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TECHNICAL REPORT

Feasibility of Proposed Quality Criteria for Monitoring and Improving HIV Services

SEPTEMBER 2011

This report was prepared by University Research Co., LLC (URC) for review by the United States Agency for International Development (USAID) and authored by Rhea Bright and Amy Stern of URC. The field test of HIV service quality criteria was funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and carried out under the USAID Health Care Improvement Project, which is made possible by the generous support of the American people through USAID.

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DISCLAIMER

The views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

Acknowledgements: Thank you to the five countries' data collection teams for their commitment, expertise, and hard work. We especially thank the team leaders for coordinating the field test logistics and for translating the data collection tools. We would like to acknowledge the contributions of Fazila Shakir, MHS, Quality Improvement Specialist, USAID Health Care Improvement Project (HCI), for designing the data collection tools and participating in the data collection; Suzanne Gaudreault, MD, MS, Senior Quality Improvement Advisor for HIV/AIDS, TB, Malaria and Other Infectious Diseases, HCI, for technical expertise; David Hales, consultant, New York; Annette Reinisch, MD, MPH, Senior Technical Officer Monitoring and Evaluation Support Team, The Global Fund; John Novak, PhD, Senior Monitoring and Evaluation Advisor for USAID, Global Bureau, Office of HIV/AIDS; and James Heiby, MD, Contracting Officer's Technical Representative for the HCI Indefinite Quality Contract, and Medical Officer, Global Health Bureau, USAID/Washington, for continued advice and support.

This study was supported by the American people through the United States Agency for International Development (USAID) and its Health Care Improvement Project (HCI). HCI is managed by University Research Co., LLC (URC), under the terms of Contract Numbers GHN-I-01-07-00003-00 and GHN-I-03-07-00003-00. URC's subcontractors for HCI include EnCompass LLC; Family Health International, Health Research, Inc.; Initiatives Inc.; Institute for Healthcare Improvement; Johns Hopkins University Center for Communication Programs; and Management Systems International. For more information on HCI's work, please visit www.hciproject.org or write hci-info@urc-chs.com.

Recommended Citation: Bright R, Stern A. 2011. Feasibility of Proposed Quality Criteria for Improving HIV Services. Published by the USAID Health Care Improvement Project. Chevy Chase, MD: University Research Co., LLC (URC).

TABLE OF CONTENTS

List of Figures and Tables	i
Abbreviations.....	ii
EXECUTIVE SUMMARY	iii
I. INTRODUCTION.....	1
II. METHODOLOGY.....	4
A. Assessment Design.....	4
B. Sampling.....	5
C. Data Collection	5
D. Analysis.....	5
III. RESULTS.....	6
A. Feasibility of Using QC to Measure the Quality of HIV Services.....	6
B. Key Findings from Rapid Assessment of Quality.....	7
C. Data Availability.....	8
D. Perceived Relevance of Quality Criteria	9
E. Use of Data to Improve Services.....	9
IV. DISCUSSION	10
A. Summary.....	10
B. Areas for Improvement.....	10
C. Areas of Strength.....	11
D. Limitations	12
V. CONCLUSION AND RECOMMENDATIONS.....	13
APPENDICES.....	15
Appendix A: Global Indicators that Were Modified for this Field Test.....	15
Appendix B: Sampling Protocol.....	18
Appendix C: Data Collection	20
Appendix D: Study Objectives	22
Appendix E: New Opioid Substitution Therapy QC and Indicator.....	24
Appendix F: Feasibility of Indicator, By Region	25

List of Figures and Tables

Figure 1: Potential use of quality criteria by health system level.....	1
Figure 2: Determining the feasibility of a quality criterion.....	5
Figure 3: Example of barriers for PMTCT data collection that arise from multiple data sources.....	11
Table 1: Proposed quality criteria, their existing indicators, and sources	2
Table 2: Feasible quality criteria by region and sub-region.....	6
Table 3: Feasibility of tracking PMTCT patients, three African countries	7
Table 4: Modified indicators to promote quality improvement at the facility level.....	15
Table 5: Feasibility of indicator, by region	25

Abbreviations

ART	Antiretroviral therapy
ARV	Antiretroviral
CD4	Human T helper cells expressing CD4 antigen (T helper cell)
HCI	USAID Health Care Improvement Project
HIV	Human immunodeficiency virus
HIV Trt	HIV treatment
HR	Harm reduction
HTC	HIV testing and counseling
IDU	Injecting drug user
M&E	Monitoring and evaluation
MOH	Ministry of Health
NSP	Needle and syringe program
OGAC	Office of the Global AIDS Coordinator
OST	Opioid substitution therapy
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PMTCT	Prevention of mother-to-child transmission of HIV
QC	Quality criterion/criteria
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV and AIDS
UNGASS	United Nations General Assembly Special Session
UNODC	United Nations Office on Drugs and Crime
USAID	United States Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

Amid an abundance of HIV data and a dearth of information on the quality of HIV programs and services, interested stakeholders—the Office of the Global AIDS Coordinator (OGAC), the United States Agency for International Development (USAID) and the Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria (Global Fund)—asked the USAID Health Care Improvement Project (HCI) to develop an approach to yield meaningful information about the quality of HIV services for users at multiple levels of the health system. HCI is managed by the University Research Co., LLC, which has decades of experience showing that information on the quality of health care programs and services, including access and coverage, enables and fosters improvements in those programs and services. This report presents the findings from a field test of the approach in five countries in three world regions: Africa, Eurasia, and Southeast Asia.

The approach proposes 16 quality criteria (QC) that were assessed through 25 existing indicators. For example, QC 3 is *HIV-positive adults and children should be assessed for antiretroviral therapy (ART) eligibility through either clinical staging or CD4 testing*, and its indicators are *Number and percentage of HIV-infected adults and children assessed for ART eligibility through either clinical staging or CD4 testing at 2 months of enrollment* and *Number and percentage of HIV-infected adults and children assessed for ART eligibility through either clinical staging or CD4 testing in the last 6 months*. The indicators were based on measures previously required or recommended by funders and other stakeholders, such as the Global Fund, PEPFAR, and the World Health Organization.

The report's findings point quite clearly to a few areas for improvement at the facility level that would need to be addressed in order for countries to be able to report on the full set of QC. For example, QC 2 posits that HIV-positive clients should be enrolled in care, but many facilities lack data on whether people enroll in care after being diagnosed. Another issue is data around expectant mothers in programs to prevent HIV transmission. Mother/newborn pairs pass through several clinics, and tracking them, especially retrospectively, can be difficult.

Also troublesome is the reports finding that only three facilities out of 35 sites were using the data they collected to improve HIV services. The national level can report on 40–44% more QC than the facility level. Nevertheless, feasibility of reporting on the QC at the facility level can be improved. Facilities were better able to provide data that met indicator requirements (e.g., a numerator and a denominator for indicators requiring a percentage) if the data were facility based. For example, the indicator, *Number and percentage of adults and children who kept scheduled appointments*, calls for data that a facility might be expected to have, whereas a facility would likely not have denominator data for *Percentage of estimated HIV-positive incident TB cases that received treatment for TB and HIV*.

The report offers three recommendations:

1. Increase facilities' ability to use indicator data by requiring denominators that reflect the number of patients who visit a facility;
2. Encourage monthly monitoring and the use of data to make decisions to manage and improve care processes; and
3. Improve the use and reporting of quality criteria data by: (a) supporting countries in using up-to-date, centralized record systems to record patient status, (b) establishing systems to track and ensure attendance, (c) linking different service areas, and (d) supporting countries in building capacity to use their data to make decisions and improve the quality of their services.

I. INTRODUCTION

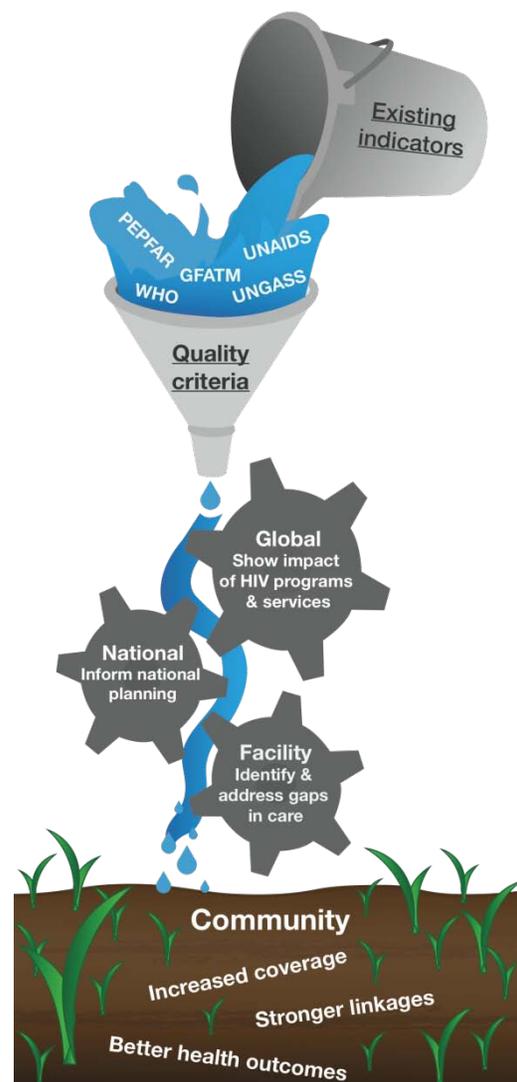
Health care facilities collect and report large amounts of data to fulfill multiple requests from donors and to report to their district/regional and national offices. Donors and technical partners use these data to make funding decisions yet have little meaningful information to assess the quality of the services. Knowledge about HIV program performance is vital for all health system levels (Figure 1). With such knowledge, donors would know the impact of the programs they fund and have greater insight for making funding decisions; a country's national level could better inform national planning and ensure that national HIV reporting requirements enable data analysis and use of data for quality improvement at the point of service; and facilities could use data to routinely identify and address gaps in their HIV services and improve care. Ultimately, improved data usage and information about services will lead to fewer gaps in care, stronger linkages between services, and better health outcomes.

This report presents the findings from field tests that sought to determine whether facilities and the national level in five countries could at least locate—and hopefully also collect, manipulate, and report—data relating to 25 indicators organized under 16 quality criteria. The countries represent three world regions (and three regions of Africa); they are not identified by name here for confidentiality, only by region.

Information about whether and how programs use data to routinely identify and address gaps in their HIV services is essential in identifying lessons learned during program implementation. Such information is also vital for ensuring that HIV reporting requirements enable data analysis and use for quality improvement at the facility level. National reporting to donors and constituents mainly consists of data obtained from national and regional censuses and surveys. Such population-based data are useful in depicting national coverage, but rarely inform facility-level efforts to improve performance. Gaining insight on facility data management processes and about whether and how data are used in facilities is integral to ensuring that program standards of care are being met.

The Global Fund to Fight AIDS, Tuberculosis and Malaria recognizes that national reporting and the collaboration of global-level partners alone will not enable nations to systematically monitor, evaluate, and improve their HIV programs and facility-level services. To build country capacity in this area, the Global Fund requested assistance from the United States Agency for International Development (USAID), Office of HIV/AIDS, and the Office of the Global AIDS Coordinator (OGAC). OGAC identified the USAID Health Care Improvement Project (HCI) to assist the Global Fund in developing an approach that would yield information that could be used to improve HIV services and strengthen country capacity at the national, regional, and facility levels to measure the quality of those services.

Figure 1: Potential use of quality criteria by health system level



This effort resulted in an approach that uses a set of 16 proposed HIV program quality criteria (QC). Global technical partner organizations—such as the Joint United Nations Programme on HIV and AIDS (UNAIDS) and the World Health Organization (WHO)—participated in defining the QC and in identifying existing mechanisms to measure those criteria. The QC relate to five HIV service delivery areas: HIV testing and counseling (HTC); HIV care and treatment (HIV Trt); prevention of mother-to-child transmission (PMTCT); tuberculosis/HIV (TB/HIV); and harm reduction (HR: needle and syringe and opioid substitution programs). Table 1 lists the QC and their corresponding indicators and the organization that served as the source for each indicator. Some QC have more than one indicator; indicators are described below.

Table 1: Proposed quality criteria, their existing indicators, and sources

I. HIV testing and counseling	
Quality Criterion #1:	Clients must know their HIV status after testing
HTC Indicator 1 UNGASS indicator #7	<i>% of women and men aged 15–49 who received an HIV test in the last 12 months and who know their results</i>
HTC Indicator 2 Additional recommended indicator #5	<i>% of sexually active young women and men aged 15–24 who received an HIV test in the last 12 months and know their results</i>
Quality Criterion #2:	Clients testing positive should be enrolled in HIV care
HTC Indicator 3a HCI indicator	<i># and % of people testing HIV-positive</i>
HTC Indicator 3b HCI indicator	<i># and % of people who subsequently enrolled in HIV care</i>
II. HIV care and treatment	
Quality Criterion #3:	HIV-positive adults and children should be assessed for antiretroviral therapy (ART) eligibility through either clinical staging or CD4 testing
HIV Trt Indicator 1a WHO-recommended indicator	<i># and % of HIV-infected adults and children assessed for ART eligibility through either clinical staging or CD4 testing at 2 months of enrollment</i>
HIV Trt Indicator 1b WHO-recommended indicator	<i># and % of HIV-infected adults and children assessed for ART eligibility through either clinical staging or CD4 testing in the last 6 months</i>
Quality Criterion #4:	HIV-positive adults and children must be enrolled in HIV care
HIV Trt Indicator 2 UNGASS indicator #4	<i># and % of adults and children with advanced HIV infection receiving antiretroviral therapy</i>
HIV Trt Indicator 3 HCI indicator	<i># and % of HIV-infected adults and children currently enrolled in HIV care programs</i>
Quality Criterion #5:	Adults and children currently enrolled in ART should adhere to their treatment regimens
HIV Trt Indicator 4 Global Fund HIV M&E Toolkit: HIV-T5	<i># and % of people starting antiretroviral therapy who picked up all prescribed antiretroviral drugs on time</i>
HIV Trt Indicator 5 HCI indicator	<i># and % of adults and children who kept scheduled appointments</i>
Quality Criterion #6:	Adults and children currently enrolled in ART should be retained in treatment
HIV Trt Indicator 6 UNGASS indicator #24	<i>% of adults and children with HIV known to be on treatment 12 months after initiation of antiretroviral therapy</i>

III. Prevention of mother-to-child transmission of HIV	
Quality Criterion #7: Pregnant women must be tested for HIV and know their results	
PMTCT Indicator 1 Additional recommended indicator #7	% of pregnant women who were tested for HIV and who know their results
Quality Criterion #8: HIV-infected pregnant women should receive an efficacious antiretroviral medicine (ARV) regimen to reduce the risk of mother-to-child transmission	
PMTCT Indicator 2 UNGASS indicator #5	% of HIV-positive pregnant women who received antiretrovirals (antiretroviral prophylaxis or treatment if eligible) to reduce the risk of mother-to-child transmission
Quality Criterion #9: Eligible HIV-positive women must receive antiretrovirals for their own health	
PMTCT Indicator 3 UNGASS indicator #5	% of HIV-positive pregnant women who received antiretrovirals (antiretroviral prophylaxis, or treatment if eligible) for their own health
Quality Criterion #10: Infants born to HIV-infected women should receive follow-up care, including HIV testing, Cotrimoxazole, prophylaxis, and, if necessary, antiretroviral therapy	
PMTCT Indicator 4 Additional recommended indicator #8	% of infants born to HIV-infected women who receive an HIV test within 12 months of birth
PMTCT Indicator 5 Additional recommended indicator #9	% of infants born to HIV-infected women starting on Cotrimoxazole prophylaxis within two months of birth
IV. Tuberculosis/HIV	
Quality Criterion #11: HIV-infected adults and children must be screened for TB	
TB/HIV Indicator 1 Global Fund indicator TB/HIV-1	# and % of adults and children enrolled in HIV care who had TB status assessed and recorded during their last visit among all adults and children enrolled in HIV care in the reporting period
TB/HIV Indicator 2 PEPFAR indicator C2.4 D	% of HIV-positive patients who were screened for TB in HIV care or treatment settings
Quality Criterion #12: HIV-infected adults and children with TB must receive treatment for TB and HIV	
TB/HIV Indicator 3 UNGASS indicator #6	% of estimated HIV-positive incident TB cases that received treatment for TB and HIV
TB/HIV Indicator 4 Global Fund indicator TB/HIV-4	# and % of adults and children newly enrolled in HIV care who start treatment for latent TB infection (Isoniazid preventive therapy) among the total number of adults and children newly enrolled in HIV care over a given time period
TB/HIV Indicator 5 Global Fund indicator TB/HIV-2	# and % of adults and children enrolled in HIV care who started TB treatment, expressed as a proportion of adults and children in HIV care during the reporting period
V. Harm reduction	
Quality Criterion #13: Injecting drug users (IDUs) should use sterile injecting equipment	
HR Indicator 1 UNGASS indicator #21	% of injecting drug users who reported using sterile injecting equipment the last time they injected
Quality Criterion #14: Sufficient quantities of syringes must be provided to injecting drug users	
HR Indicator 2 UNODC Technical Guide 4.1.7	# of syringes distributed per injecting drug user per year

Quality Criterion #15:	Patients in opioid substitution therapy (OST) should receive the optimal maintenance dose
HR Indicator 3 UNODC Technical Guide 4.2a.9	% of patients in OST receiving recommended maintenance dose
Quality Criterion #16:	Patients in opioid substitution therapy should remain in treatment for an optimal period
HR Indicator 4 UNODC Technical Guide 4.2a.10	# and % of individuals currently on OST who have been on OST continuously for the past 12 months

Note: M&E stands for monitoring and evaluation; UNGASS stands for United Nations General Assembly Special Session; PEPFAR stands for U.S. President's Emergency Plan for AIDS Relief; and UNODC stands for the United Nations Office on Drugs and Crime.

The QC were designed to be general enough to allow country programs flexibility in evaluating the quality of program performance for reporting and improvement purposes without restricting countries to indicators that may not all be applicable or feasible in their context. Twenty-one existing global HIV indicators (from UNGASS, PEPFAR, WHO, etc.) were selected because they correspond closely to the QC. We also chose four additional indicators that HCI uses on an ongoing basis. Countries will thus have the option of using the field-tested indicators to assess progress toward meeting the QC or using other indicators that would be more relevant in their situations.

HCI led the field testing of the proposed QC and corresponding indicators in five countries representing different types of HIV epidemics: three in Africa and one each in Eurasia and Southeast Asia. The African countries are in East Africa, West Africa, and Southern Africa.

All QC were field-tested in the Eurasian country. The four harm reduction QC were not field-tested in the African countries, but they were in the others, where a higher HIV prevalence had been observed in key populations, such as injecting drug users (IDUs). Two of the four harm reduction QC (QC 15: Patients in OST should receive the optimal maintenance dose and QC 16: Patients in OST should remain in treatment for an optimal period) were not field-tested in the Southeast Asian country because the OST programs had not been implemented at the field-test sites.

II. METHODOLOGY

A. Assessment Design

The field test combined quantitative and qualitative methods to determine feasibility, utility, and relevance of the proposed QC and indicators. We used retrospective cohort analyses, record abstraction, documentation review, and qualitative interviews. Quantitative data collection occurred at the facility level, whereas qualitative interviews were conducted at the national, regional, district, and facility levels. Interviewees varied by country and site and included ministers, deputy directors, and program managers at the national level; chief medical officers at the regional level; focal persons and medical records officers at the district level; and counselors, data clerks, directors, nursing officers, physicians, and records persons at the facility level.

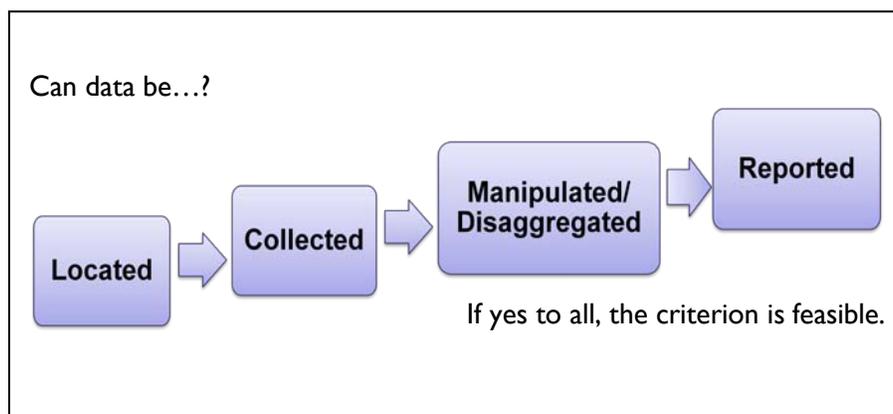
1. Variables of interest

A proposed QC's *relevance* was measured using ordinal variables on a three-point Likert scale: "not useful," "useful," and "very useful." Additional variables, e.g., staff members' capacity to report on the QC, were included in the field test to measure *utility*. Records were also examined for *completeness of the data source*; *legibility of the data source*; *orderly storage of data*; and *data availability*. *Data use* at the facility level was also assessed.

Figure 2 depicts the rationale for determining the *feasibility* of reporting on each QC. A QC was rated feasible if required data for the related indicator(s) could be located, collected, manipulated/disaggregated, and reported. If any of these functions could not be performed for a QC, then indicators

were slightly modified to determine the feasibility of reporting on the QC using those modified indicators.

Figure 2: Determining the feasibility of a quality criterion



2. Modifying indicators

One or more existing indicators were proposed to assess the reporting feasibility of each QC. Ten of those indicators are national coverage indicators, three of which are survey indicators requiring numerator and denominator data usually collected from surveys conducted outside a facility on a regional or national scale. The seven other national coverage indicators have population-estimate denominators. Their numerator data are typically generated at a facility, whereas denominator data are projected based on population-based censuses or surveys. We modified the 10 indicators slightly to assess feasibility at the facility level (Appendix A). We rephrased numerators and denominators of the three survey indicators to show how many clients at a facility actually received the service for which they were eligible. For the seven other national survey indicators, we made no changes to the affiliated numerators, but we converted the population-based estimate denominators to provide the actual number of clients who visited a facility and were eligible for a service.

B. Sampling

Randomization was used to pull samples for the medical record abstraction of pre-ART, ART, OST, and needle and syringe program (NSP) patients at each facility. The sampling frame for the medical record reviews was the total number of patients enrolled in the specified program at the facility. A sample size of 50 patients was used for the pre-ART medical record review that consisted of both pre-ART and ART patients. That sample size was also used for each of the ART, OST, and NSP medical record reviews. The sampling protocol, including instructions relative to all medical record reviews, is in Appendix B.

C. Data Collection

Teams used three procedures for data collection: interviews, medical record abstraction, and documentation review. Appendix C provides information on instrument development and data collection procedures.

D. Analysis

Analyses were structured to meet the five field-test objectives that are described in Appendix D and listed here:

- *Objective 1:* Compare proposed criteria, indicators, and data points to existing in-country indicators.

- *Objective 2:* Assess the feasibility of proposed criteria and indicators in terms of ability to locate patient information; collect data in a timely fashion; extrapolate data from the data sources; and maintain a complete data source from which data can be manipulated, disaggregated, and reported.
- *Objective 3:* Assess the relevance of proposed criteria, indicators, and data points as perceived by national, regional, district, and facility staff as to the usefulness of this information for making improvements in the quality of care.
- *Objective 4:* Assess capacity through current country- and facility-level mechanisms to collect, manipulate, and report information collected as well as analyze and use data.
- *Objective 5:* Rapidly assess the quality of services.

III. RESULTS

A. Feasibility of Using QC to Measure the Quality of HIV Services

Across the African countries, the national level can report on 40–44% more QC than the facility level (Table 2). Conversely, reporting feasibility between the national and facility levels only differed by 7% and 18% in the Eurasian and Southeast Asian countries, respectively. The marked difference in reporting ability between the two levels was due to data availability. At the facility level, QC reporting depended on data for facility-based numerators (number who received the service) and facility-based denominators (number eligible for the service). Reporting at the national level required numerator data from facilities (on the number of patients who received a service or the number of patients surveyed who said that they had received it) and a population-based denominator (estimate of the number of people expected to be eligible for the service or the number of people surveyed). Details of this section are provided in Appendix F.

The difference in feasibility of reporting at the national versus the facility level was most evident relative to the QC for PMTCT, for which the African facilities were largely unable to report. Monthly reports contained aggregate numerator data on the number of patients who received a PMTCT service during the reporting period in all five countries. Facilities report raw numerator data up to the national level, where facility-level data is compiled and a national estimate obtained to report on national coverage. All PMTCT QC were feasible for reporting from the national level, but in the African countries, not all required data were available to report on the slightly modified indicators for the PMTCT QC at the facility level. An exception was QC 7 (*Pregnant women must be tested for HIV and know their results*).

Table 2: Feasible quality criteria by region and sub-region

Region	Feasible quality criteria n(%) N=16	
	National level	Facility level
East Africa	9(75%)*	5(42%)*
Eurasia	15(94%)	14(88%)
West Africa	9(75%)*	5(42%)*
Southeast Asia	11(79%)+	9(64%)+
Southern Africa	10(83%)*	6(50%)*

* Excludes four harm reduction quality criteria.

+ Excludes two harm reduction quality criteria.

When data collectors could identify those who should be in the denominator, an absence of tracking mechanisms and the use of numerous registers and multiple patient identifiers prevented the collectors from locating data for the numerator (the number, out of those eligible, who received the service). The three infeasible PMTCT QC (QC 8, 9, and 10, relating to transmission prevention, ARVs for the

mother, and HIV care for the infant) are not likely to be feasible using alternative indicators: the field tests exposed an inability to track HIV-positive mothers and their exposed infants through the PMTCT cascade of service in the African countries. Table 3 illustrates this by showing the data that could be located when collectors attempted such tracking in the African countries.

Table 3: Feasibility of tracking PMTCT patients, three African countries

Country	Pregnant women newly enrolled in PMTCT program	Mothers assessed for ART eligibility	Mothers started on ART	Mothers started on ARV prophylaxis	Mothers received ARVs at labor and delivery	Birth to live infant	Infants received ARVs <72 hours of birth	Infants received ARVs for one week	Infants started on Cotrimoxazole within 2 months of birth	Infant's 1 st HIV test	Infant's 2 nd HIV test	Infants tested HIV positive	HIV-positive infants enrolled in HIV trt program	Mothers enrolled in HIV treatment program
A	2/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites
B	5/5 sites	1/5 sites	2/5 sites	2/5 sites	0/5 sites	0/5 sites	0/5 sites	0/5 sites	0/5 sites	0/5 sites	0/5 sites	0/5 sites	0/5 sites	0/5 sites
C	3/4 sites	2/4 sites	2/4 sites	2/4 sites	1/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites	0/4 sites

Country A = East African country; Country B = West African country; Country C = Southern African country.

Data collectors tried to obtain data on the PMTCT cascade of services by attempting to track cohorts (grouped into a certain month) of HIV-positive mothers from enrollment in a PMTCT program to an HIV care and treatment program for her and her infant. Results from two countries show that as data collectors moved through this continuum, none of the sites could report the number of women in the cohorts who received ARVs at labor and delivery. The collectors could not retrospectively follow a cohort through the points of care and determine whether the cohort members received a service at each point. The data collectors' difficulties arose not only from failures to provide or record services but also from facilities having multiple registers and identification numbers in different wards and clinics, mothers using different name combinations in wards and clinics, and infants having different last names than their mothers.

B. Key Findings from Rapid Assessment of Quality

In addition to revealing substantial gaps in the coordination and tracking of PMTCT services for both mothers and exposed infants, the QC revealed that the mechanisms for linking patients between service areas were generally weak (for example, from counseling and testing to HIV treatment, from PMTCT to HIV treatment, and from PMTCT to exposed-infant follow-up). Data show that a very high proportion of both pre-ART and ART patients did not return to the clinic, and often no documentation indicated what happened to those patients. Moreover, there were no systematic mechanisms in any field-test site for tracking patients who tested positive and subsequently enrolled in care.

C. Data Availability

1. Data available at the national level

All three survey indicators (QC 1 indicators 1 and 2 and QC 13 indicator 1) received a “feasible” rating for reporting at the national level, given that all five countries should have the capacity to conduct national surveys. In regards to the seven other national indicators,¹ corresponding QC received a feasible rating at the national level when required numerator data could be reported by the facility level and a national estimate could be obtained for the denominator.

The 15 remaining indicators² were all facility based and did not require modification for the assessment. When they were feasible at the facility level, then the data could be compiled and reported to the national level, rendering them feasible at that level. For example, both of the QC proposed for TB/HIV (QC 11: HIV-infected adults and children must be screened for TB and QC 12: HIV-infected adults and children with TB must receive treatment for TB and HIV) and harm reduction QC 14 (Sufficient quantities of syringes must be provided to IDUs) were all feasible at the national and facility levels. Two harm reduction QC (QC 15: Patients in OST should receive the optimal maintenance dose and QC 16: Patients in OST should remain in treatment for an optimal period), field-tested in only the Eurasian country, were feasible for reporting at the facility and national levels.

2. Data available at the facility level

When data were not available, the facility-based indicator was not feasible for reporting at either level. In several cases, data availability was affected by a lack of tracking systems. QC 2 (Clients testing positive should be enrolled in HIV care) was not feasible in any country because no data were available on patients who tested positive for HIV and subsequently enrolled in a care and treatment program. Patient testing information was recorded for those who were tested, received their results, and tested positive and in some facilities for those who were referred to a care and treatment program. However, no country documented the number of patients who tested positive and subsequently enrolled in care.

The African countries could not report at the facility or national level on two care and treatment QC (QC 4: HIV-positive adults and children must be enrolled in HIV care and QC 6: Adults and children currently enrolled in ART should be retained in treatment). These QC were infeasible due to a lack of data. Even in the Southern African country, with a computer program that could perform queries to disaggregate inactive patients from active ones, data were not updated in the database. Overall, weak linkages between different types of care, non-existent or informal patient follow-up, and the lack of an up-to-date system to distinguish between inactive patients (lost, deceased, transferred-out, stopped-treatment) and active ones prevented data collectors from obtaining all required data to report on QC 2, 4, and 6.

3. Data unavailable at either level

The three national survey indicators (QC 1 indicators 1 and 2 and QC 13 indicator 1) were adjusted to capture patients who visit the facility, resulting in data that would reflect facility performance. The two modified testing and counseling indicators for QC 1 (related to clients having to know their HIV status after testing) were not feasible in any country due to their requirements for data on age ranges and sexually active status. That is, testing and counseling data were available in computer databases and registers and compiled in monthly reports but could not be easily disaggregated into the age strata (15–

¹ QC 4 indicator 2, QC 7 indicator 1, QC 8 indicator 2, QC 9 indicator 3, QC 10 indicators 4 and 5, and QC 12 indicator 3.

² QC 2 indicators 3a and 3b, QC 3 indicator 1a and 1b, QC 4 indicator 3, QC 5 indicators 4 and 5, QC 6 indicator 6, QC 11 indicators 1 and 2, QC 12 indicators 4 and 5, QC 14 indicator 2, QC 15 indicator 3, and QC 16 indicator 4.

49 and 15–24). Documentation in registers, monthly reports, and databases with preset strata aligned with the countries' national reporting requirements rather than indicator definitions. Data collectors attempted hand-tallying from registers to sort data into the indicator age strata, but it proved too time-consuming to be feasible. Furthermore, no facility maintained data on the sexually active status of patients tested at age 15–24. Conversely, all facilities could report on the number of patients tested and those who received their test results, so QC 1 would be feasible if the age and sexual activity requirements were deleted from the indicators.

The modified version of QC 13 indicator 1, used to assess harm reduction (QC 13: *Injecting drug users should use sterile injecting equipment*), was also not feasible for reporting at the facility level in the Eurasian and Southeast Asian countries, but was feasible at the national level. It was largely not feasible at the facility level because facilities did not collect data on the use of sterile injecting equipment. These data are usually collected on the regional level in a behavioral surveillance survey.

D. Perceived Relevance of Quality Criteria

National officials, providers, and facility staff who were interviewed found the QC to be “very useful” or “useful” for all service delivery areas, with the exception of the harm reduction QC proposed for OST programs, QC 15: *Patients in OST should receive the optimal maintenance dose* and QC 16: *Patients in OST should remain in treatment for an optimal period*. Therefore, data collectors proposed a new QC: *Clients should be stabilized in OST treatment during a 12-month period*. In order to determine the relevance of this new QC, data collectors formulated and field-tested a new indicator: *Percentage of individuals currently on OST who are stabilized in OST treatment in the past 12-month period*. The new OST QC was relevant and feasible for reporting. For a full description and data points of the new QC see Appendix E.

E. Use of Data to Improve Services

While donors have valid reasons for requesting data, they may be even more important to facilities and countries, which should use data to improve their services. We found two important results in this concern.

1. Little to no use of data at the facility level

There was little evidence that facilities used the data they collected to improve their HIV services. Of 35 facilities visited during the field test, data collectors noted three where staff members used quality improvement methods, such as analysis and use of data, to make and track changes to address facility needs and client services. One such facility was located in each of the three regions in Africa.

2. Analysis and use at the national level

Interviews revealed that in all five countries, after the data leave a facility, they flow through sub-national (i.e., district, regional, and/or provincial) levels and then are compiled and reported as national data. We found evidence in the Eurasian and Southeast Asian countries of data analysis taking place only on the national level to meet donor and country national reporting requirements. An epidemiologist team in the Eurasian country regularly compiled and conducted quality checks of facility-level data for reporting national data to the Ministry of Health and donors. In the Southeast Asian country, at the national level, data are synthesized and analyzed for national annual and periodic reports that inform policy and strategic planning.

IV. DISCUSSION

A. Summary

Countries should be able to report on the QC if comprehensive data are available in the facilities. Field-test results showed that survey indicators and indicators with population-estimate denominators were useful for measuring coverage at the national level. However, indicators with facility-based denominators that reflect the actual number of patients who visit a facility were the most useful for enabling facility staff to track their performance on a consistent and frequent basis. These indicators were most useful because they generated data that could be analyzed by facility staff to make decisions to improve services. Information gained from those facility-level data could also be used to inform national planning and provide insight to the donor community about the impact of HIV programs and services.

B. Areas for Improvement

Challenges to the feasibility of reporting on the QC arose when data were inconsistently documented, could not be disaggregated to the required stratifications (e.g., age ranges, inactive patients), or were located in multiple data sources using multiple ID numbers. In both HIV care and treatment and PMTCT, the field test identified significant opportunities for improving tracking and linking of services. Cooperation from all levels of the system will be necessary to ensure timely, accurate, and consistent documentation of patient services to enable frequent and routine reporting and use of data for decision-making. Furthermore, modifying the two HTC survey indicators to facility-based numerators and denominators and removing the age ranges and sexually active classification would enable reporting of these two indicators. Facilities may also benefit from the option of reporting their facility age stratifications rather than the 15–49 and 15–24 age ranges.

Tracking patients

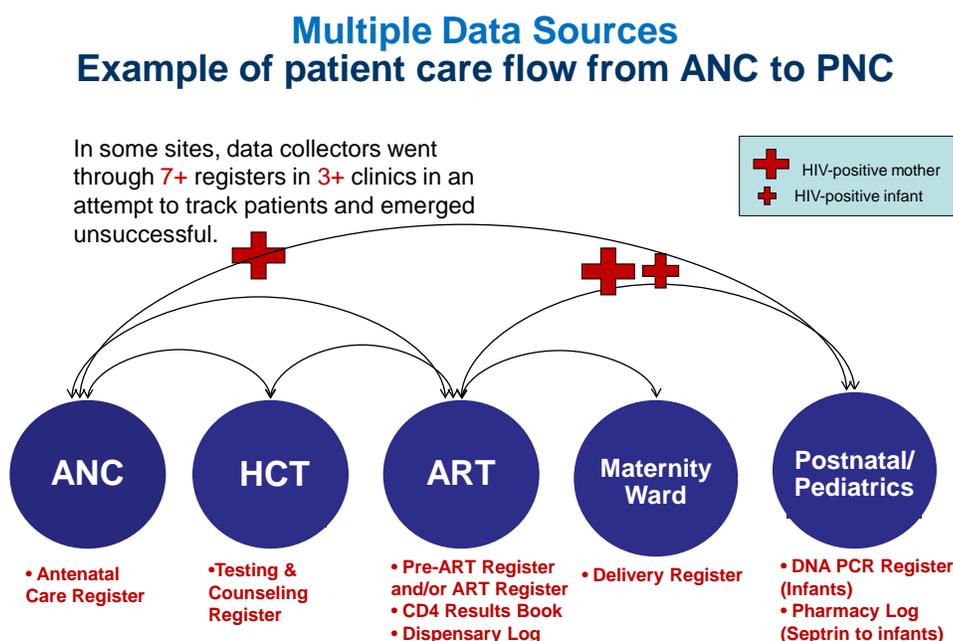
Due to the diffused structure of PMTCT services, data on who was eligible to receive a service (the denominator) and whether or not those patients received that PMTCT service (numerator) could not be located. Required data for HIV-positive mothers and exposed infants were stored in multiple data sources that were located in several different departments of a facility. The use of multiple patient identifiers in different clinics within a facility made it impossible for data collectors to track patients across clinics (Figure 3). Attempts were made to match patient names, rather than identifies, but that proved infeasible when patients reported more than one name or two or more patients had the same name. Consequently, data collectors were unable to obtain all required data using the modified indicators to report on the PMTCT QC 8, 9, and 10 at the facility level in the African countries. Conversely, smaller patient loads and database systems in the Eurasian and Southeast Asian countries enabled data collectors to track small cohorts of (about one to nine) patients and report on the modified PMTCT indicators at the facility and national levels.

Figure 3 below illustrates both patient flow and the multiple registers that data collectors reviewed in the different wards and clinics to collect data. The arrows show the many wards and clinics that pregnant women and their exposed infants visit, often multiple times, to obtain their services.

Multiple data sources

When up-to-date data were regularly maintained in one data source (e.g., a database or register), required data were easily extracted from that source. However, the largest inhibitor to data collection was when data required hand-tallying from multiple sources (i.e., patient charts and registers). Data collectors experienced this challenge largely when attempting to collect PMTCT data across the continuum of services, including those for the newborns of PMTCT clients (Table 3 and Figure 3).

Figure 3: Example of barriers for PMTCT data collection that arise from multiple data sources



Knowing the denominator

A common finding across the countries in every service area was that facilities could report raw numerator data when data were available and could be compiled in a timely manner. However, numerator data do not show how many patients should have received a service. This was acutely apparent in PMTCT services where facility staff could provide data on the volume of patients who received a service but not on the percentage of eligible patients actually received it.

Raw numbers reported by facilities are mostly useful at the national level to indicate national coverage with a population-estimate denominator. To have data to indicate their own performance, facilities need to determine how many received a service and how many should have. Knowing how many clients received each service (the numerator) and how many should have (the denominator) would inform staff of gaps in service delivery and support efforts to close those gaps.

Use of data

The finding that most facilities are not using the data that they collect to improve the quality of their HIV services underscores the need to support and encourage data analysis and the use of data for managing and improving services. Facility staff reported that they receive little to no feedback from regional and national staff on the data they report. This finding highlights the need to educate national officials on the importance of supporting sub-national and facility staff in analyzing and using their data to manage and improve HIV services.

C. Areas of Strength

Perceived relevance

A very encouraging finding was that national officials, providers, and facility staff who were interviewed found the QC to be “very useful” or “useful” for all service delivery areas, with the exception of the harm reduction QC proposed for OST programs. We therefore believe it likely that countries will be

amenable to reporting on the QC. Given that significant overlap appeared between current reporting requirements and the proposed QC, facilities will likely not experience an increase in reporting burden proportionate to the number of criteria that was feasible at each site.

Match of in-country indicators

Many indicators contributing to QC are currently used by bi-lateral and multi-lateral donors and normative bodies: PEPFAR, USAID, UNGASS, and the Global Fund. The reasoning behind using this set of QC is in part that, if the indicators are already in use, the reporting burden will not increase excessively. This is supported by the finding that 75%–93% of the indicators (from the Global Fund, PEPFAR, UNGASS, WHO, and HCI) were feasible for reporting at the national level.

Consensus on the quality criteria

A global partners meeting convened at the Global Fund in Geneva in June 2011 was attended by partners from HCI, OGAC, PEPFAR, UNAIDS, USAID, and WHO. HCI presented the QC findings of the five field tests, and partners agreed that now is an opportune time to focus on quality. Everyone showed great interest in gaining a better understanding about the content of the HIV programs they support. They also concurred on the use of the QC as a measurement framework for improving the quality of HIV services.

The QC approach supports the United States Government's Global Health Initiative

Adoption of the QC would not only encourage monitoring, evaluation, and improvement of essential HIV services, but would aid in fulfilling four of the seven principles of the United States Government's Global Health Initiative³:

1. Strengthen and leverage key multilateral organizations, global health partnerships, and private sector engagement;
2. Encourage country ownership and invest in country-led plans;
3. Build sustainability through health systems strengthening; and
4. Improve metrics, monitoring, and evaluation.

D. Limitations

It is possible that the capacity of visited sites was lower than that of other in-country facilities, although the facility selection process was designed to reduce that possibility. In order to minimize the possibility of random error or bias and maximize the external validity of the results, we selected facilities that would represent others in each country. Facilities differed in size, type, geography, caseload, staffing, and catchment area. There is also the possibility that, despite efforts to select a diverse range of facilities, the selected sites may differ from others in each country, which would reduce the generalizability of the results.

The field test was designed to capture as much relevant data for each QC and indicator as possible in the limited duration of country and facility visits. If data that were relevant to a QC or indicator were not collected during the field test, feasibility may have changed for that QC or indicator. To minimize the possibility that relevant data existed but were not collected, data collectors had pre-designed data collection tools designed to determine whether suitable data were available. In addition, collectors attempted to locate any additional data relevant to QC and also added qualitative data on staff perspective and site capacity. When data were hard to find but available, facility staff guided data collectors to relevant data sources.

³ USAID. 2010. Fact Sheet: The U.S. Government's Global Health Initiative. Accessed 9/9/2011 at <http://www.usaid.gov/ghi/factsheet.html>.

Data were collected through examination of patient medical records and compiled cross-sectional data in periodic reports. There is a chance that in extracting and manipulating data alongside facility staff members from a sample of patient medical records, data collection teams exceeded the true capacity of facility staff to conduct similar procedures. It is also possible that data gathered through our sample of medical records would be infeasible to collect from every file if the site served a large number of patients.

V. CONCLUSION AND RECOMMENDATIONS

Improving the quality of HIV services depends on facilities accurately documenting services, routinely tracking data relative to the components of services, conducting data analyses, and using their findings to address weaknesses and build on strengths. Monitoring performance frequently can enable facilities to identify trends, observe changes, and demonstrate improvement. Forming collaborations among the facility, sub-national, national, and donor levels may be useful in fostering dialogue and allowing feedback to flow regularly to and through the health system levels. The proposed QC were selected with these goals in mind to equip facilities with guidance on monitoring their performance, improving services that need it, and closing coverage gaps.

The finding that three of four PMTCT QC were not feasible for reporting on facility-level performance in the three high-burden countries highlights a significant opportunity. Donors and nations can work together with facilities to create systems for tracking PMTCT patients to enable reporting from the facility level on the slightly modified PMTCT indicators. Monitoring performance on a monthly basis would allow facilities to track data indicating whether all patients received the services for which they are eligible. Modifications to existing PMTCT indicators may encourage staff to ensure that PMTCT clients receive the entire continuum of care rather than merely the service each staff provides.

There is a great need to develop tools and provide guidance to countries so that national and regional staff, and facility managers and staff can continuously monitor, assess, and make decisions that improve the quality of HIV services. To empower and support countries in continuously and routinely using their data to assess and improve HIV services, global technical partners and donors should work together to build in-country capacity, not only to report program data, but also to cultivate a culture of quality improvement where data are used to strengthen program performance. Recommendations for enhancing the feasibility of reporting and using the QC and indicators to improve the quality of HIV services are as follows:

Key Recommendations

I. Increase facilities' ability to use indicator data

- A. Denominators should reflect the number of patients who visit the facilities
- B. Indicator descriptions should be adjusted to support monthly monitoring

II. Encourage monthly monitoring and use of data to make decisions to manage and improve care processes

III. Improve the use and reporting of data for the QC by:

- A. Supporting countries in using up-to-date, centralized record systems for recording patient status (including PMTCT);
- B. Establishing systems to track and assure attendance (including PMTCT);
- C. Linking different service areas, including HTC, to care and treatment enrollment and PMTCT; and
- D. Supporting countries in building capacity to use their data to make decisions and improve the quality of their services.

In conclusion, the field tests found that quality criteria can be used to help countries achieve performance targets and coverage levels satisfactory to themselves and their donors. It also found that countries can largely generate data that make the indicator measurements feasible but that facilities need guidance in creating systems that will help them generate the data they need. Last but hardly least, facilities also need help in analyzing data and using them to improve HIV services.

The field tests revealed that it would be most beneficial to use facility-based indicators and track performance on a monthly basis. Monthly tracking will enable facility staff to review their own performance, identify patients who should have received a service, and follow-up with those patients to ensure that they receive care. The QC approach is designed to be harmonized globally and can be implemented by the donor community, such that facility staff can track their progress, and performance data can be shared with donors to spread lessons learned and success stories and monitor program performance. Data from facility-based indicators can be aggregated to contribute to the national picture. The QC should produce vital data for improvement and inform decision-making while countries continue to develop and strengthen internal capacity to meet the needs of their citizens.

APPENDICES

Appendix A: Global Indicators that Were Modified for this Field Test

Below are 10 of the field-tested existing global indicators that would be more feasible if revised. We slightly modified their numerators and/or denominators to reflect patients who come into the facility. These indicators promote monthly data collection. We recognize that not all facilities collect the data these indicators require, and acknowledge that not all facilities have access to data required for current denominators. Even more, slight modifications to data requirements of the proposed HTC QC (i.e., age ranges and sexually active classification) may also increase the feasibility of reporting on the QC.

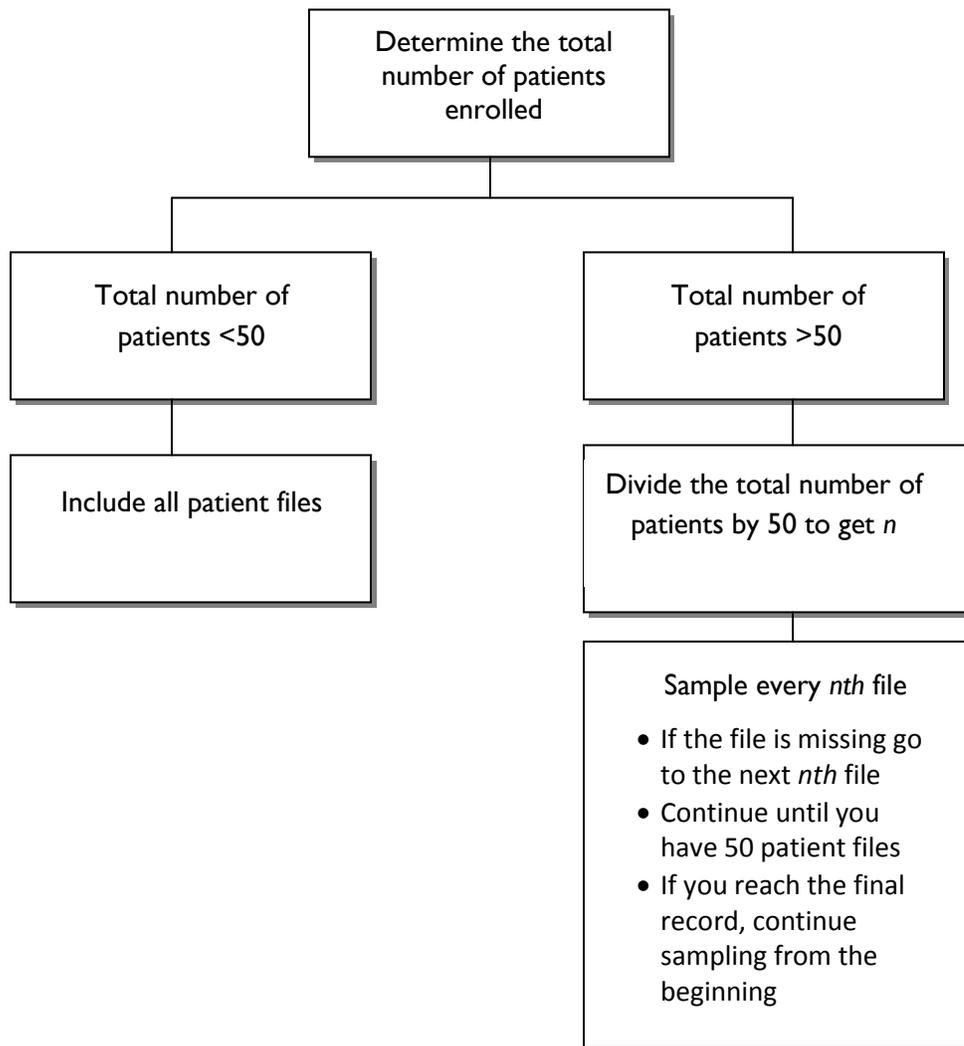
Table 4: Modified indicators to promote quality improvement at the facility level

Proposed indicator	Current numerator & denominator	HCI-recommended numerator and denominator
I. HIV testing and counseling		
HTC Indicator 1. <i>% of women and men aged 15-49 who received an HIV test in the last 12 months and who know their results</i> UNGASS indicator #7	Numerator: # of respondents aged 15–49 years who have been tested for HIV in the last 12 months and who know their results	New Numerator: # of women and men aged 15–49 years who received an HIV test in the last month and who received their results
	Denominator: # of respondents aged 15–49 years	New Denominator: # of women and men aged 15-49 tested in the last month
HTC Indicator 2. <i>% of sexually active young women and men age 15–24 who received an HIV test in the last 12 months and know their results</i> Additional Recommended Indicator #5	Numerator: # of respondents aged 15–24 years who had an HIV test in the last 12 months and who know their results.	New Numerator: # of sexually active women and men aged 15–24 who were tested and received their test results in the last month *Can only be reported by facilities that currently document age by the 15–24 age range and would not require additional hand-tallying
	Denominator: # of respondents aged 15–24 who have had sexual intercourse in the last 12 months	New Denominator: # of sexually active women and men aged 15–24 who were tested for HIV in the last month
II. HIV care and treatment		
HIV Trt Indicator 2. <i># and % of adults and children with advanced HIV-infection receiving antiretroviral therapy</i> UNGASS indicator #4	Numerator: # of adults and children with advanced HIV infection who are currently receiving antiretroviral therapy in accordance with the nationally approved treatment protocol (or WHO/UNAIDS standards) at the end of the reporting period	No changes recommended for current numerator
	Denominator: Estimated # of adults and children with advanced HIV infection	New Denominator: # of adults and children with advanced HIV infection who visited the facility in the last month who are eligible in accordance with the nationally approved treatment protocol (or WHO/UNAIDS standards) to receive antiretroviral therapy that month

Proposed indicator	Current numerator & denominator	HCI-recommended numerator and denominator
III. Prevention of mother-to-child transmission of HIV (PMTCT)		
PMTCT Indicator 1. <i>% of pregnant women who were tested for HIV and who know their results</i> Additional Recommended Indicator #7	Numerator: # of women attending antenatal care, labor and delivery, and postpartum services, who were tested for HIV and received their result, plus women with known HIV infection attending antenatal care for a new pregnancy in the last 12 months	New Numerator: # of women who received an HIV test in the last month and who received their results
	Denominator: Estimated # of pregnant women in the last 12 months	# of women newly enrolled in the facility in the last month for antenatal care, labor and delivery, and/or postpartum services, excluding women with known HIV infection attending antenatal care for a new pregnancy
PMTCT Indicator 2. <i>% of HIV-positive pregnant women who received antiretrovirals (antiretroviral prophylaxis, or treatment if eligible) to reduce the risk of mother-to-child transmission</i> UNGASS indicator #5	Numerator: # of HIV-infected pregnant women who received antiretroviral drugs to reduce risk of mother-to-child transmission	No changes recommended for current numerator
	Denominator: Estimated # of HIV-infected pregnant women in the last 12 months	New Denominator: # of HIV-infected pregnant women eligible to receive antiretroviral prophylaxis or treatment during the last month
PMTCT Indicator 3. <i>% of HIV-positive pregnant women who received antiretrovirals (antiretroviral prophylaxis or treatment if eligible) for their own health</i> Numerator “d” of UNGASS indicator #5	Numerator: # of HIV-infected pregnant women who received antiretroviral drugs for their own health	No changes recommended for current numerator
	Denominator: Estimated # of HIV-infected pregnant women in the last 12 months	New Denominator: # of HIV-infected pregnant women eligible to receive antiretroviral drugs for their own health during the last month
PMTCT Indicator 4. <i>% of infants born to HIV-infected women who receive an HIV test within 12 months of birth</i> Additional Recommended Indicator #8	Numerator: # of infants in the last 12 months who received an HIV test within 12 months of birth, disaggregated by: 1.infants who received virological testing in the first 2 months; and 2.infants who were tested either virologically between 2 and 12 months, or by antibody testing between 9 and 12 months	New Numerator: # of infants in the last month who received an HIV test within 12 months of birth, disaggregated by: 1.infants who received virological testing in the first 2 months and 2.infants who were tested either virologically between 2 and 12 months or by antibody testing between 9 and 12 months
PMTCT Indicator 5. <i>% of infants born to HIV-infected women starting on Cotrimoxazole prophylaxis within two months of birth</i> Additional Recommended Indicator #9	Numerator: # of infants born to HIV-infected women in the last 12 months started on Cotrimoxazole prophylaxis within two months of birth	New Numerator: Total # of HIV-exposed infants who are 3 months old in the reporting month and who started on cotrimoxazole prophylaxis within 2 months of birth.
	Denominator: Estimated # of pregnant women giving birth in the last 12 months	New Denominator: Total # of HIV-exposed infants who are 3 months old in the reporting month

Proposed indicator	Current numerator & denominator	HCI-recommended numerator and denominator
IV. Tuberculosis/HIV (TB/HIV)		
TB/HIV Indicator 3. <i>% of estimated HIV-positive incident TB cases that received treatment for TB and HIV</i> UNGASS indicator #6	Numerator: # of adults with advanced HIV infection who are currently receiving antiretroviral therapy in accordance with the nationally approved treatment protocol (or WHO/UNAIDS standards) and who started TB treatment (in accordance with national TB programs guidelines) within the reporting year	<i>New</i> Numerator: # of adults with advanced HIV infection who are receiving antiretroviral therapy in accordance with the nationally approved treatment protocol (or WHO/UNAIDS standards) and who started TB treatment (in accordance with national TB programs guidelines) within the last month
	Denominator: Estimated # of incident TB cases among people living with HIV	<i>New</i> Denominator: # of incident TB cases among clients living with HIV who were screened for TB at the facility in the last month
IV. Harm reduction		
HR Indicator 1. <i>% of IDUs who reported using sterile injecting equipment the last time they injected</i> UNGASS indicator #21	Numerator: # of respondents who reported using sterile injecting equipment the last time they injected drugs	<i>New</i> Numerator: # of clients who used sterile injecting equipment the last time they injected drugs *Can only be reported by facilities who ask clients about and document use of sterile injecting equipment at last use
	Denominator: # of respondents who reported having injected in the past month	<i>New</i> Denominator: # of clients seen during the last month

Appendix B: Sampling Protocol



Instructions for Sampling of Pre-ART Records for Pre-ART Medical Record Review:

- Determine total number of patients enrolled in pre-ART
- If total enrolled in pre-ART is less than 50, include all patient files
- If total enrolled in pre-ART is greater than 50, divide total number of pre-ART patients by 50 to get n (round down)
- Then, sample every n th file from the pre-ART register and pull that record for review
- If that file is missing, go the next n th file and continue sampling
- If you reach the final record, and still have not collected a sample of 50 patient files, continue sampling from the beginning of the records
- Exclude only files of patients who transfer-in, already on ART (meaning received pre-ART services elsewhere)
- It is acceptable to include patients who have initiated ART since enrolling in this care program at this facility

Instructions for Sampling of ART Records for ART Medical Record Review:

- Determine total number of patients enrolled in ART
- If total enrolled in ART is less than 50, include all patient files
- Divide total number of ART patients by 50 to get n (round down)
- Then, sample every n th file from the ART register and pull that record for review
- If that file is missing, go the next n th file and continue sampling
- If you reach the final record, and still have not collected a sample of 50 patient files, continue sampling from the beginning of the records
- Exclusion Criteria
 - Exclude those who initiated ART after July 1, 2009
 - Exclude those who died or transferred-out before July 1, 2009
 - Include patients who are lost-to-follow-up in the sample

Instructions for Sampling of OST Records for OST Medical Record Review:

- Determine total number of clients receiving OST services at this facility
- If total enrolled is less than 50, include all client files
- If total enrolled is greater than 50, divide total number of clients by 50 to get n (round down)
- Then, sample every n th file and pull that record for review
- If that file is missing, go the next n th file and continue sampling
- If you reach the final record, and still have not collected a sample of 50 patient files, continue sampling from the beginning of the records

Instructions for Sampling of NSP Records for NSP Medical Record Review:

- Determine total number of clients receiving NSP services at this facility
- If total enrolled is less than 50, include all client files
- If total enrolled is greater than 50, divide total number of clients by 50 to get n (round down)
- Then, sample every n th file and pull that record for review
- If that file is missing, go the next n th file and continue sampling
- If you reach the final record, and still have not collected a sample of 50 patient files, continue sampling from the beginning of the records

Appendix C: Data Collection

Data collection

1. Interviews

Teams interviewed staff at the selected sites. These interviews were used to determine whether the QC and proposed indicators and data points are currently being collected or reported by facility staff, the perceived relevance of the indicators and data points, ease of data collection, additional data sources, and to understand and identify opportunities for improvement.

2. Record Abstraction

Patient records were randomly selected and reviewed to conduct the medical record review of pre-ART and ART patients.

3. Documentation Review

Facility registers, log books, monthly reports and patient files were reviewed to conduct the ART, pre-ART, and PMTCT cohort analyses. Retrospective cohort analyses were performed to track receipt of HIV services. Several groups of patients were selected from specified periods in time. Facility records were reviewed to record services received by each person in the cohorts.

Instrument Development

Quantitative data collection tools

Data collection instruments were designed to capture necessary information for reporting on the proposed QC and selected indicators. Four data collection instruments were created, one for each service delivery area, with the exception of HIV Care and Treatment and TB/HIV combined on one instrument: Testing and Counseling; HIV Care and Treatment; TB/HIV; PMTCT; and Harm Reduction. Instruments were modeled off of existing HCI quality improvement data collection instruments.

Qualitative interview questionnaires

Interview questionnaires were created as a supplement to the quantitative data collection tools. Interview guides for in-depth interviews using open-and close-ended questions were developed for national, regional and facility level staff. HCI staff members performed 15-60 minute interviews with key informants. Questionnaires were created to aid in capturing the full context of HIV care and delivery at the national, district, regional, and facility levels. Qualitative data are intended to frame the context of the quantitative data by filling in the gaps that the indicators alone are unable to address, providing a greater understanding of the meaning behind the numerical value of the quantitative data. Interview questions inquired about the country context of HIV care and clinical care processes to substantiate quantitative data.

Indicator Selection

Indicators were selected as measures of the proposed QC. Existing Global Fund Toolkit indicators, United Nations General Assembly Special Session (UNGASS) indicators, and PEPFAR indicators were reviewed. The selected indicators are existing indicators that many countries currently use to report on HIV program performance. In addition to the UNGASS indicators, several HCI quality improvement indicators that HCI currently employs in various countries were selected.

Indicator Modifications

Two of the indicators proposed as measures of the Counseling & Testing QC required slight modifications based on data availability at the sites. These indicators were modified to remove the age ranges that were not attainable based on documentation processes used by facility staff. Exact modifications to the indicators are shown in Appendix A.

Country Selection

In order to define a harmonized globally agreed upon performance measurement framework for monitoring and evaluating the quality of HIV services, the PC and indicators were tested in various settings that are representative of the global community. The Global Fund and USAID selected five countries based on the following considerations:

- Generalized and concentrated epidemics (Africa versus Asia/Eastern European Countries/Latin American Countries)
- Geographical representation in the African countries (south, east, west)
- Countries represent a variety of levels of development of their HIV delivery systems (see below).
- Years offering ART

The following factors were considered when reviewing the degree to which a country's HIV program is established in order to achieve a sample of countries that represent variation in:

- Degree of decentralization for delivering HIV Care including:
 - Number of facilities that offer HIV Care,
 - Variety of levels of the health system where care is offered (health post, health clinic, district hospital, regional hospital, referral hospital, national hospital), and,
 - Geographic distribution of facilities within the country.
- Mechanisms to evaluate the quality of HIV Care and Services.
 - Is there a National Quality Program/Quality Assurance Department?
 - Is quality integrated into HIV country policies or initiatives?
 - Do facilities report data regarding quality to a central source?
- Does the Ministry of Health have an office that actively collects and processes health statistics?

Ethics

Institutional Review Board approval was not required for this assessment. Approval by the MOH and USAID mission teams was sought and granted for this assessment. Site selections and data collection instruments were approved by in-country national officials prior to the field test assessments.

Appendix D: Study Objectives

Analyses were structured to fulfill the five field test objectives.

Objective 1: *Compare proposed criteria, indicators and data points to existing in-country indicators.*

Teams collected samples of reporting instruments used by facilities, district hospitals, and the MOH. An indicator comparison instrument was developed to compare indicators currently collected at the facility, district, and national levels. Teams compared in-country indicators to proposed PC and indicators based on the following three-point Likert scale: (1=exact match, 2=close match and 3=no match). Exact match was assigned when an indicator used wording identical to the proposed indicator. Close match was defined as an indicator at the country level whose wording varied from the proposed indicator but was measuring a similar phenomenon. No match was defined as the absence of a country level indicator addressing the topic of the proposed indicator.

Objective 2: *Assess the feasibility of proposed criteria, indicators, and data points in terms of ability to locate patient information, collect data in a timely fashion, extrapolate data from the data sources, maintain a complete data source from which data can be manipulated and disaggregated, report, analyze and use data at the facility level.*

Feasibility of proposed criteria was assessed by examining completeness of data source, ease of manipulating data, time to compile and ease of data collection, and whether the data are currently being analyzed and used by facilities.

Team members considered the completeness of each data source in determining feasibility of each indicator. Completeness of data source was noted in data collectors' qualitative notes. When manipulating data was a factor in feasibility of reporting on proposed indicators, data collectors measured the ease of manipulating data using the following three-point Likert scale: 1=difficult; 2=moderate; and 3=easy.

Observations were used to assess whether data are currently being analyzed and used at the facility level.

Objective 3: *Assess the relevance of proposed criteria, indicators and data points as perceived by ART, PMTCT, harm reduction service managers, providers, data officers, and district/provincial and MOH staff as to the usefulness of this information for making improvements in the quality of care.*

The perceived relevance of the proposed PC was assessed in terms of the perceived usefulness of the PC. Staff in provincial, district and the MOH offices, including, service managers, providers, and data officers at the facility level were asked to review the proposed PC and rate the usefulness of each using the following three-point Likert scale: (1=not useful, 2=useful, and 3=very useful). Usefulness ratings were collected from each facility and means were calculated for each PC across all sites.

Objective 4: *Assess capacity in terms of working with data, current country and facility level mechanisms to collect, manipulate, and report information collected.*

Capacity was considered for both human resources and for procedures and mechanisms in place at facilities. Human capacity was considered as the ability of facility staff to locating, collecting, manipulating and reporting data necessary for proposed indicators. Procedural capacity was the presence of mechanisms and procedures to record, collect or compile data necessary for proposed indicators.

Data availability was assessed by four criteria: Are data accessible; are data compiled or do they require hand tallying; are data documented; and are data able to be manipulated and disaggregated. This was done for each indicator.

Objective 5: *Rapid assessment of quality of services.*

A rapid assessment of quality of service was conducted for each facility and across each HIV service delivery area. Quality of service was assessed as *performance*. For each indicator, a performance score was assigned as the percentage of patients receiving the specific service designated by the indicator. For example, HTC QC indicator 3b asks for the number and percentage of people testing HIV positive and subsequently enrolling in HIV care. Performance for this indicator is calculated as the number of HIV positive people who enrolled in care divided by the total number who tested HIV positive multiplied by 100 in order to get the percentage.

Appendix E: New Opioid Substitution Therapy QC and Indicator

Data collectors proposed a new QC: *Clients should be stabilized in OST treatment during a 12-month period.*

The new OST indicator has three data points. Clients must:

- Maintain a stable dose +/- 20 mg range of methadone for more than 6 months
- Not miss more than five visits a month
- Urine test free of drugs for 6 of the 12 tests (based on monthly tests over 12-month period)
(number of drug free urine samples/total # of urine samples over 12 months)

Although the new OST quality criterion was feasible for reporting in the one country it was field tested in, much more discussion is needed to define a “patient stabilized in OST.” Additional field tests on harm reduction programs in other nations may inform this QC and others that may be perceived as useful measures of quality of OST programs.

Evidence shows that OST programs are more effective and have a greater impact when provided with psychosocial support,⁴ so the addition of a measure to address the psychosocial treatment component of OST programs may be necessary.

⁴ WHO. 2009. WHO, UNODC, UNAIDS technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users. Accessed March 15, 2011 and available at: http://www.who.int/hiv/pub/idu/idu_target_setting_guide.pdf

Appendix F: Feasibility of Indicator, By Region

Table 5: Feasibility of indicator, by region

QC and indicator	Feasibility (System level)	Generalized epidemic (3 African countries)	Concentrated epidemic (Eurasia and Southeast Asia)	
I. HIV Counseling and Testing				
Performance Criterion #1: Clients must know their HIV status after testing				
C&T Indicator 1: <i>Percentage of women and men aged 15–49 who received an HIV test in the last 12 months and who know their results</i> UNGASS indicator #7	FACILITY	Not feasible When indicators are modified to use a facility-based denominator, facilities cannot disaggregate data by 15-49 age range	Feasible in Eurasia Data can be disaggregated to the 15–49 age range	Not feasible in SE Asia When indicators are modified to use a facility-based denominator, facilities cannot disaggregate data by 15-49 age range
	NATIONAL	Feasible National level should be able to conduct a population-based survey	Feasible National level can compile all necessary facility-level data	
C&T Indicator 2. <i>Percentage of sexually active young women and men age 15–24 who received an HIV test in the last 12 months and know their results</i> Additional recommended indicator #5	FACILITY	Not Feasible When indicators are modified to use a facility-based denominator, facilities cannot disaggregate data by 15-49 age range Facilities do not document sexually active status	Not feasible Facilities do not document sexually active status In Eurasia only, data can be disaggregated by the 15-24 age range	
	NATIONAL	Feasible National level should be able to conduct a population-based survey	Feasible National level should be able to conduct a population-based survey	
Performance Criterion #2: Clients testing positive should be enrolled in HIV care				
Indicator 3a. Number and percentage of people testing HIV-positive HCI indicator	FACILITY	Feasible Data for numerator & denominator were collected	Feasible	
	NATIONAL	Feasible Facilities can report numerator & denominator Facility data can be compiled	Feasible	
Indicator 3b. Number and percentage of people who subsequently enrolled in HIV care HCI indicator	FACILITY	Not feasible No mechanisms to track HIV-positive patients from testing to care	Not feasible No mechanisms to track HIV-positive patients from testing to care	
	NATIONAL	Not feasible Facilities cannot report data	Not feasible Facilities cannot report data	

Table 5: Feasibility of indicator, by region

QC and indicator	Feasibility (System level)	Generalized epidemic (3 African countries)	Concentrated epidemic (Eurasia and Southeast Asia)	
II. HIV Care and Treatment (HIV Trt)				
Performance Criterion #3	HIV-positive adults and children should be assessed for antiretroviral therapy (ART) eligibility through either clinical staging or CD4 testing			
Indicator 1a. Number and percentage of HIV-infected adults and children assessed for ART eligibility through either clinical staging or CD4 testing at 2 months of enrollment WHO recommended indicator	FACILITY	Feasible Data were available in pre-ART patient files Facilities can report numerator & denominator	Feasible Data were available in pre-ART patient files Facilities can report numerator & denominator	
	NATIONAL	Feasible National level can compile facility data	Feasible National level can compile facility data	
1b. Number and percentage of HIV-infected adults and children assessed for ART eligibility through either clinical staging or CD4 testing in the last 6 months WHO recommended indicator	FACILITY	Feasible Data were available in patient files Facilities can report numerator & denominator	Feasible Data were available in patient files Facilities can report numerator & denominator	
	NATIONAL	Feasible National level can compile facility data	Feasible National level can compile facility data	
Performance Criterion #4	HIV-positive adults and children must be enrolled in HIV care			
Indicator 2: Number and percentage of adults and children with advanced HIV-infection receiving antiretroviral therapy UNGASS indicator #4	FACILITY	Not feasible Incomplete data on patients leaving care, lost to follow-up, or stopped treatment Difficult to define catchment population for denominator	Not feasible Incomplete data on patients leaving care, lost to follow-up, or stopped treatment Difficult to define catchment population for denominator	
	NATIONAL	Not feasible Facilities cannot report numerator National level should be able to obtain population estimate for denominator	Not feasible in SE Asia country	Feasible in Eurasia country
Indicator 3. Number and percentage of HIV-positive adults and children currently enrolled in HIV care programs HCI indicator	FACILITY	Not feasible No mechanism to track deaths, lost-to follow-ups, or transfer-outs Difficult to define catchment population for denominator	Not feasible in SE Asia country	Feasible in Eurasia country

Table 5: Feasibility of indicator, by region

QC and indicator	Feasibility (System level)	Generalized epidemic (3 African countries)		Concentrated epidemic (Eurasia and Southeast Asia)	
	NATIONAL	Not feasible Facilities cannot report numerator National level should be able to obtain population estimate for denominator		Not feasible in SE Asia country	Feasible in Eurasia country
Performance Criterion #5	Adults and children currently enrolled in ART who adhere to their treatment regimens				
Indicator 4. Number and percentage of people starting antiretroviral therapy who picked up all prescribed antiretroviral drugs on time Global Fund HIV M&E Toolkit: HIV-T5	FACILITY	Not feasible in two countries Sites lacked data	Feasible in one country Data were collected in three out of four sites	Feasible	
	NATIONAL	Not feasible in two countries Facilities cannot report numerator data	Feasible in one country Facilities can report numerator & denominator National level can compile facility data	Feasible Facilities can report numerator & denominator National level can compile all facility-level data	
Indicator 5. Number and percentage of adults and children who keep scheduled appointments HCI indicator	FACILITY	Feasible Data were collected from ART patient files		Feasible	
	NATIONAL	Feasible Facilities can report numerator & denominator National level can compile facility data		Feasible Facilities can report numerator & denominator National level can compile facility data	
Performance Criterion #6	Retention rate among adults and children currently enrolled in ART				
Indicator 6. Percentage of adults and children with HIV known to be on treatment 12 months after initiation of antiretroviral therapy UNGASS indicator #24	FACILITY	Not feasible in two countries Incomplete data on deaths, lost to follow-ups, or stopped treatment	Feasible in one country Data were collected from database	Feasible	

Table 5: Feasibility of indicator, by region

QC and indicator	Feasibility (System level)	Generalized epidemic (3 African countries)		Concentrated epidemic (Eurasia and Southeast Asia)
	NATIONAL	Not feasible in two countries Facilities cannot report numerator data	Feasible in one country National level can compile facility data	Feasible National level can compile facility data
III. PMTCT				
Performance Criterion #7	Pregnant women must be tested for HIV and know their results			
Indicator 1. Percentage of pregnant women who were tested for HIV and who know their results Additional recommended indicator #7	FACILITY	Not feasible Difficult to define catchment population for denominator, but technical assistance would enable such calculation	Feasible in Eurasia country	Not feasible in SE Asia country Difficult to define catchment population for denominator, but technical assistance would enable such calculation
	NATIONAL	Feasible Facilities can report numerator data National level should be able to obtain population estimate for denominator	Feasible Facilities can report numerator & modified denominator National level can compile facility data	
Performance Criterion #8	HIV-infected pregnant women should receive antiretroviral medicine (ARV) to reduce the risk of mother-to-child transmission			
Indicator 2. Percentage of HIV-positive pregnant women who received antiretrovirals (antiretroviral prophylaxis or treatment if eligible) to reduce the risk of mother-to-child transmission UNGASS indicator #5	FACILITY	Not feasible Can report numerator Difficult to define catchment population for denominator but technical assistance would enable such calculation	Feasible in Eurasia country	Not feasible in SE Asia country Difficult to define catchment population for denominator but technical assistance would enable such calculation
	NATIONAL	Feasible	Feasible Facilities can report on the numerator & modified denominator National level can compile facility-level data to report national performance	

Table 5: Feasibility of indicator, by region

QC and indicator	Feasibility (System level)	Generalized epidemic (3 African countries)	Concentrated epidemic (Eurasia and Southeast Asia)	
Performance Criterion #9	Eligible HIV-positive women must receive an efficacious regime of antiretrovirals for their own health			
Indicator 3. Percentage of HIV-positive pregnant women who received antiretrovirals (antiretroviral prophylaxis, or treatment if eligible) for their own health UNGASS indicator #5	FACILITY	Not feasible Can report numerator data Difficult to define catchment population for denominator, but technical assistance would enable such calculation	Feasible in Eurasia country	Not feasible in SE Asia country Difficult to define catchment population for denominator, but technical assistance would enable such calculation
	NATIONAL	Feasible Can compile facility data	Feasible Can compile facility data	
Performance Criterion #10	Infants born to HIV-infected women should receive follow-up care, including HIV testing, Cotrimoxazole, prophylaxis and, if necessary, antiretroviral therapy			
Indicator 4. Percentage of infants born to HIV-infected women who receive an HIV test within 12 months of birth Additional recommended indicator #8	FACILITY	Not feasible Can report numerator Difficult to define catchment population for denominator, but technical assistance would enable such calculation	Feasible in Eurasia country	Not feasible in SE Asia country Difficult to define catchment population for denominator, but technical assistance would enable such calculation
	NATIONAL	Feasible National level can compile facility-level data	Feasible National level can compile facility-level data	
Indicator 5. Percentage of infants born to HIV-infected women starting on Cotrimoxazole prophylaxis within two months of birth Additional recommended indicator #9	FACILITY	Not feasible Can report the numerator Difficult to define catchment population for denominator, but technical assistance would enable such calculation	Feasible in Eurasia country	Not feasible in SE Asia country Difficult to define catchment population for denominator, but technical assistance would enable such calculation

Table 5: Feasibility of indicator, by region

QC and indicator	Feasibility (System level)	Generalized epidemic (3 African countries)	Concentrated epidemic (Eurasia and Southeast Asia)
	NATIONAL	Feasible Can compile facility data on numerator & denominator calculated with technical assistance	Feasible Should be able to obtain population estimate for denominator
IV. TB/HIV			
Performance Criterion #11	HIV-infected adults and children must be screened for TB		
Indicator 1. Number and percentage of adults and children enrolled in HIV care who had their TB status assessed and recorded during their last visit among all adults and children enrolled in HIV care in the reporting period Global Fund indicator TB/HIV-1	FACILITY	Feasible Data were collected from patient medical records	Feasible Data were collected from patient medical records
	NATIONAL	Feasible National level can compile all facility-level data to report national performance	Feasible National level can compile all facility-level data to report national performance
Indicator 2. Percentage of HIV-positive patients who were screened for TB in HIV care or treatment settings PEPFAR indicator C2.4 D	FACILITY	Feasible Data were collected from patient records Facilities can report numerator & denominator	Feasible Data were collected from patient records Facilities can report numerator & denominator
	NATIONAL	Feasible National level can compile facility data	Feasible National level can compile facility data
Performance Criterion #12	HIV-infected adults and children must receive treatment for TB and HIV		
Indicator 3. Percentage of estimated HIV-positive incident TB cases that received treatment for TB and HIV UNGASS indicator #6	FACILITY	Not feasible Technical assistance needed for calculating estimate denominator Incidence data can be difficult to obtain at this level	Not feasible Technical assistance needed for calculating denominator Incidence data can be difficult to obtain at this level
	NATIONAL	Feasible National level can compile numerator data from facilities National level should be able to obtain population estimate for denominator	Feasible National level can compile facility data

Table 5: Feasibility of indicator, by region

QC and indicator	Feasibility (System level)	Generalized epidemic (3 African countries)	Concentrated epidemic (Eurasia and Southeast Asia)
Indicator 4. Number and percentage of adults and children newly enrolled in HIV care who started treatment for latent TB infection (isoniazid preventive therapy) among the total number of adults and children newly enrolled in HIV are over a given time period Global Fund indicator TB/HIV-4	FACILITY	Feasible Data were collected from patient records	Feasible Data were collected from patient records
	NATIONAL	Feasible National level can compile facility data	Feasible National level can compile facility data
Indicator 5. Number and percentage of adults and children enrolled in HIV care who started TB treatment, the percentage is expressed as a proportion of adults and children in HIV care during the reporting period Global Fund indicator TB/HIV-2	FACILITY	Feasible Data were collected from patient records	Feasible Data were collected from patient records
	NATIONAL	Feasible National level can compile facility data	Feasible National level can compile facility data

Table 5: Feasibility of indicator (harm reduction only), by region – Southeast Asia & Eurasia

QC and indicator	Feasibility (System level)	Southeast Asia	Eurasia
V. HARM REDUCTION EASTERN EUROPE AND SOUTHEAST ASIA ONLY			
Performance Criterion #13	Injecting drug users (IDUs) should use sterile injecting equipment		
Indicator 1. Percentage of injecting drug users who reported using sterile injecting equipment the last time they injected. UNGASS Indicator #21	FACILITY	Not Feasible Behavioral surveillance survey usually conducted on regional or national scale	Not feasible Behavioral surveillance survey usually conducted on regional or national scale
	NATIONAL	Feasible National level should be able to conduct a behavioral surveillance survey to report this indicator	Feasible National level should be able to conduct a behavioral surveillance survey to report this indicator
Performance Criterion #14	Sufficient quantities of syringes must be provided to injecting drug users		

Table 5: Feasibility of indicator, by region

QC and indicator	Feasibility (System level)	Generalized epidemic (3 African countries)	Concentrated epidemic (Eurasia and Southeast Asia)
Indicator 2. Number of syringes distributed per IDU per year UNODC Technical Guide 4.1.7	FACILITY	Feasible Facilities recorded numbers of syringes distributed to each IDU	Feasible Facilities recorded numbers of syringes distributed to each IDU Data were collected from client charts
	NATIONAL	Feasible National level can compile facility data	Feasible National level can compile facility data
Performance Criterion #15	Patients in opioid substitution therapy (OST) should receive the optimal maintenance dose		
Indicator 3. Percentage of patients in OST receiving recommended maintenance dose UNODC Technical Guide 4.2a.9	FACILITY	Not applicable	Feasible Facilities recorded doses of methadone given to each IDU Data were collected from client charts and were also compiled in an Excel spreadsheet
	NATIONAL	Not applicable	Feasible National level can compile all facility data
Performance Criterion #16	Patients in OST should remain in treatment for an optimal period		
Indicator 4. Number and percentage of individuals currently on OST who have been on OST continuously for the past 12 months UNODC Technical Guide 4.2a.10	FACILITY	Not applicable	Feasible All required data were available in client charts
	NATIONAL	Not applicable	Feasible National level can compile facility data
NEW Performance Criterion	Clients should be stabilized in OST treatment during 12-month period		
Indicator 5. Percentage of individuals currently on OST who are stabilized in OST treatment in the past 12 month period (Informed by field test)	FACILITY	Not applicable	Feasible All required data were available in client charts Facilities can report numerator & denominator
	NATIONAL	Not applicable	Feasible National level can compile facility data

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