

**FY 2014**

# **QUALITY STRATEGY**

## **Phase I: Institutionalization of Countries' Ability to Improve HIV Clinical Programs**

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**March 2014**

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## EXECUTIVE SUMMARY

PEPFAR has made incredible strides over the last decade, saving millions of lives through care, treatment, and prevention programs. Now, as the global community continues towards the goal of achieving an AIDS-free generation, the need for a comprehensive quality approach – one that ensures adequate services for every patient, every time – has become clear. The PEPFAR Quality Strategy (PQS) strives to do just that, to institutionalize the ability of countries to continually improve HIV programs, which will sustain reductions in morbidity, mortality, and transmission of HIV towards achieving an AIDS-free generation. The PQS, the first global strategy of its kind, builds upon PEPFAR’s successful partnerships with host countries and existing quality infrastructure, approaches, and mechanisms.

The PQS provides a framework for implementing quality assurance and quality improvement practices while helping to facilitate country ownership and sustainability. Based upon quality improvement principles, the PQS is informed by the understanding that improving health processes is a collective mandate and responsibility, involving everyone from individual patients to health systems, managers and clinicians, and that the productivity and efficiency of health care processes need attention. The PQS’s commitment to evidence-based interventions and shared learning seeks to ensure that quality improvement in one location can facilitate improvement elsewhere. This first phase of the PQS focuses on Clinical Services and associated crosscutting program areas; however, the principles can be applied broadly, and future iterations of the strategy will encompass other program areas.

The approach to implementation of the PQS is not meant to be prescriptive; the following sections provide considerations for how countries can best operationalize this strategy, but ultimately PEPFAR country teams, in consultation with governments and key stakeholders, must appropriately apply them to their own contexts. This Strategy is not a comprehensive guidance on Quality Improvement implementation but rather a plan of action designed to achieve PEPFAR’s goal of institutionalization of countries’ ability to continually improve HIV programs; other guidance, resources and technical assistance may be forthcoming. While all countries are encouraged to operationalize this strategy, the following 22 countries are required to.

**Table 1. Countries Required to Operationalize the PQS in FY 2014**

<b>Botswana</b>	<b>Cambodia</b>	<b>Cameroon</b>	<b>Côte d’Ivoire</b>
<b>DRC</b>	<b>Ethiopia</b>	<b>Guyana</b>	<b>Haiti</b>
<b>Kenya</b>	<b>Lesotho</b>	<b>Malawi</b>	<b>Mozambique</b>
<b>Namibia</b>	<b>Nigeria</b>	<b>Rwanda</b>	<b>South Africa</b>
<b>Swaziland</b>	<b>Tanzania</b>	<b>Uganda</b>	<b>Vietnam</b>
<b>Zambia</b>	<b>Zimbabwe</b>		

## **ACRONYMS**

**AIDS – Acquired Immune Deficiency Syndrome**  
**CDC – Centers for Disease Control and Prevention**  
**COP – Country Operational Plan**  
**CQI – Continuous Quality Improvement**  
**CSTL – Country Support Team Lead**  
**EQA – External Quality Assurance**  
**FY – Fiscal Year**  
**GAO – Government Accountability Office**  
**GFATM – Global Fund for AIDS, Tuberculosis, and Malaria**  
**HIV – Human Immunodeficiency Virus**  
**HQ – Headquarters**  
**HRH – Human Resources for Health**  
**HSS – Health Systems Strengthening**  
**IOM – The Institute of Medicine**  
**IQA – Internal Quality Assurance**  
**KP – Key Populations**  
**LTS – Long Term Strategy**  
**MAT – Medication-Assisted Treatment**  
**M&E – Monitoring and Evaluation**  
**MER – Monitoring, Evaluation and Reporting**  
**MOH – Ministry of Health**  
**NGO – Non-Governmental Organization**  
**OGAC – Office of the US Global AIDS Coordinator**  
**PEPFAR – The US President’s Emergency Plan for AIDS Relief**  
**PF/PFIP – Partnership Framework/Partnership Framework Implementation Plans**  
**PHDP – Positive Health, Dignity and Prevention**  
**PLHIV – People Living with HIV**  
**PMTCT – Prevention of Mother to Child Transmission**  
**PQS – PEPFAR Quality Strategy**  
**QA – Quality Assurance**  
**QI – Quality Improvement**  
**QM – Quality Management**  
**SCMS – Supply Chain Management System**  
**STI – Sexually Transmitted Infections**  
**TA – Targeted Assistance**  
**TB/HIV – Tuberculosis/HIV**  
**TC – Technical Collaboration**  
**TQM – Total Quality Management**  
**UNICEF – United Nations Children’s Fund**  
**USG – US Government**  
**VMMC – Voluntary Medical Male Circumcision**  
**WHO – World Health Organization**

## INTRODUCTION

Since 2003, PEPFAR, in partnership with host country governments, has achieved unprecedented success in supporting HIV programs that have provided life-saving care and treatment to millions, as well as prevented millions of new infections through HIV prevention services. Continuing these efforts, and in consideration of the evaluations of PEPFAR from both the Government Accountability Office (GAO)<sup>1</sup> and the Institute of Medicine (IOM),<sup>2</sup> PEPFAR is committed to institutionalizing countries' ability to improve HIV programs that will lead to sustained reductions in morbidity, mortality, and transmission of HIV.

This commitment requires attention to the quality of HIV programs, in which PEPFAR continues to invest in partnership with host country governments. Quality is addressing the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.<sup>3</sup> More concretely, "Quality care is what happens at all the points of service along the continuum of care, and high quality care is a function of the system's ability to produce care that will address the client's needs in an effective, responsive and respectful manner..." (David Nicholas).

*Quality is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.*

Improving quality in health care is achieved by:

- Implementing interventions according to established standards that ensure programs are effective and outcomes are achieved
- Collecting and using reliable data to understand the level of service quality, identify problems, and make improvements
- Evaluating programs for outcomes and impact

The end of the AIDS epidemic is within reach if governments, donors, and civil society attain and maintain high-quality national HIV programs.

<sup>1</sup> U.S. Government Accountability Office. *President's Emergency Plan for AIDS Relief: Millions Being Treated, but Better Information Management Needed to Further Improve and Expand Treatment*. 2013. <http://www.gao.gov/products/GAO-13-688>

<sup>2</sup> Institute of Medicine. *Evaluation of PEPFAR*. 2013. <http://iom.edu/Reports/2013/Evaluation-of-PEPFAR.aspx>

<sup>3</sup> National Research Council. *Medicare: A Strategy for Quality Assurance, Volume II: Sources and Methods*. Washington, DC: National Academies, 1990. 20.

## PURPOSE

**The central purpose of the PEPFAR Quality Strategy (PQS) is to support building and institutionalizing host country capacity to monitor and continually improve the quality of HIV programs.** This institutionalization includes building the capacity of country health systems to improve the processes that they use to implement HIV services. The PQS requires country teams to plan and monitor development of the health system's capacity to manage, monitor, and improve the process of care, with the eventual goal of achieving this without external support. Providing more resources may be necessary to have effective HIV services in resource-constrained settings, but this approach alone fails to address the root of many problems within health care systems.

Successfully meeting the improvement challenge is an opportunity to leverage the expertise, motivation, and work of all staff in clinical and community settings to strengthen systems, improve the patient and provider experience, and save lives through improving the outcomes of people living with and affected by HIV.

## PROGRAM AREAS COVERED

The first phase of the PQS, outlined in this document, provides a general framework for U.S. Government (USG) field teams to consider for assessment and improvement of national HIV clinical program planning, implementation, and oversight. This first phase of the broader PQS addresses clinical program areas from the continuum of care, including facility and community service delivery points.

In FY 2014, these program areas are:

- HIV Testing and Counseling
- Adult and Pediatric Care, Support, and Treatment
- TB/HIV
- PMTCT
- Food and Nutrition
- VMMC

Associated crosscutting areas supporting HIV clinical services include:

- Laboratory for HIV clinical services
- Strategic information for HIV clinical services, including monitoring, evaluation, and reporting, surveillance, and health information systems
- Health Systems Strengthening (HSS), including Human Resources for Health (HRH)
- Supply Chain Management System (SCMS)

- Positive Health, Dignity and Prevention (PHDP)
- Key Populations (KP)
- Gender

Future phases of the strategy will encompass areas beyond clinical services and will build on the lessons learned from the implementation of this first phase.

The operationalization of this strategy is about progressing to the next phase of a maturing partnership with host countries and provides the opportunity to institutionalize these practices within host country health systems. This strategy does not supplant ongoing program specific assurance and improvement activities, which support the shared responsibility for the HIV response between PEPFAR, its implementing agencies, partners and host governments.

## GOAL & AIMS

In alignment with the Vision Statement and four roadmaps of the *PEPFAR Blueprint for an AIDS-Free Generation*, the Goal of the PQS reflects a shared global responsibility to achieve future generations living without AIDS. Through smart investments, based on sound principles of quality and country-led responses, PEPFAR will partner with countries to achieve better health and longer lives for People Living with HIV (PLHIV).

### Long-Term Goal of PQS:

*To institutionalize countries’ ability to continually improve HIV programs, which will sustain reductions in morbidity, mortality, and transmission of HIV towards achieving an AIDS-free generation.*

**Table 2. The Four Roadmaps that Guide the PEPFAR Blueprint**

<b>1. Saving Lives</b>	<b>2. Smart Investments</b>	<b>3. Shared Responsibility</b>	<b>4. Driving Results with Science</b>
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The four PQS Aims offer a practical and common reference for improvement approaches that can be applied across different country and epidemiological settings. They are designed to guide dialogue between PEPFAR, host country governments and partner organizations about how to collectively ensure the quality of clinical services as they are scaled up in the target countries. The PQS presents four categories of aims for the health care systems in partner countries that map directly to the Blueprint.

### **Aim 1: Improving Health Outcomes & Saving Lives**

- Improve health outcomes by improving the quality of HIV diagnosis, care, treatment, MAT, STI, VMMC, and other services, as they are scaled-up in high-burden countries through testing, learning and adapting local ideas and approaches.
- Increase acceptability and accessibility of services that promote linkage, engagement, retention, adherence, and virologic suppression through interventions that address relevant social and environmental determinants of health and health care-seeking behavior.
- Address patient safety, treatment as prevention and prevention with positives, including retention in care and adherence to medication, to avoid drug resistance.
- Ensure engagement of hard-to-reach populations, including key populations, rural communities and children, in the health system.
- Enable clinical team collaboration and identification of optimal skill mix for efficient and effective high quality care.

**Aim 2: Smart Investments for Sustainability**

- Increase efficiencies through innovations in service delivery and rapid cycles of improvement of HIV clinical care that are reproducible and scalable with national health systems.
- Make quality care more affordable, with attention to the opportunity costs, and reduce stigma, which may often keep PLHIV away from HIV care.
- Strengthen private sector capacity for delivery of cost effective/user friendly HIV care and treatment services and VMMC for long-term sustainability, particularly in middle income and transition countries.
- Encourage continuous, life-long learning among health professionals, such as through continuous professional development programs required for credentialing and improvement of HIV programs.

**Aim 3: Make Improvements Happen through Shared Responsibility**

- Strengthen the capacity of host-country health systems to improve HIV care and treatment services and sustain those improvements over time.
  - Reorient health care leadership priorities to include the continual improvement of health care, involving acquisition and use of new knowledge and skills, potential policy changes, and a system-wide introduction of rewards for achievements of improved outcomes of care as well as optimizing their capacity for organization, administration, and commitment of funds.
  - Empower health care professionals for ownership of health care improvement through building their capacity to allow for critical analysis of existing structure and systems and application of methodologies for making improvements. This empowerment is also likely to involve system-level changes at facility, district, and national levels.

- Facilitate shared learning within and across health systems and countries.
- Make work processes visible to reinforce the shared responsibility to make improvements happen.
- Work with local communities to optimize access, linkage, engagement, retention, and adherence towards HIV virologic suppression.
  - Ensure effective communication and coordination within care systems.
  - Engage PLHIV and their families as partners to increase disclosure and sustain commitments to HIV care.
  - Empower individuals and families to provide feedback that informs improvement of health care processes.
  - Integrate respect and recognition of the rights of individuals and families within policies, procedures and staff behavior throughout the health care experience.

**Aim 4: Repeatedly Test & Adapt Ideas to Drive Results with Science**

- Support tests of promising innovations and changes that improve care for patients navigating the stages of HIV diagnosis, care and treatment.
- Use small, rapid tests of change to test the processes of change and facilitate organizational learning.
- Disseminate the gains of systematic improvement efforts and demonstrate their relevance in day-to-day health care work.

**TESTING PROMISING CHANGES IN HEALTH CARE PROCESSES**

Quality improvement (QI) refers to a properly rationalized sequence of steps to implement evidence based care, while quality assurance (QA) refers to the oversight process, including the adherence to standards and guidelines. The PQS commits PEPFAR to move beyond and build upon simply assessing compliance with standards and guidelines to an approach that *tests promising changes in health care processes* with the goal of improving health outcomes and systems performance. The idea behind “rapid” cycles or “small” tests of change is to make these tests adequate for the next decision, but without meeting traditional design requirements for research. This always involves a judgment call, but these are basically management decisions-- e.g., deciding that the idea tested did not work. If the idea did seem to work, the decision is usually to repeat the test on a larger scale.

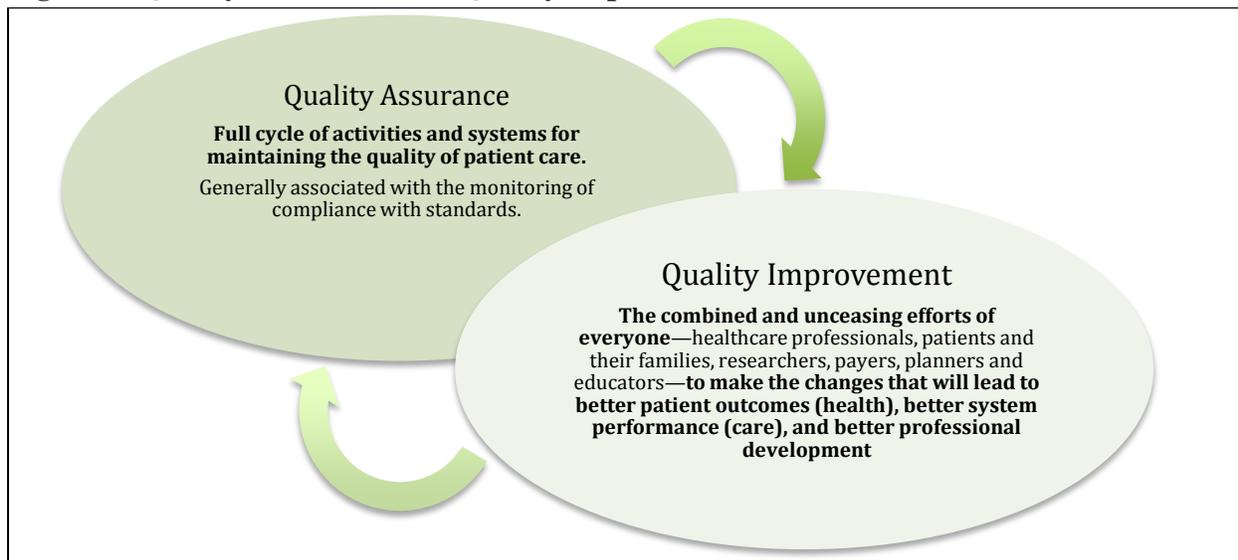
There is a statistical basis for this kind of measurement using a time-series chart, but overall, regular providers, not trained researchers carry out these tests of change. That puts QI at more risk of error than science traditionally tolerates, but QI uses an iterative approach: it keeps testing the process over time until the team concludes that the new process is better than the old one, or that the new process has failed. Further, this testing is done under real world conditions, suitable

for practical applications.

In summary, the concept behind “rapid” is to invest just enough in the testing process to be reasonably confident that the change should be tested on a larger scale, or discarded. QI does not, and should not, try to duplicate the rigorous methodologies of hypothesis testing used by researchers. What QI can do is efficiently test a number of promising changes at an extremely low cost. Due to resource constraints, it will never be feasible to address all of these issues with formal research; however, a less rigorous, but nevertheless evidence-based approach to improving health care processes, is more feasible. Research can complement QI, but the two are distinct approaches.<sup>4</sup>

## QUALITY ASSURANCE AND QUALITY IMPROVEMENT: AN INTEGRATED RELATIONSHIP

Figure 1. Quality Assurance and Quality Improvement<sup>5</sup>



Comprehensive quality programs encompass both QI and QA as distinct but intersecting components, both of which are critical. They are not mutually exclusive terms and neither can be successful without the other. QI activities address the methodology and infrastructure necessary for making improvement shifts and may involve training of leaders and health care workers in the science of improvement and the development of a learning agenda designed to expand knowledge about a wide range of improvement issues. **On a more micro level, QA strategies are more specific and can be deployed to meet the broader QI goal. These may include the planning and evaluation of programs (such as site assessments), compliance with**

<sup>4</sup> For further reading see: Berwick, Donald M. "Developing and Testing Changes in Delivery of Care." *Annals of Internal Medicine* 128.8 (1998): 651-56.

<sup>5</sup> Batalden, Paul B., and Frank Davidoff. "What is "Quality Improvement" and How Can It Transform Healthcare?" *Quality and Safety in Health Care* 16.1 (2007): 2-3.

**guidelines, protocols, and standards, identification of technical country-specific priorities, and assessments of costs and efficiencies gained throughout the process.** QA and QI activities should be monitored throughout with the aim of building an evidence base for quality strategies that can be used to develop sustainable country-wide practices, as well as spread and shared with other countries and partners.

QA methods have been found more likely to be effective if they consider local circumstances, are linked specifically to evidence, are disseminated through active education, and use client-specific reminders<sup>6</sup>. Quality assurance systems generally work better when they are based on strong leadership and senior buy-in and focus on improvement rather than punitive measures.

## CONCEPTUAL FRAMEWORK

To advance the PQS aims, PEPFAR plans to initially focus on seven priorities that reflect the needs of the response to the epidemic. These priorities are based on the six domains of quality<sup>7</sup> described by the Institute for Healthcare Improvement, latest research, input from a broad range of stakeholders, lessons from the USG National Quality Strategy,<sup>8</sup> and global examples.

### Priorities

Consistent with the goal and aims of the PQS and the directions of PEPFAR, efforts need to be institutionalized at every level of the health care system and should harmonize and leverage existing structures and resources. Institutionalizing countries' ability to improve HIV programs will ultimately lead to improved health outcomes through the following priorities:

1. **Compliance** for HIV clinical services with clinical, administrative, and other guidelines, protocols, and standards in support of optimal patient outcomes
2. **Costs and efficiencies** gained through institutionalizing countries' ability to improve HIV programs
3. **Sustainability** of improvement methods
4. **Rapid scaling** of lessons from successful quality improvement initiatives
5. **Institutionalization** of the ability of the host country to improve HIV programs
6. **National capacity** in collecting and using high quality improvement related data
7. **Learning agendas** to support activities specifically designed to expand knowledge about a wide range of improvement issues

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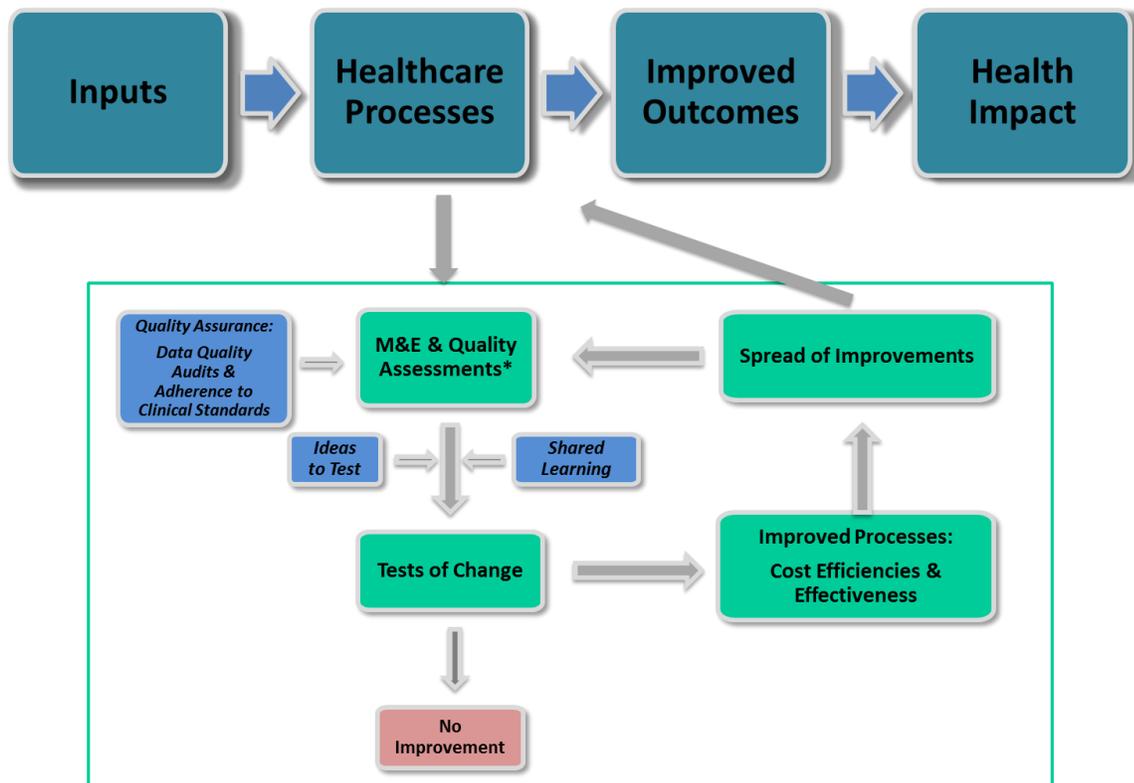
<sup>7</sup> "Care should be safe, effective, patient-centered, timely, efficient and equitable." Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, D.C.: National Academy, 2001.

<sup>8</sup> United States Department of Health and Human Services. *National Quality Strategy for the Affordable Care Act*. 2011. <http://www.ahrq.gov/workingforquality/>

*Over time, the PQS will help to ensure that all individuals with HIV consistently receive the right care, at the right time, in the right setting.*

## SCIENCE OF IMPROVEMENT

Figure 2. Improvement Conceptual Model



\*Quality Assessments are more detailed evaluations of healthcare processes than M&E (i.e. flow charting).

The PQS recognizes and seeks to address the reality that delivering HIV clinical services is complex, and many challenges may continue to arise. PEPFAR must support a legacy of country programs that consistently deliver these services well by institutionalizing continuous quality improvement capacity. The US health system is a globally recognized leader in the field of health care improvement, and it has been found that the approaches used in the US can be adapted to resource-limited settings.<sup>9</sup> Where performance is low, these approaches can produce striking improvements with modest investments.

<sup>9</sup> Franco, L.M., and L Marquez. "Effectiveness of collaborative improvement: evidence from 27 applications in 12 less-developed and middle-income countries." *BMJ Qual Saf* 20 (2011): 658-665

The PEPFAR Quality Strategy seeks to introduce these modern improvement techniques into country health systems in a way that follows these basic principles:<sup>10</sup>

- **Improving health processes is a collective mandate and responsibility, involving everyone from individual patients to health systems.** PEPFAR's support aims to build operating design and develop the capacity for improvement within the health system, resulting in host country providers and managers making improvement an integral part of delivering HIV services and continuing to improve care without external assistance.
- **All improvement efforts are based on evidence.** Teams of providers and managers define an appropriate quantitative indicator to measure if a process has been improved.
- **Complementary and integral to improvement is quality assurance, which includes the degree to which providers follow written clinical guidelines for common conditions.** Such guidelines summarize what medical science tells us should be done, and most countries have adopted guidelines for the services PEPFAR supports. **But there is more to HIV care than administrative tasks—managing supplies, records, and human resources—that are usually standardized with the intent of realizing continual reliable execution.**
- Whether or not there is a resource-constrained environment for HIV care, the **productivity and efficiency of health care processes need attention.** Patients' access to services, patient-centered delivery of care, and community level services are each central issues for retention in HIV care and treatment which require improvement.
- The overall number of health care processes that are candidates for improvement is large. Fortunately, experience to date indicates that the knowledge generated by **quality improvement in one location is broadly applicable and can facilitate improvement in other facilities, other regions, and even other countries.** If this knowledge is captured and shared, improvement efforts across PEPFAR could become increasingly efficient and contribute to the development of learning agendas.<sup>11</sup>

The PQS envisions an approach that builds on traditional top-down management strategies, emphasizing bottom-up and shared improvement strategies. Modern information technology makes it feasible to share the knowledge from improvement activities on a large scale. PEPFAR leadership and financial support at headquarters and in country will be needed to initiate a functional knowledge management system to do this, with an emphasis on *how* improvement interventions were carried out.

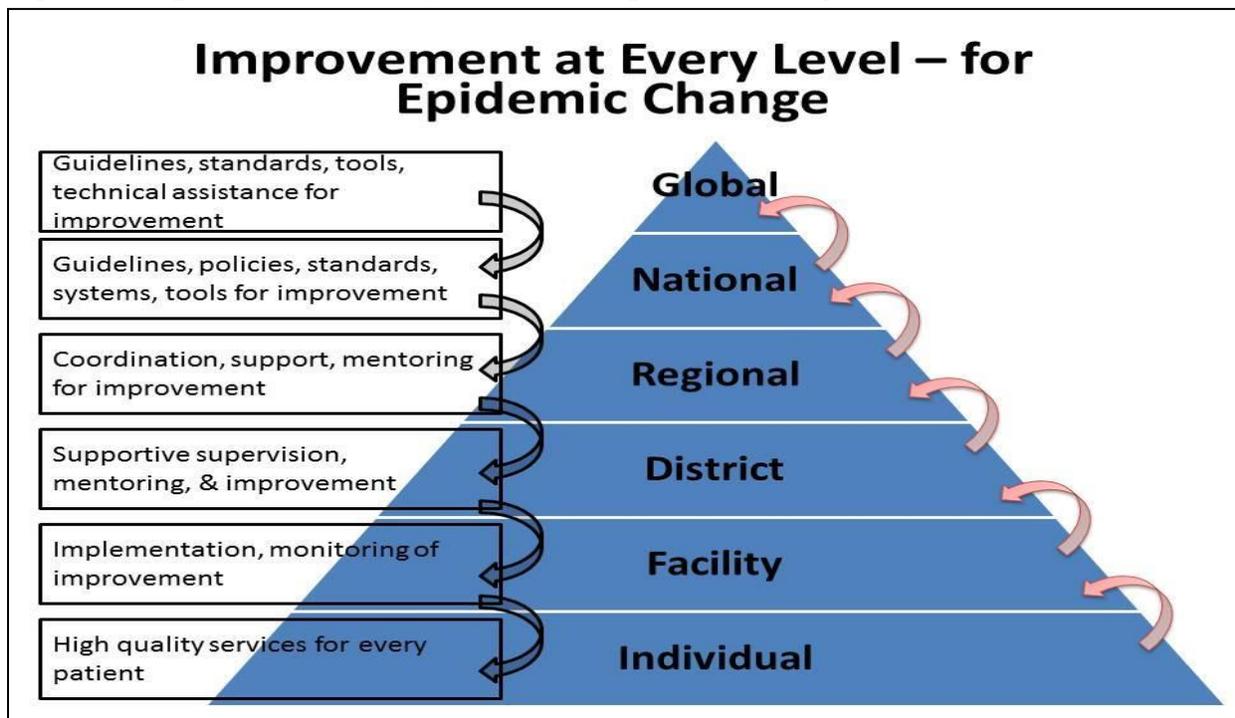
While experience with applying modern process improvement approaches is extensive and encouraging, the PQS recognizes the need for increased investments in refining this field. In particular, improvement initiatives require descriptive research and process evaluations as the

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<sup>10</sup> Leatherman, S., T. G. Ferris, D. Berwick, F. Omaswa, and N. Crisp. "The Role of Quality Improvement in Strengthening Health Systems in Developing Countries." *International Journal for Quality in Health Care* 22.4 (2010): 237-43.

basis for accelerated learning. The learning agenda includes priorities such as the design of programs to scale up documented improvements, studies of the factors in successful institutionalization of improvement, and demonstration of the cost-effectiveness of approaches. A major challenge in the study of improvement interventions is to take advantage of the learning potential of interventions that did not produce the desired results. Success in this area requires that a culture of blame be avoided.

**Figure 3. Improvement at Every Level – for Epidemic Change**



HIV programs must be implemented with quality at all levels (down the left of Figure 3) in order to achieve epidemic change in populations (up the right of Figure 3). Quality in HIV programs means that support, care, and services adhere to accepted standards, are assessed and evaluated against those standards, are continuously improved, and result in desired, measurable outcomes and impact.

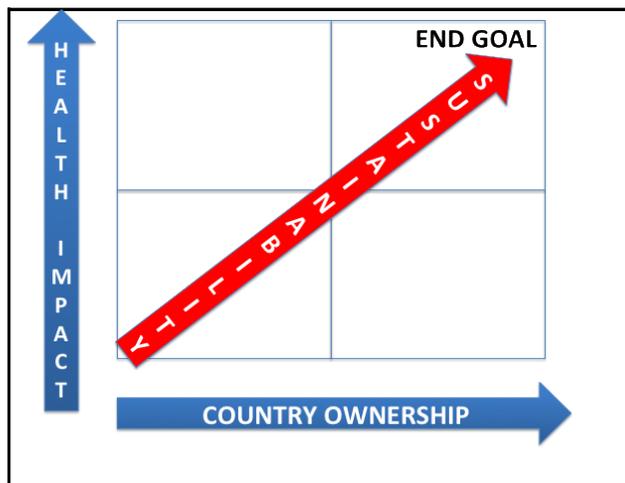
Quality improvement must be a continuous process of program assessment, evaluation, and improvement with interdependent responsibilities at each level of the health system. Individual level HIV health outcomes (e.g. viral load reduction) roll up to population level epidemic change (e.g. incidence reduction). Epidemic change (i.e. population level incidence reduction) can only be achieved if services and programs achieve quality at every level. If quality is not implemented well at every level, achieving quality outcomes for each patient or epidemic change in populations remains unattainable.

## FRAMEWORK FOR ACTION

As with all PEPFAR efforts, to achieve durable and effective national HIV/AIDS responses, the PQS will support high-impact efforts that are country-owned—that is, owned by government, civil society, the private sector, and other stakeholders in the partner country.

**Figure 4. Sustainability Plan Goal**<sup>12</sup>

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Approaches will differ based on where countries lie on a spectrum of country ownership and the depth of existing attention to HIV or other health sector quality improvement. The PQS encourages PEPFAR teams to engage in existing national quality improvement processes as they can be leveraged in efforts to improve the quality of HIV services.

*The PQS encourages PEPFAR teams to engage in national quality improvement processes where they are already being undertaken, as they can be leveraged in efforts to improve the quality of HIV services.*

While the starting point for developing a comprehensive plan for quality improvement will differ depending on the context, all PEPFAR teams in consultation with Ministries and other partners should consider creating the following:

- A strategic plan with accompanying operationalization plans to support quality improvement that is minimally applicable to include attention to HIV services
- A policy and legal framework that is supportive of quality improvement and is sensitive to cultural or other potential barriers

<sup>12</sup> PEPFAR. *Sustainability Planning Guidance Document*, 2013.  
<http://www.pepfar.gov/documents/organization/217767.pdf>

- Fiscal and operational frameworks to implement and monitor quality improvement operating plan

**This framework for action is not meant to be prescriptive, and countries will operationalize the PEPFAR Quality Strategy in different ways based on their context.** It is critical that countries develop their own plans and implement their own improvement interventions. To achieve robust, sustainable, and country-owned quality improvement efforts, PEPFAR operating units are encouraged to consider the following framework for action.

PEPFAR will be conducting a workshop in June 2014 to assist countries in the operationalization of the PEPFAR Quality Strategy. This workshop may include a subset of the 22 countries required to operationalize the PQS. PEPFAR HQ and members of PEPFAR country teams with mature QI infrastructure are also available to provide technical assistance, and TWGs across technical areas at Headquarters are working to ensure coordinated messages and recommendations aligned with the PQS.

### **Years 1-5: PEPFAR Structures for Success**

#### **PEPFAR Headquarters and Country Teams**

Organizational structure plays a key role in organizational performance. PEPFAR Agencies at both headquarters and in the field have variable organizational structures, which may or may not be well aligned to support quality improvement coordination. PEPFAR Agencies at HQ and in the field are encouraged to evaluate their team structures and complement of skills to identify how they will support quality improvement coordination within their own agencies and between PEPFAR agencies. The USG staff responsible for the technical areas covered under this strategy is typically spread across multiple technical teams (e.g. HIV Prevention, Care & Treatment, and Health Systems Strengthening). If, for example, a QI activity is meant to improve linkages from HTC to HIV care and treatment, HTC advisors from prevention teams would need to work closely with their HIV care and treatment counterparts to ensure successful implementation. Effective design and oversight of QI activities that cut across technical areas may require reconfiguration of teams, consolidation of management and supervision structures, and staff evaluations that incorporate the degree of collaboration between teams working on QI initiatives.

PEPFAR Agencies at both headquarters and in the field have contractual, cooperative and grant-based relationships with governments and partner organizations (e.g. task orders and indefinite quantity contracts, cooperative agreements, grants, etc.). Such a contract vehicle has narrowly specified activities and reporting requirements, and it may pose unintentional barriers to testing new activities and changing course based on the results of those tests. Agencies are encouraged to work with partners to ensure that their work plans are structured to enable iterative tests of

change and resulting shifts and implementation activities, and to review contract and agreement language with contracting officers to ensure that it is supportive and enabling of quality improvement activities. Agencies are further encouraged to work with contracting officers to ensure that contract and agreement language is supportive of any programmatic changes that might occur as a result of quality improvement activities.

PEPFAR Agencies should also review federal regulations applicable to their operations (e.g. HHS protection of human subjects in research regulations, 45 CFR part 46) to clarify whether or not proposed quality improvement activities will be considered nonexempt human subjects research. This will not only be especially relevant for projects that introduce interventions for the purpose of improving the quality of care, but also for collecting information about patient outcomes for establishing scientific evidence to determine how well the intervention achieves its intended results.<sup>13</sup>

## **Years 1-5: HQ Support for the PQS Implementation**

### **PQS Task Force**

The PQS Task Force will:

- Expand participation on the Task Force to include representation from PEPFAR country teams. Currently, the participants include HQ representatives from CDC, DOD, HRSA, and USAID.
- Continue participation in global, evidence-based consultative processes, including those spearheaded by normative agencies such as the World Health Organization. Additionally, collaborate with organizations such as the Global Fund to Fight AIDS, TB and Malaria towards common commitments through strategic planning for improvement. Such efforts will continue to build on international standards and definitions for quality assurance and quality improvement and apply them to improve health outcomes.
- Provide support to the PEPFAR Country Teams which request assistance in the design of their comprehensive situational analyses or to support their engagement with Ministries of Health related to this Strategy. PEPFAR will inform this support and additionally facilitate cross-country country learning using its own experiences in QI.
- Provide a repository, most likely on PEPFAR.net, of key journal articles and global policy documents, and where possible, country documents to help PEPFAR Country Teams and in-country stakeholders ground their quality improvement efforts in the best evidence.
- Support dissemination of global guidance related to quality improvement, consultative, multi-stakeholder international process led by the World Health Organization.

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<sup>13</sup> United States Department of Health and Human Services. “Quality Improvement Activities – FAQs.” <http://answers.hhs.gov/ohrp/categories/1569>

- Provide continued virtual and in-person technical assistance to PEPFAR Country Teams.
- Assemble resources, guidelines and examples, and may develop those into a more formal guidance for PEPFAR Country Teams.

## **Year 1-2: Build the Framework and Evidence-base**

### **PEPFAR Country Teams**

#### ***Set the Stage***

The development of a National Quality Improvement Framework and/or Operating Plan should be informed by lessons from a comprehensive evaluation of the quality of care and an analysis of existing quality improvement structures and activities, including among implementing partners, in alignment with national health policy. Key stakeholders for the Strategy may include Program managers, public and private sector health providers, policy makers, implementing partners, community-based organizations, health consumers, and others.

Operationalizing the PQS in countries will require multiple steps, ideally beginning with a desk analysis, reviewing literature and documents to frame quality improvement issues relevant to the country through a global and a national lens. PEPFAR country teams are encouraged to support a review of journals, existing health sector operating plans, technical efforts and reports, WHO and other documents.

#### ***Build Consultative, Multi-stakeholder Processes and Structures***

Country teams should support the Ministry of Health to initiate a consultation of key stakeholders working in quality improvement and assurance across the health sector as well as those working throughout the HIV cascade of care. Teams should also assist the Ministry of Health in identifying reliable operating structures and clarifying the various roles and responsibilities and reporting lines of communication within and among the different key stakeholders.

Consistent with the Sustainability Planning Guidance, efforts to improve the quality of HIV clinical services through this Strategy are best embedded within or integrated with existing infrastructure; the PQS affirms this approach.

Countries should also develop plans to engage a representative cross-section of stakeholders in policy and program development, including national and local governmental leadership, civil society, health consumers, PLHIV, private sector, academia, local and international partners supporting implementation, local WHO staff, PEPFAR, and other bilateral and multilateral agencies (including GFATM) working on related issues in country. These plans should include ways of engaging stakeholders who are harder to reach or seldom heard, with particular attention

to representation from the voluntary, civil society, and NGO sectors. Careful attention to ensuring a participatory and transparent process is critical. Additional consultation will be needed to raise public awareness and share information in ways that are accessible to PLHIV.

Other ministries should be brought in to the discussion as appropriate (e.g. Ministry of Finance, Ministry of Women, Children and Social Development). Based on their local contexts, PEPFAR teams should determine how best they could collaborate with their Ministries to institutionalize the country's ability to improve.

USG and Government oversight structures and personnel need to be grounded in QI. Individuals in these roles who do not truly understand QI could do real harm, particularly at sites, by being heavy-handed with feedback in relation to the efforts of QI teams. In addition to being supportive and assuring that tools and resources such as training and data management capacity are available, these individuals can also evaluate documentation of QI activities and be a conduit for sharing lessons learned between and among sites.

### ***Establish Baselines***

Assignment of responsibility for conducting the situational or baseline assessment will also include the nomination of initial members for a Steering Committee or the identification of an existing body that can serve as a Steering Committee. This committee will provide high-level oversight for the national implementation of a National Quality Improvement Strategy and will be the body to which key stakeholders will report on assessment, design, and implementation efforts. The Steering Committee will build upon existing National HIV Strategies, and at a future date, develop Action Plans to identify definitions and standards for the government's effort to improve the quality of HIV services.

Countries should conduct a comprehensive situational analysis, which will help to refine a picture of the context and build both a quantitative and qualitative baseline against which the impact of implementation efforts can be later measured. This evaluation must include both clinical quality and the quality of administrative processes such as human resources management, information systems and drug supply. It should also include an analysis of the policy context, identifying any policy-related barriers or facilitators and coordination mechanisms that could be addressed or strengthened through the strategic planning process. The consultative, multi-stakeholder process, led by the Ministry of Health, will assist with the identification and definition of boundaries to be included in the situational analysis. Headquarters will be available to provide TA to countries as they conduct their analyses.

The comprehensive situational analysis will be among the first steps of the Quality Improvement Strategy Planning Cycle and will help to identify the policy and regulatory barriers, opportunities, and trends. It will also address the pressures being exerted on PLHIV, both within

their local communities and within the health system, that affect the individual or family's decision to seek care, their ability to access care (e.g. physical and economic), and the health system's ability to provide adequate care. It will also examine and potentially build upon the impact of current solutions. The design of a quality improvement implementation strategy will be contextually informed.

### ***Develop the Plan for Implementation***

Through the consultative process, countries should develop an implementation plan, which will include a framework for initiation of pilot efforts within a targeted geographic area, and/or population, and between related technical areas along the cascade of care. The development of the pilot should include interdisciplinary teams working at the local level and will be informed by the results of the comprehensive situational analysis and the experience of the consultation partners. The pilot design phase should be conducted with an attention to developing an evidence base for potential PEPFAR programs and to opportunities for shared learning between countries. The major recommendation of the PQS is to emphasize incremental quality improvement achievements, which may be effective in yielding sustainable improvements in health care quality of the national or regional level. It is key that, in the process of implementing QI activities, countries engage in an ongoing learning process by diligently documenting activities and continuously self-evaluating through team self-reports and case studies of improvement activities, which will contribute to both the sharing of information between countries and individual country sustainability. Countries that already have a plan for implementation may wish to start in years 2 and 3 of this proposed framework.

## **Years 2-3: Continue, Expand, and Learn from Existing and Pilot Efforts**

### **PEPFAR Country Teams**

#### ***Lessons from Previous, On-going and Pilot Efforts and Adaptation for Scale***

Country teams should systematically review the lessons learned from previous and on-going activities as well as any pilot efforts to inform scale-up. This process should include objective, quantitative measures of any improvements achieved by the strategies and efforts under review. Country teams should then disseminate these findings to the Steering Committee and key stakeholders, and should consider sharing them with other countries in support of shared learning. Based on the outcomes and lessons learned from any initial pilot, the consultative team, under the direction of the Steering Committee, should develop a phased plan for national scale-up. The role for the Government, USG and others should be made clear, including actions to prevent behaviors and approaches that are inconsistent with the principles of quality improvement.

## **Years 3-5: Phased Scale-up of Quality Improvement Efforts**

During this phased scale-up, it will be important to ensure that activities are informed through ongoing learning processes, including documentation of QI activities, self-evaluation, case studies of improvement activities, and other strategies that will promote PEPFAR-wide sharing of QI information. Over time, we anticipate a decreasing implementation role for partners as quality improvement becomes institutionalized within country governments and health care structures.

## **PEPFAR Country Teams**

### *Phased Expansion of Quality Improvement*

This phased plan for scale up will include attention to which regions or sites require intense support for their scale-up efforts versus those that require less support.

### **Years 4-5: Evaluate the Impact of the Quality Improvement Efforts**

Plans should include a strong emphasis on evaluation, recognize the improvement that has been accomplished, promote evidence based QI interventions and QI sustainability in the future.

### *Multi-Country Evaluation*

Headquarters should consider undertaking or supporting special studies.

## **SETTING PRIORITIES FOR QUALITY IMPROVEMENT IN COUNTRIES**

### *Fiscal Year 2014 Considerations*

The FY 2014 COP Guidance instructs PEPFAR teams to consider implications of the PQS for HIV clinical care programs, focusing initially on a small number of high priority quality concerns in each program area. (See Appendix E for more detail on FY 2014 COP Guidance requirements). While all countries are encouraged to operationalize this strategy, the following 22 countries are required to.

**Table 1. Countries Required to Operationalize the PQS in FY 2014**

<b>Botswana</b>	<b>Cambodia</b>	<b>Cameroon</b>	<b>Côte d’Ivoire</b>
<b>DRC</b>	<b>Ethiopia</b>	<b>Guyana</b>	<b>Haiti</b>
<b>Kenya</b>	<b>Lesotho</b>	<b>Malawi</b>	<b>Mozambique</b>
<b>Namibia</b>	<b>Nigeria</b>	<b>Rwanda</b>	<b>South Africa</b>
<b>Swaziland</b>	<b>Tanzania</b>	<b>Uganda</b>	<b>Vietnam</b>
<b>Zambia</b>	<b>Zimbabwe</b>		

Overall approaches should include efforts to maintain compliance with local and national standards and establish or promote processes for improving clinical care. Plans should be developed in collaboration with national and local governments and implementing partners and address changes, structures and processes at the site, district, and national levels.

Following rollout of the PQS in FY 2014, country teams may be expected to develop and share documents in addition to budgetary COP planning requirements. These documents would serve as aids in institutionalizing countries' ability to improve HIV programs in order to sustain reductions in morbidity, mortality, and transmission of HIV in their respective countries, as well as across country systems. In the next year, these requests could include documents such as a situational analysis, an action plan, and/or a strategy to implement and scale up the institutionalization of countries' ability to improve HIV programs. In preparation for possible follow-up to Phase 1, in the next year, it is recommended that countries begin to gather necessary information and conduct appropriate planning measures to effectively respond and produce these documents. Information for consideration includes an enumeration of countries' efforts to institutionalize their ability to improve HIV programs in the past and present, noting such variables as who is implementing the work (partners, donors, government), required resources, coverage, identification of leadership and human resources capacity at all levels of government applicable to implementing and sustaining modern improvement methods, and existing national plans and strategies.

## PEPFAR OPERATIONAL CONSIDERATIONS

### **Budget**

#### *Consideration for resources, both financial and human*

Some of the interventions to address quality will not require additional funding, and others could be carried out through leveraging funds; however, many activities will require dedicated and continuing resources. Countries will need to find means to allocate resources within their existing budgets to support improvements for quality; some considerations include allocating a percentage of prevention, clinical services and/or crosscutting budgets or pipeline to quality assurance activities and improvement interventions.

In order to allocate appropriate resources within existing budgets, it is suggested that countries:

- **Utilize data** to determine host country situation: In preparing for the operationalization of the PQS, teams should use various sets of data to inform deliberations and decide priorities. These might include: financial, epidemiological, and programmatic trend analyses; assessments or evaluations of key technical areas; quality mapping; epidemiological and programmatic maps; gender analysis; expenditure or costing studies;

human resources for health (HRH) data (e.g. from an HR information system, HRH strategies and plans); PF/PFIP evaluation findings.

- **Analyze Capacity:** Teams should assess the current investments by PEPFAR with the host country and analyze stakeholders' capacity and transfer responsibilities appropriately for leading QA and QI activities for HIV programs. These program functions include, but are not limited to management, technical oversight, and/or financing of programs or activities. (See Appendix C for suggestions on how to structure this analysis). This should be undertaken in a manner that does not jeopardize the public health approach to the continuum of care for populations. Assessments of risk and factors to mitigate risk are important considerations for PEPFAR teams as PEPFAR advances this policy agenda.
- **Assess US government staffing:** As countries progress and partnerships between the US government and host countries mature, in-country PEPFAR teams will need to review their current staffing and reconsider their staffing requirements and the skill sets needed to operationalize, scale, and sustain QI efforts in-country.

## DATA, RESULTS, AND MONITORING, EVALUATION & REPORTING

PEPFAR programs currently collect data on a wide range of indicators that measure quality of care. Many PEPFAR indicators summarize the outputs and certain outcomes of a number of health care processes. The goal of the PQS is to support efforts to improve the performance of these processes, and in turn, improve results as measured by the corresponding indicator. Site level improvement efforts, if conducted across many sites, can be consolidated at the district or other level and tracked over time. As more process improvements are implemented and scaled up, impact on national level PEPFAR indicators can be expected.

The central data collection challenge of the PQS is documenting and learning from efforts to improve the health care processes involved in addressing HIV. In modern improvement approaches, these efforts consist primarily of tests of change carried out by teams of providers. The results of these tests are measured through one or more quantitative indicators for the desired outcome of the process. For example, a PMTCT program may include steps intended to motivate HIV+ mothers to bring not only their HIV-exposed infant, but also their other children for HIV testing. An indicator for the outcome of those processes might be the percentage of children tested by a certain age. Indicators like this one are important for understanding the results of improvement efforts, but they are not suitable for program-wide monitoring. In order to learn from such efforts, we also need to understand how the improvement teams attempted to improve the indicator. Thus, Country Teams should support reporting that includes both quantitative indicators of process improvement and descriptions of how the teams went about testing changes. These descriptions should be sufficiently detailed to provide guidance to other teams that wish to use a similar approach in a different setting.

**Table 3. Data Collection under the PQS**

Changes in current metrics as proposed through PEPFAR’s <b>forthcoming</b> Monitoring, Evaluation & Reporting (MER) Strategy <b>and Operational Guidance</b>
Indicators for specific processes as part of tests of change
Narrative descriptions of how the teams implemented the tests of change

**Table 4. Components Narrative Descriptions for Test of Change Should Address**

<b>Validation</b> of self-reported data from the teams
<b>Sustainability</b> of improvements
<b>Evidence of institutionalization</b> of QI and country ownership, including information on the role of external technical assistance
<b>Scaling up</b> or spread of improved practices
<b>Considerations</b> related to cost-effectiveness and efficiency in service delivery

This strategy will rely on a program learning approach to set priorities for improvement activities, rather than defining a central improvement agenda. Country Teams will be held accountable for learning how to effectively support improvement activities that are increasingly carried out by host country counterparts. For evaluation-specific requirements for PEPFAR, please refer to the PEPFAR Evaluation Standards of Practice. As the PQS is operationalized across countries, a global M&E framework will be developed in order to monitor progress. As part of this global and national monitoring, metrics monitoring progress towards institutionalization of countries’ ability to continually improve HIV programs will be developed, piloted, and implemented in future years of the strategy.

Of note, it is important to underscore that routine central reporting requirements to PEPFAR for country programs are articulated within the MER. Within the MER there are metrics that monitor overall clinical program quality, QI implementation, and supportive supervision including:

**Table 5. MER Metrics for Quality**

Percent of PEPFAR-supported clinical care sites at which at least 80% of PLHIV received all of the following during the reporting period: 1) clinical assessment (WHO staging) OR CD4 count OR viral load, AND 2) TB screening, AND 3) if eligible, cotrimoxazole
Percentage of adults and children known to be alive and on treatment 12 months after initiation of antiretroviral therapy (Recommended: 6, 24, 36 months)
Proportion of TB basic management units receiving PEPFAR support or TA at which 80% of registered TB cases who are HIV-positive initiate ART
Percentage of PEPFAR-supported sites achieving 90% ARV or ART coverage for HIV+ pregnant and breastfeeding women
Percentage of PEPFAR-supported clinical service sites with quality improvement activities implemented that address clinical HIV program processes or outcomes and have documented process results in the last 6 months
Percentage of Districts Health Offices with documented routine supportive supervision visits to 75% of HIV care and treatment sites supported by the District

**The PQS is not currently requiring a central roll-up of data and narratives collected as part of countries' ongoing tests of change for improvement. However, these data and narratives should be collected and shared within country-programs as part of in-country knowledge management of programs. PEPFAR anticipates developing a broader knowledge management approach at which time there will be a more formalized opportunity to share these lessons across programs and countries.**

### **M&E Framework Considerations for the PQS**

As countries operationalize the PQS with host governments, careful consideration should be given to the M&E of strategy implementation including:

- Joint identification of activities and benchmarks that demonstrate how identified priorities and objectives will be advanced through the PQS.
- Establishment of a plan for monitoring progress towards achieving the PQS's objectives and measuring its impact. This will involve two concepts: measuring progress in movement toward institutionalization of assurance and of countries' ability to improve HIV programs, and measuring impact of HIV programs to ensure continued coverage and quality.
- Involvement of host partner country and how they will be involved in monitoring the implementation of the PQS, including periodic joint reviews (semi-annual or annual) that assess progress toward articulated priorities and objectives and any steps to allow for mid-course corrections, as needed. Indicators reflected in the new PEPFAR MER Strategy should be included in such a framework. Reporting on these indicators will be through the PEPFAR semi-annual and annual reporting process.
- Other considerations for the M&E of the in-country operationalization of the Quality Strategy:
  - What are the overarching goals and objectives?
  - How do you know if they are reached? Timeframe, methods, etc.
  - What are the objectives of the country's quality strategy?
  - Does each objective have output, outcomes associated?
  - How will progress be monitored and evaluated and by whom these key objectives?
  - Who does the monitoring and evaluation?
  - What can/should be routinely monitored? At what level of health system?
  - What is recommended for evaluation? (What are key evaluation questions?)
  - What might be questions needed for research, operational research, etc.
  - What is PEPFAR supporting and therefore tracking for reporting?

## APPENDIX/RESOURCE GUIDE

*PEPFAR will develop a resource guide after the release of the first phase PQS in collaboration with PEPFAR country teams and HQ TWGs and implementing agencies.*

### Appendix A: Examples of QA and QI practices

Note: List is not exhaustive

Quality Assurance Practices	Quality Improvement Practices
Planning and evaluation of programs (e.g. site assessments)	Methodology and infrastructure for making improvement shifts
Identification of country-specific priorities	Changes in day-to-day operations (e.g. hours of operations, improving record-keeping)
Assessments of costs and efficiencies gained throughout QA/QI processes	Integrating patient feedback into quality improvement
Audit of how well providers are meeting accepted guidelines, protocols, and standards (combined with larger QI strategy)	Practices supporting employees' ability to influence the decisions that matter <sup>14</sup>
Clear definition of quality and parameters for assessment	Building of political will at all health systems levels for institutionalization of countries' ability to improve HIV programs
National, regional, or local peer-review methods	Development of a learning agenda
Structured learning and mentoring with a focus on communication, human factors, systematized ways of interacting and improvement science for leaders and health care workers	

<sup>14</sup> McHugh, M., A. Garman, A. McAlearney, P. Song, and M. Harrison. *Using Workforce Practices to Drive Quality Improvement: A Guide for Hospitals*. Chicago: Health Research & Educational Trust, 2010.

## Appendix B: Quality Definitions

TERMS	DEFINITION/ELEMENTS	SOURCE
<b>Quality</b>	The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.	National Research Council. <i>Medicare: A Strategy for Quality Assurance, Volume II: Sources and Methods</i> . Washington, DC: National Academies, 1990. 20.
<b>Quality in health care – 6 dimensions</b>	<ul style="list-style-type: none"> <li>• Safe</li> <li>• Effective</li> <li>• Patient-centered</li> <li>• Timely</li> <li>• Efficient</li> <li>• Equitable</li> </ul>	Institute of Medicine. <i>Crossing the Quality Chasm: A New Health System for the 21st Century</i> . Washington, D.C.: National Academy, 2001. 6.
<b>Quality Assessment (QA)</b>	The measurement of the technical and interpersonal aspects of health care and the outcomes of that care. Assessment is expressly a measurement activity, the first step in quality assurance.	National Research Council. <i>Medicare: A Strategy for Quality Assurance, Volume II: Sources and Methods</i> . Washington, DC: National Academies, 1990. 45.
<b>Quality Assurance (QA)</b>	Full cycle of activities and systems for maintaining the quality of patient care. A “formal and systematic exercise in identifying problems in medical care delivery, designing activities to overcome the problems, and carrying out follow-up monitoring to ensure that no new problems have been introduced and that corrective steps have been effective”. Generally associated with the monitoring of compliance with standards.	National Research Council. <i>Medicare: A Strategy for Quality Assurance, Volume II: Sources and Methods</i> . Washington, DC: National Academies, 1990. 46.
<b>Quality Improvement (QI)</b>	A set of techniques for continuous study and improvement of the processes of delivering health care services and products to meet the needs and expectations of the customers of those services and products.	HRSA. “What is Quality Improvement?” <a href="http://www.hrsa.gov/healthit/toolbox/HealthITAdoptiontoolbox/QualityImprovement/whatisqi.html">http://www.hrsa.gov/healthit/toolbox/HealthITAdoptiontoolbox/QualityImprovement/whatisqi.html</a>
<b>Quality Improvement (QI)</b>	The combined and unceasing efforts of everyone—health care professionals, patients and their families, researchers, payers, planners and educators—to make the changes that will lead to better patient outcomes (health), better system performance (care), and better professional development	Batalden, Paul B., and Frank Davidoff. "What is "Quality Improvement" and How Can It Transform Healthcare?" <i>Quality and Safety in Health Care</i> 16.1 (2007): 2-3.
<b>Internal Quality Assurance (IQA)</b>	Implemented by organizations or systems (i.e. hospitals)	National Research Council. <i>Medicare: A Strategy for Quality Assurance, Volume II: Sources and Methods</i> . Washington, DC: National Academies, 1990. 47.
<b>External Quality Assurance</b>	Typically serve a broader social purpose and clientele (i.e. accrediting bodies)	National Research Council. <i>Medicare: A Strategy for Quality Assurance, Volume II: Sources and Methods</i> . Washington, DC:

<b>(EQA)</b>		National Academies, 1990. 48.
<b>Continuous Quality Improvement (CQI)</b>	CQI is an approach to quality management that builds upon traditional quality assurance methods by emphasizing the organization and systems. It focuses on the 'process' rather than the individual, recognizes both internal and external 'customers' and promotes the need for objective data to analyze and improve processes.	HRSA. "What is Quality Improvement?" <a href="http://www.hrsa.gov/healthit/toolbox/HealthITAdoptiontoolbox/QualityImprovement/whatisqi.html">http://www.hrsa.gov/healthit/toolbox/HealthITAdoptiontoolbox/QualityImprovement/whatisqi.html</a>
<b>Total Quality Management (TQM)</b>	A set of management practices throughout the organization, geared to ensure the organization consistently meets or exceeds customer requirements.	HRSA. "What is Quality Improvement?" <a href="http://www.hrsa.gov/healthit/toolbox/HealthITAdoptiontoolbox/QualityImprovement/whatisqi.html">http://www.hrsa.gov/healthit/toolbox/HealthITAdoptiontoolbox/QualityImprovement/whatisqi.html</a>

## Appendix C: Organizational and Technical Domains

Organizational Domains	Technical Domains
Governance/Leadership	Clinical HIV service delivery
Strategic planning & execution	Routine supervision of HIV services
Human resource management	Training (clinical and other in-service) for HIV program/service delivery
Performance measurement, analysis and quality improvement systems	Clinical mentoring
External relationships, networks, and partnerships	Laboratory services
Financial management	Infrastructure rehabilitation
Ability to apply for and manage US government and other donor grants	Supply chain support/management
Strategic resource mobilization (other than US government)	Community and patient services
	Monitoring and evaluation
	Technical assistance to MOH on policy, procedures, and guidelines

## **Appendix D: Accreditation, Site Monitoring & Supportive Supervision**

**Accreditation** is a related, but distinct approach from quality assurance and quality improvement in which an external body evaluates a facility periodically, using a detailed set of standards. While a 2011 systematic review suggests that hospital accreditation programs, including those in South Africa and Zambia, may improve compliance with accreditation standards, the evidence of its impact on quality measures is inconsistent.<sup>15</sup> These standards are designed for evaluation during a brief visit. In addition to providing feedback, this method provides the incentive of accreditation, widely recognized as a noteworthy achievement for the facility. Accreditation is foundational to laboratory programs in PEPFAR.

### ***Site Monitoring and Supportive Supervision***

PEPFAR implementing agencies and partners may use site monitoring and supportive supervision to provide for more direct observation of care, as well as an opportunity for constructive feedback. These approaches also provide an opportunity to provide feedback to providers regarding their performance and how it could be improved.

USG and Government oversight structures and personnel need to be grounded in QI. Individuals in these roles who do not truly understand quality improvement could do real harm, particularly at sites, by being heavy-handed with feedback in relation to the efforts of QI teams. In addition to being supportive and assuring that tools and resources such as training and data management capacity are available, these individuals can also evaluate documentation of QI activities and be a conduit for sharing lessons learned between and among sites.

Site level supervision is an integral part of ensuring quality of patient services from both a clinical and data quality perspective. In a resource-constrained setting in which clinics may primarily be staffed by health workers in isolated settings, such supervision is especially important. By improving and focusing on supportive facility supervision, gaps in quality of clinical care, data quality, and infrastructure can be continuously addressed, and facility staff are empowered and trained to address deficiencies themselves.

The PEPFAR Quality Strategy recommends that all USG teams work in concert with Ministries of Health to strengthen or develop and implement standards-based HIV clinical program supervisory systems using supportive supervisory approaches which are based on country-specific needs and focus on helping to make things work, rather than checking for errors. Supportive supervision differs from traditional supervision in a number of ways.

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<sup>15</sup> Alkhenizan, Abdullah, and Charles Shaw. "Impact of Accreditation on the Quality of Healthcare Services: A Systematic Review of the Literature." *Ann Saudi Med* 31 (2011): 407-16.

## Comparison of Traditional and Supportive Supervision<sup>16</sup>

	Traditional Supervision	Supportive Supervision
Who performs supervision	External supervisors designated by the service delivery organization	External supervisors designated by the service delivery organization, staff from other facilities, colleagues from the same facility (internal supervision), community health committees, staff themselves through self-assessment
When supervision happens	During periodic visits by external supervisors	Continuously: during routine work, team meetings, and visits by external supervisors
What happens during supervision encounters	Inspection of facility, review of records and supplies, supervisor makes most of the decisions, reactive problem-solving by supervisor, little feedback or discussion of supervisor observations	Observation of performance and comparison to standards; provision of corrective and supportive feedback on performance, discussion with clients; provision of technical updates or guidelines; on-site training; use of data and client input to identify opportunities for improvement; joint problem-solving; follow-up on previously identified problems
What happens after supervision encounters	No or irregular follow-up	Actions and decisions recorded, ongoing monitoring of weak areas and improvements, follow-up on prior visits and problems

Rather than being imposed from above, supportive supervision directly involves the staff of the health care facility (in addition to external or internal supervisors) in program design and implementation. Supportive supervision also focuses on meeting staff needs for management support, logistics, training, and continuing education.

A recent Cochrane review<sup>17</sup> concluded that feedback from site monitoring and supportive supervision “generally leads to small but potentially important improvements in professional practice.” A review of the evidence found limited impact of supervision on program

<sup>16</sup> Marquez, Lani, and Linda Kean. “Making supervision supportive and sustainable: new approaches to old problems.” *MAQ* 4 (2002).

<sup>17</sup> Ivers, N, et al. “Audit and feedback: effects on professional practice and healthcare outcomes.” *Cochrane Database Syst Rev* (2012).

improvement, especially as a stand-alone method of quality assurance.<sup>18</sup> PEPFAR agencies and partners implementing supervisory and site monitoring systems should not rely only on supportive supervision interventions to improve quality, but are encouraged to prepare evaluations to assess the impact of such systems as part of a learning agenda.

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<sup>18</sup> Bosch-Capplanch, X., and P Garner. "Primary health care supervision in developing countries." *Trop Med International Health* 13 (2008): 369-383.

## Appendix E: FY 2014 COP Guidance Quality Requirements

Below are the specific requirements for quality that are in the FY 2014 COP Guidance.

### Section 9

COP submissions should include the current or planned PEPFAR country approach for HIV clinical services to:

- Implement quality assurance activities
- Assess costs and efficiencies gained through improvement practices
- Foster sustainability of improvement methods
- Scale and increase coverage of improvement activities
- Institutionalize improvement practices in the host country
- Strengthen national capacity in collecting and using high quality improvement related data
- Develop a learning agenda

### Treatment TAN

Does PEPFAR support the following activities?

- National plans to ensure and measure quality for clinical services as governments and local partners take on increasing financial and clinical management of the HIV response?
- National framework for support and supervision of ART programs under the umbrella of the national HIV and/or health quality strategy?
- Harmonized quality management (QM) and quality improvement (QI) activities among country teams and implementing partners, which are in alignment with national, Ministry-led, quality plans and initiatives?
- Performance measurement data used for quality improvement at the site level?
- Standardized, periodic supportive site supervision and regular program reviews as an integral part of U.S. government-supported ART programs?
- Geographic alignment processes to focus service provision in areas with highest concentration of HIV transmission, prevalence, and numbers of people in need of services?
- Efficient and effective algorithms for treatment failure monitoring?
- Surveys for HIV drug resistance?
- National pharmacovigilance systems?

### Care TAN

In the Care TAN, please address the following:

- Based on the principles and approaches outlined in the PQS, how will PEPFAR programs, in collaboration with national and local governments and implementing partners, address quality in clinical care programs? Please describe your overall

approach, and specific areas of focus related to priority quality issues in each program area, addressing both quality assurance and quality improvement.

- What is the national plan to ensure and measure quality for clinical services, particularly in reference to clinical care programs? How will PEPFAR support further development and implementation of the national plan?
- What efforts are planned or underway in terms of standardized, periodic supportive site supervision and regular program reviews for PEPFAR-supported clinical care programs?
- What efforts are underway to harmonize quality management and quality improvement activities for clinical care with implementing partners and to align and institutionalize activities in accord with national, Ministry-led quality plans?