

**EngenderHealth**  
for a better life

**ENSURING CLINICAL QUALITY:  
Guidance for Sexual and Reproductive  
Health Programs**

**January 2015**

# CONTENTS

I. Introduction .....	2
A. Purpose .....	2
B. Audience .....	2
C. Accompanying Documents .....	2
II. Ensuring Clinical Quality.....	3
A. Definition .....	3
B. The ECQ Framework.....	3
C. Components of ECQ .....	4
1. Clinical Guidelines and Standards.....	4
2. Clinical Training .....	5
3. Clinical Monitoring and Coaching .....	6
D. ECQ Roles and Responsibilities .....	9

# Ensuring Clinical Quality: Guidance for Sexual and Reproductive Health Programs

## I. Introduction

Quality improvement (QI) approaches and tools have been the hallmark of EngenderHealth's support to programs for assessing and addressing quality of services. EngenderHealth's QI processes are designed to help health systems and health care staff move from current practices to best practices ensuring quality of care in the areas of family planning, maternal health, and HIV. **Ensuring clinical quality (ECQ)** is an important aspect of delivering high-quality, client-centered services. Clinical quality refers to the aspects of quality that relate to clinical procedures and the environment in which these procedures are performed. It encompasses all processes related to defining and managing individuals' health needs and problems (Campbell, Roland, & Buetow, 2000).

### A. Purpose

This document is designed to provide guidance in programming for, implementing, and evaluating the clinical aspects of sexual and reproductive health programs. It defines the critical components of ECQ and outlines key functions related to each component. It also provides guidance on the various EngenderHealth QI tools and resource materials that can be used in ECQ. Other, equally important aspects of quality, including interpersonal and nonclinical or nontechnical dimensions of care (Campbell, Roland, & Buetow, 2000; Valentine, Darby, & Bonsel, 2008), are not the focus of this document. However, ensuring both clinical and nonclinical aspects of quality relies on a common set of concepts, principles, and approaches, and many of the same tools used in ECQ also address nonclinical aspects of quality. In addition, other EngenderHealth QI approaches and tools, such as facilitative supervision and COPE<sup>®</sup>, focus more specifically on such dimensions of care.

### B. Audience

The audience of this document is EngenderHealth program staff, clinical staff, and in-country partners. For some of the functions described in this framework, EngenderHealth has produced (and will produce) resources to be shared and used with and adapted by its partners (sister organizations and in-country partners).

### C. Accompanying Documents

The following documents support the operationalization of the framework:

- Clinical Monitoring and Coaching Toolkit
- Clinical Training Toolkit
- Clinical Training Curricula and Materials
- Facilitative Supervision for Quality Improvement
- Programming for Training: A Resource Package
- Clinical Support Standards and Practices (under development)

## II. Ensuring Clinical Quality

Medical monitoring has been one of EngenderHealth's well-known QI interventions. It concerns medical site visits in which the *readiness* and the *processes of service delivery* are assessed in an objective and ongoing way. Based on field experience and lessons learned, the "medical monitoring" concept has evolved into a framework that includes not just medical site visits, but other interventions that support clinical quality as well. This framework is called ECQ. It ensures the **clinical quality and safety** of services by helping in-country partners adapt and institutionalize best practices.

### A. Definition

**ECQ** is a **framework comprising processes, approaches, and tools** to guide EngenderHealth staff in **planning and programming** technical assistance. The framework is intended to support and guide in-country partners on their **capacity building** and **systems strengthening**, to ensure the quality and safety of clinical services.

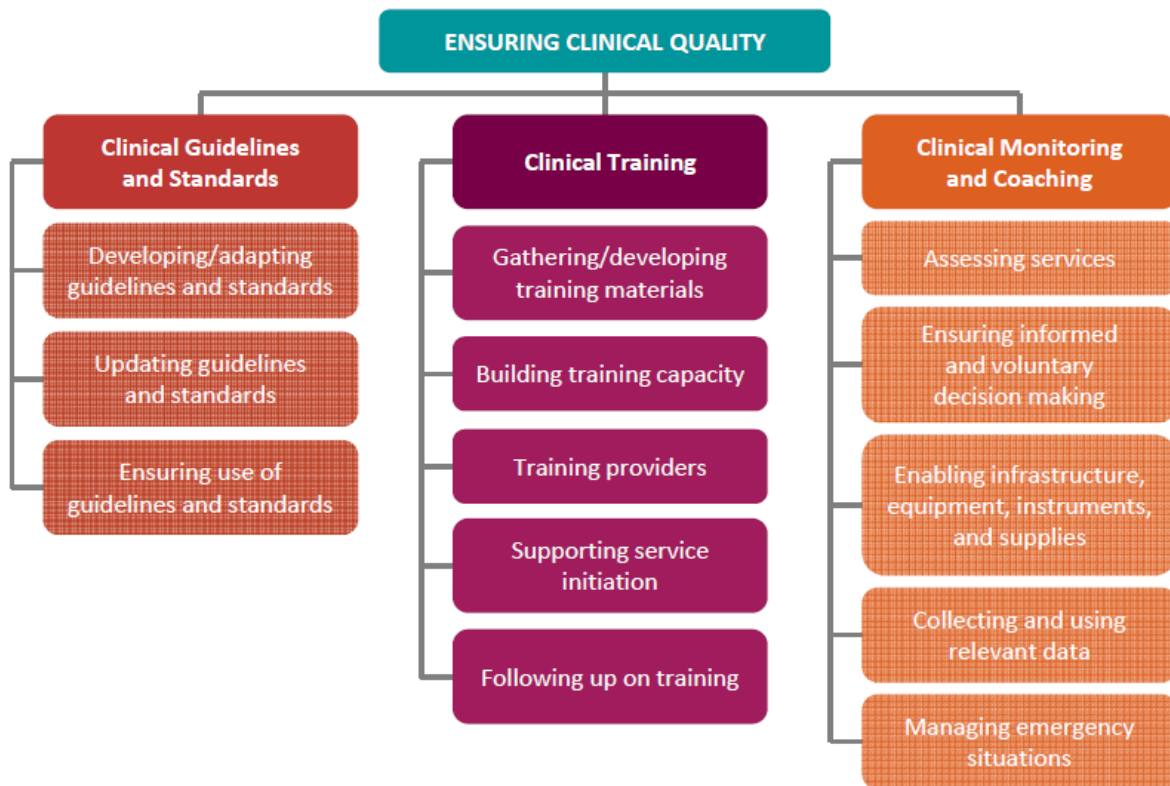
### B. The ECQ Framework

The ECQ framework should inform EngenderHealth staff and in-country partners about their respective responsibilities in clinical activities (see Figure 1). The implementation of this framework requires use of approaches and tools such as facilitative supervision, clinical training curricula, clinical monitoring and coaching tools, COPE, etc. The **ECQ** framework has three main components:

- ***Clinical guidelines and standards*** constitute the reference for clinical work, and EngenderHealth supports development, dissemination, and use of these materials. They contribute to the enabling environment for quality services. EngenderHealth uses international guidelines to inform implementation at the country level.
- ***Clinical training*** is one of the major capacity building/investment activities in programs. It is essential for introducing new technologies, practices, and services, as well as for improving existing approaches to get programs up and running.
- Finally, ***clinical monitoring and coaching*** involves looking into the provision of services while at the same time providing appropriate support to ensure clinical quality.

Each component and its processes represent the range of activities that EngenderHealth staff and in-country partners undertake to support and improve the clinical quality of programs and projects. Under each component, EngenderHealth staff work closely with partners (e.g., ministries of health, nongovernmental organizations, etc.), toward the eventual goal of building local capacity and strengthening health systems by helping partners adapt, internalize, institutionalize, and effectively implement these processes.

Figure 1. The Ensuring Clinical Quality Framework



## C. Components of ECQ

### 1. Clinical Guidelines and Standards

Internationally developed and endorsed clinical guidelines and standards constitute the reference for clinical work. EngenderHealth supports the development, dissemination, and use of such clinical guidelines and standards.

#### a) *Developing and adapting guidelines and standards*

- National guidelines and standards and related clinical norms and protocols are derived from evidence-based practices and international guidance, such as those developed by the World Health Organization (WHO). Similarly, experience and evidence from the field informs the development and updating of guidelines and standards at the international level. EngenderHealth plays a key role in advocating for the development of international standards through participation in generating new evidence and data.
- EngenderHealth clinical staff and in-country partners also identify (often during site visits), analyze, and correct written and “unwritten” medical/clinical policies and practices that can be detrimental to quality service provision. These policies and practices are sometimes called “medical barriers.” To address such barriers, EngenderHealth contributes to

developing/reviewing policies and guidelines, both in individual country programs and through international efforts such as the WHO's Implementing Best Practices initiative.

**b) *Updating guidelines and standards***

EngenderHealth clinical staff provide support to local institutions to review, update, and use their national guidelines and standards to support the provision of quality services. Service quality is assessed against these standards.

**c) *Ensuring dissemination and use of guidelines and standards***

EngenderHealth clinical staff and in-country partners promote the use of service delivery guidelines and standards during program implementation. Promotion and dissemination can also be accomplished by corresponding via e-mail, by referring to service delivery guidelines and standards in reports, or while reviewing documents produced by the program/project. Adherence to the standards is verified during training follow-up and clinical monitoring as well.

## **2. Clinical Training<sup>1</sup>**

Clinical training is used to introduce new services and improve existing ones—e.g., training covering no-scalpel vasectomy (NSV), postabortion care (PAC), fistula repair, male circumcision, and antiretroviral therapy (ART). Training may be on new skills for trainees or it may represent refresher training. Once training needs are assessed and identified in a clinical area, the following training-related activities are carried out by EngenderHealth clinical staff and in-country partners. Please note that these activities are not listed in chronological order. Often, they occur simultaneously.

**a) *Gathering/developing training materials and job aids***

When preparing for training on clinical procedures, EngenderHealth staff and in-country partners should check whether there are already-developed materials that are appropriate. If training materials already exist, they should be used as they are or adapted or updated, if necessary. Otherwise, these materials can be developed jointly by EngenderHealth and in-country partners.

**b) *Building training capacity***

Creating a sustainable training system within institutions is the ultimate goal of any training collaboration. Work in this area can be grouped as follows:

- i. ***Creating a pool of trainers***—Potential trainers go through a process known as **training of trainers (TOT)**. The first part of a TOT entails the **standardization of clinical skills** among potential trainers and the design, adaptation, or improvement of an existing learning guide. The standardized learning guide for any clinical procedure (e.g., intrauterine device insertion/removal, implant insertion/removal, fistula repair, and male circumcision) is essential to ensure the quality of the clinical training aiming to ensure standardization among existing or future trainers. Then these potential trainers go through the second part of the TOT—**training skills standardization**. This is where the trainers use these adapted training materials to conduct training in the presence of advanced and master trainers and receive feedback on their facilitation skills. Through experience, further training, and coaching, trainers become advanced trainers and master trainers.

---

<sup>1</sup> Details about EngenderHealth's approach to clinical training can be found in *Programming for Training* (ACQUIRE Project, 2008).

- ii. ***Finalizing training curricula and materials***—Adapted or newly developed training materials should first be field-tested. Accordingly, they can then be revised and finalized jointly with in-country partners.
- iii. ***Developing training guidelines and protocols***—Additionally, international and EngenderHealth training guidelines should inform the development of locally adapted training protocols that describe how clinical training in a given area will be planned and coordinated. This will include the selection of training sites, trainees, and trainers, the description of performance to standard,<sup>2</sup> criteria for certification, etc.

**c) *Training providers***

Service providers receive training on knowledge, skills, and attitudes, applying adult learning principles and using humanistic training techniques. This training is competency-based and is linked to desired performance on the job. Therefore “performance to standard” is assessed both at the end of the training and during training follow-up and subsequent supervisory visits.

**d) *Supporting service initiation***

In addition to training, the trained service providers need an enabling environment in which to transfer their learning into performance at the workplace. This is achieved by attending to the remaining performance factors, such as infrastructure, supplies, instruments, and equipment; ensuring well-defined job expectations; supplying motivation to perform; and offering immediate feedback on performance. These factors should be planned and addressed before the provider is trained, as well as during and immediately after the training.

**e) *Following up training***

Training follow-up, through visits to the trainee’s facility, other communication (phone calls, surveys, mailing, e-mailing, meetings, etc.), or any combination of visits and communication, is essential for transforming learning into practice. During follow-up visits, trainers coach their trainees at their workplaces by observing them while they perform the procedures, by assessing performance to practice, and by providing immediate feedback for improvement. This is one of the most effective ways of addressing all performance factors<sup>3</sup>.

**3. Clinical Monitoring and Coaching**

At one time, clinical monitoring and coaching was called “medical monitoring” (see page 3). It has evolved to encompass more than the site visit to assess *site readiness* and the *processes of service delivery* in an objective and ongoing way. One needs to attend to several other aspects of service provision, some of which can be assessed during site visits, while others do not require waiting for a site visit and can be accomplished through ongoing communication by other means.

Since clinical monitoring and coaching produces and captures a lot of useful data, it should be closely linked to the monitoring and evaluation (M&E) plans (or performance management plans [PMPs]) of the programs being supported.

---

<sup>2</sup> “***Performance to standard*** in the RH/FP service delivery setting” is defined as the measure of performance based on established standards of care (ACQUIRE Project, 2008).

<sup>3</sup> “***Performance factors***” To improve performance, providers need clear job expectations, feedback on performance, motivation, adequate infrastructure, supplies and equipment, and up-to-date knowledge and skills. (<http://www.intrahealth.org/sst/intro.html#subsection2>)

Following are the five main components of clinical monitoring and coaching:

**a) *Assessing services***

Assessing services is the process of objective assessment of services and of the environment in which these services are offered (actual compared with desired standards), determination of the cause(s) of any gaps, and development of interventions for improvement based on the cause(s). Services can be assessed in two ways:

- *Internally*—Ongoing facility-based assessment may be undertaken by staff and on-site supervisors (through facilitative supervision and QI tools such as COPE<sup>®</sup> or other assessment tools).
- *Externally*—Periodic site visits may be conducted by off-site supervisors of the same institution or by EngenderHealth staff accompanied by those supervisors.

Regardless of how assessments are done, they should be completed in a facilitative manner. Assessment entails certain activities:

- i. Interviewing staff, managers, and clients
- ii. Conducting facility walk-throughs and record reviews
- iii. Observing service provision

Guidance on how to conduct these assessment activities and on the tools needed is provided in the ***Clinical Monitoring and Coaching Toolkit<sup>4</sup>***, which includes Clinical Monitoring and Coaching Guidelines and a set of checklists.

Skills development to implement ongoing clinical monitoring and coaching happens during clinical and training skills standardization workshops, as part of a specific training (such as facilitative supervision for quality improvement) and on the job—i.e., during a site visit—through modeling and coaching.

**b) *Ensuring informed and voluntary decision making***

***Informed and voluntary decision making*** is one client's rights, and EngenderHealth is dedicated to ensuring that across all programs it supports, all decisions are made voluntarily, based on complete and accurate information. There are numerous opportunities for EngenderHealth's clinical staff and in-country partners to collect firsthand data on clients' decision making, through on-site visits and via different communication channels. These include:

- i. Observation of counseling sessions
- ii. Interviews with service providers and clients
- iii. Observation of the availability of an ample range of contraceptive methods (of particular importance for ensuring family planning choice) or of an ample range of treatment options and the accessibility of services to the client (including elimination of medical barriers)
- iv. Availability and correct use of behavior change communication materials

---

<sup>4</sup> (Working draft available at [http://intranet.engenderhealth.org/global/Clinical%20Support/ECO/Clinical%20Monitoring%20Toolkit\\_0311%202\\_.pdf](http://intranet.engenderhealth.org/global/Clinical%20Support/ECO/Clinical%20Monitoring%20Toolkit_0311%202_.pdf))



- v. Documentation of informed and voluntary decision making and/or informed consent for surgical procedures
- vi. Review of client records and service statistics

As part of the EngenderHealth's Family Planning Compliance SOPs, clinical, program, and operations staff are also required to check for compliance with U.S. government policies and statutory requirements that relate to choice and voluntarism as they implement their activities, such as conducting site visits, reviewing documentation for disbursements, etc.

**c) *Enabling infrastructure, equipment, instruments, and supplies***

One needs to make sure that clinical equipment and instruments are available and are in good working condition. During site visits, EngenderHealth staff and in-country partners observe available equipment, instruments, and supplies, and note their condition and whether they are correctly utilized, cared for and maintained, and stored.

When EngenderHealth directly purchases clinical equipment, instruments, and supplies, clinical staff should review and approve the purchase to ensure that they meet program needs, local specifications, and EngenderHealth recommendations. If EngenderHealth's in-country partners or third parties are the purchasers, EngenderHealth clinical staff can provide advice and support.

For facility renovation and furnishing, clinical staff should make sure that these follow international guidelines and standards for quality service provision.

**d) *Collecting and using relevant data***

Collecting and using data is a component of clinical monitoring and coaching and is accomplished through site visits and other means of communication, such as regular data reporting, data analysis, and communication with site staff responsible for clinical service data.

EngenderHealth's clinical, monitoring, and evaluation staff and in-country partners work together to improve data gathering and use. Staff are encouraged to regularly collect data, analyze it, and make data-supported changes to service provision as a result of the analysis. Staff are encouraged to submit service data in a timely manner to higher levels within the system so that they can be used for management and administrative decision making to support quality service delivery. To ensure the quality of reported service statistics, data quality assessment (DQA) can be used. Detailed information on DQA can be found in the ***Clinical Monitoring and Coaching Toolkit***.

During ongoing facility-based assessments and site visits, data are collected from various sources—interviews, observations, and facility walk-throughs. The data are captured on structured tools such as checklists provide a better understanding of the volume and type of service provision, the extent of informed choice, the quality of service delivery, any complications (including mortality), unmet need, and the gaps that require attention. Some of the data are intended for immediate use, to allow corrective action to be taken on the spot.

Some data, however, need to be entered into databases and analyzed to help identify needs for quality improvement and other programmatic gaps.

To accomplish the above-mentioned functions, EngenderHealth staff and in-country partners are trained in the use of data for decision making. Programs and projects define the scope and extent of the data that need to be collected and used in their M&E plans (PMPs), based on indicators.

**e) *Managing emergency situations***

As with any other health program, complications and death may occur during the implementation of a sexual and reproductive health program. Additionally, vulnerabilities or violations of informed and voluntary decision making may be detected. EngenderHealth and in-country partner staff should be educated on how to manage such situations. These emergency situations should be reported immediately within EngenderHealth, within the in-country recipient organization, and to the donor. Detailed guidance on this issue is provided in the following documents:

- i. ***Clinical Monitoring and Coaching Toolkit*** (Working draft available at [http://intranet.engenderhealth.org/global/Clinical%20Support/ECQ/Clinical%20Monitoring%20Toolkit\\_0311%202020.pdf](http://intranet.engenderhealth.org/global/Clinical%20Support/ECQ/Clinical%20Monitoring%20Toolkit_0311%202020.pdf))
- ii. ***EngenderHealth Policy for Clinical Staff Direct Provision of Clinical Care and Surgical Procedures*** (Available at [http://intranet.engenderhealth.org/global/Clinical%20Support/Clinical%20Care%20and%20Surgical%20Procedures%20Policy\\_053013.docx](http://intranet.engenderhealth.org/global/Clinical%20Support/Clinical%20Care%20and%20Surgical%20Procedures%20Policy_053013.docx))
- iii. ***Guidelines for Complications Reporting, Protocol for Auditing*** (soon to be posted on intranet)
- iv. ***Reporting Mortalities Related to LAPM*** (soon to be posted on intranet)
- v. ***FP Compliance SOPs*** (Available at [http://intranet.engenderhealth.org/global/fp/standard\\_operating\\_procedures.htm](http://intranet.engenderhealth.org/global/fp/standard_operating_procedures.htm))

## **D. ECQ Roles and Responsibilities**

The role of EngenderHealth staff is to provide technical assistance (TA) and support for facilitating the implementation of ECQ processes by in-country partners. While providing this TA and support, EngenderHealth staff should help to build capacity among in-country partners to ensure that they are able to adapt and use these ECQ processes in a sustained manner. All three components of the ECQ framework should ultimately be handed over to in-country partners.

In this regard, while providing TA, EngenderHealth staff responsibilities are as follows:

1. Invest in one's own development to be able to implement all ECQ processes
2. Familiarize oneself with the host institution/partners
3. Listen to the perspectives of the host institution/partners
4. Involve in-country partners and all stakeholders (including EngenderHealth's Clinical Support Team) in programming for and designing ECQ processes
5. Promote globally accepted and up-to-date standards
6. Work with in-country partners to tailor one's approach and ECQ processes and tools to the country context (need, working style of the host institution)
7. Be thorough in operationalizing all components of the ECQ framework

8. Develop a local capacity-building plan right from the start and orient in-country partners to that end, so that they set realistic expectations
9. Make sure that ownership rests with the host institution/partner
10. Work in a collegial atmosphere in planning, implementing, and evaluating ECQ processes
11. Model behavior, attitudes, and skills while implementing ECQ processes (such as during clinical training, when conducting a site visit to assess services, etc.)
12. Gradually decrease EngenderHealth involvement and responsibility while encouraging and coaching in-country partner staff to take responsibility for conducting ECQ processes—starting with cultivating “know-how” followed by logistics and funding
13. Hand over ECQ functions to in-country partners
14. At every stage, share lessons learned and materials produced with EngenderHealth Clinical Support Team

By accomplishing the above-mentioned responsibilities, EngenderHealth’s global knowledge is transferred to the country, and the country experience contributes to the pool of global knowledge.

In summary, EngenderHealth clinical staff are responsible to their program managers at the program level and to the Clinical Support Team at the global level for implementation of this framework. Clinical staff should work in close collaboration with the members of the Clinical Support Team in the design and implementation of ECQ activities, as well as in transferring the learning in both directions. Program managers should provide clinical staff with support and hold them accountable to make this happen.

## References

The ACQUIRE Project. 2006. *The fundamentals of care: Ensuring quality in facility-based services—A resource package*. New York.

The ACQUIRE Project. 2008. *Programming for training: A resource package for trainers, program managers, and supervisors*. New York: EngenderHealth/The ACQUIRE Project.

Campbell, S. M., Roland, M. O., and Buetow, S. A. 2000. Defining quality of care. *Social Science and Medicine* 51(11):1611–1625.

Valentine, N., Darby, C., & Bonsel, G. J. 2008. Which aspects of non-clinical quality of care are most important? Results from WHO's general population surveys of health systems responsiveness in 41 countries. *Social Science and Medicine* 66(9):1939–1950.