomes. This evaluation includes assessing whether CQM program activities have been implemented as prescribed by the quality management plan (including the action plan). Recipients should include regular evaluation of their CQM activities in order to maximize the impact of the program. Evaluation provides the opportunity to learn the processes and resources needed in implementing CQM activities through the collection of detailed information. Part of the evaluation should include identifying factors (i.e., staff acceptance of change, improved clinical performance, etc.) that affect the quality improvement activities. Evaluation also identifies effective improvement strategies that can be scaled up or implemented in other facets within a system of care.

Additional elements of an evaluation include effectiveness of the team and its ability to meet timelines and deliverables as described in the action plan in order to determine the success of the planned process.

Although the infrastructure will vary in scope among recipients, the inclusion of all these elements creates a strong foundation for the CQM program.

B. Performance Measurement

Performance measurement is the process of collecting, analyzing, and reporting data regarding patient care, health outcomes on an individual or population level, and patient satisfaction.

In order to appropriately assess outcomes, measurement must occur. Measures should be selected that best assess the services the recipient is funding. A sound performance measure portfolio is reflective of RWHAP funded services, local HIV epidemiology, and identified needs of PLWH. Recipients are strongly encouraged to include HRSA HIV/AIDS Bureau⁶ and HHS⁷ measures that align with the National HIV/AIDS Strategy (updated July 2015). Recipients should have an identified process to regularly collect and analyze performance measure data which would occur more frequently than data collection for reporting (i.e., the annual Ryan White HIV/AIDS Service Report). It is also important for recipients to collect and analyze performance measure data that allows for inspection and improvement of health disparities across different target populations. In order to optimally support quality improvement activities, data collection for the CQM performance measures should occur quarterly at a minimum^{8,9, 10} as this

⁶ HIV/AIDS Bureau HIV Performance Measures. 2013. Accessed at <http://hab.hrsa.gov/deliverhivaidscares/habperformmeasures.html>

⁷ Department of Health and Human Services. Common Indicators for HHS-funded HIV Programs and Services. Accessed at <https://www.aids.gov/pdf/hhs-common-hiv-indicators.pdf>

⁸ Institute for Healthcare Improvement. How to Improve. Accessed at <http://www.ihl.org/resources/Pages/HowtoImprove/ScienceofImprovementEstablishingMeasures.aspx>

affords appropriate reevaluation of the effects of improvements that have been implemented. All funded service categories need to have at least one performance measure. For each highly utilized and highly prioritized RWHAP-funded service category recipients should identify two performance measures and collect the corresponding performance measure data.

C. Quality Improvement

Quality improvement entails the development and implementation of activities to make changes to the program in response to the performance data results. To do this, recipients are required to implement quality improvement activities aimed at improving patient care, health outcomes, and patient satisfaction.¹¹ Recipients are expected to implement quality improvement activities using a defined approach or methodology (e.g., model for improvement¹², Lean¹³, etc.). Quality improvement activities should be implemented in an organized, systematic fashion. As a result, the recipient is able to understand if specific changes or improvements had a positive impact on patient health outcomes or were indicative of further necessary changes in RWHAP funded services. All quality improvement activities should be documented.

Related Activities

Quality Assurance

⁹ Joint Commission. Tools for Performance Measurement in Health Care: a Quick Reference Guide. Access at http://www.jointcommissioninternational.org/assets/1/14/TPMHC200_Sample_Pages.pdf

¹⁰ The timing of data collection for performance measures should be dependent on the availability of the data element. However, the HIV/AIDS Bureau recommends quarterly data collection for quality improvement projects.

¹¹ See §§ 2604(h)(5), 2618(b)(3)(E), 2664(g)(5), and 2671(f)(2) of the PHS Act.

¹² Institute for Healthcare Improvement. Model for Improvement. Accessed at <http://www.ihl.org/resources/Pages/HowtoImprove/ScienceofImprovementHowtoImprove.aspx>

¹³ Lean Enterprise Institute. What is Lean? Accessed at <http://www.lean.org/WhatsLean/>

Quality assurance refers to a broad spectrum of activities aimed at ensuring compliance with minimum quality standards. Quality assurance activities include the retrospective process of measuring compliance with standards (e.g., [HHS guidelines](#), professional guidelines, service standards). Site visits and chart reviews are examples of commonly used quality assurance activities. Quality assurance is not the same as quality improvement, although the results of quality assurance activities can be used to develop quality improvement activities.

Quality assurance is part of the larger administrative function of a recipient's program or organization and informs the clinical quality management program, but quality assurance activities by themselves do not constitute a CQM program. Data collected as part of quality assurance processes should feed back into the CQM program to ensure improvement in patient care, health outcomes, and patient satisfaction.

Grant Administration

Grant administration refers to the activities associated with administering a RWHAP grant or cooperative agreement.¹⁴ These include contracting of services, receipt and disbursement of program funds, data collection and submission of reports, monitoring of subrecipients, and compliance with audit requirements. Although these functions are necessary to comply with the terms and conditions of the award, their intent is not on improving health outcomes. Therefore, they are not CQM activities.

See Appendix.

¹⁴ See PCN #15-01 Treatment of Costs Under the 10% Administrative Cap for RWHAP Parts A, B, C, and D available at <http://hab.hrsa.gov/affordablecareact/pcn1501.pdf>

Applicability to Subrecipients

Recipients are to identify the specific CQM program activities for their service area (Part A and B recipients) or network (Part C and D recipients). Specific CQM program activities include a performance measure portfolio, frequency of performance measure data collection, and identification of quality improvement activities, among other items. Recipients need to ensure that their subrecipients that provide services have the capacity to contribute to the recipient's CQM program, have the resources to conduct CQM activities in their organizations, and implement a CQM program in their organizations, as identified in the written agreements between the recipient and subrecipient. Recipients are expected to provide guidance to subrecipients on prioritizing measures and collecting data. Recipients need to work with subrecipients to identify improvement opportunities and monitor quality improvement activities at the subrecipient locations. Prioritization of CQM activities should be coordinated across RWHAP recipients within service areas and subrecipients funded through the recipient.

Resources

Department of Health and Human Services Guidelines: Each set of Guidelines (see examples below) is developed by Panels or working groups from the National Institutes of Health's Office of AIDS Research and Advisory Council, Centers for Disease Control and Prevention, Health Resources and Services Administration, and other agencies. These guidelines are meant to provide HIV care practitioners with recommendations based on current knowledge. The working group or Panel reviews new evidence and updates recommendations in the Guidelines, when needed.

- Adult and Adolescent Antiretroviral Guidelines

- Adult and Adolescent Opportunistic Infection (OI) Prevention and Treatment Guidelines
- Perinatal Guidelines
- Pediatric Guidelines
- Pediatric OI Prevention and Treatment Guidelines
- HIV Prevention with Adults and Adolescents with HIV in the United States (Prevention With Positives) Recommendations
- Pre-exposure Prophylaxis Guidelines

<https://aidsinfo.nih.gov/guidelines>

<http://www.cdc.gov/hiv/prevention/programs/pwp/index.html>

<http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf>

National HIV/AIDS Strategy: First released in 2010 by the White House Office of National AIDS Policy and updated in July 2015, NHAS is a concise plan that will identify a set of priorities and strategic action steps tied to measurable outcomes. The objectives and recommendations of the HIV Care Continuum Initiative have been fully integrated into the updated NHAS.

<https://www.aids.gov/federal-resources/national-hiv-aids-strategy/overview/>

HIV Care Continuum: *(Included as part of the NHAS as of July 2015)* The HIV care continuum—sometimes also referred to as the HIV treatment cascade—is a model that outlines the sequential steps or stages of HIV medical care that PLWH go through, from initial diagnosis to achieving the goal of viral suppression (a very low level of HIV in the body). The HIV care continuum also shows the proportion of individuals living with HIV who are engaged at each stage.

<https://www.aids.gov/federal-resources/policies/care-continuum/>

National Quality Center: The HIV/AIDS Bureau funds a cooperative agreement that focuses on providing training and technical assistance to the RWHAP recipients to improve quality of care through an understanding of quality improvement concepts; as well as the use of tools, techniques and various approaches to implement quality management and quality improvement initiatives in their respective programs.

<http://nationalqualitycenter.org/>

Institute for Healthcare Improvement (IHI): IHI is a recognized innovator, convener, and generous leader, a trustworthy partner, and a place to turn for expertise, help, and encouragement for anyone, anywhere who wants to profoundly change health care for the better.

<http://www.ihl.org/>

Appendix:

Relationship between Grant Administrative Functions/Administrative Costs/Quality Assurance and CQM:

Grant administration functions/administrative costs are capped pursuant to the RWHAP legislation and include those activities associated with administering a RWHAP grant or cooperative agreement. These include contracting of services, receipt and disbursement of program funds, data collection and submission of reports, monitoring of subrecipients, and compliance with audit requirements. Although these functions are necessary to comply with the terms and conditions of the award, their intent is not on improving health outcomes. Grant administrative activities may include components of quality assurance and may provide important information to the CQM program, but by themselves are not CQM activities nor constitute a CQM program. The chart below demonstrates the overlap between Quality Assurance activities and CQM activities.

The following table illustrates relevant activities under CQM and QA:

Activity	Quality Assurance (Administrative Costs)	Clinical Quality Management
Performance measurement prioritization and alignment with other RWHAP Parts in the service area		X
Development of Service Standards	X	
Data extraction for clinical quality management purposes (collect, aggregate, analyze, and report on measurement data)		X

Chart audits/reviews	X	X
Monitoring site visits	X	If the purpose for the site visit is to assess or monitor the CQM Program
Extracting data for reporting to internal and external stakeholders	X	
Electronic health records interface with other providers; system operations	X	
CQM committee in planning for quality improvement projects		X