

FHI Standards Development

A Guide to Developing,

Communicating, and

Monitoring Standards

FHI Standards Development:
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The framework for this document was developed during a standards development workshop held at the FHI offices in Arlington, Virginia, in July 2009. Joanne Ashton, a consultant with Joint Commission International (JCI), prepared the original draft, which was reviewed by the workshop participants and also by Gary West, FHI's senior vice-president.

FHI staff members who participated in the workshop were Bruno Bouchet, Esther Braud, Gina Etheridge, Carla Horne, Michelle Huff, Claudes Kamenga, Justin Mandala, Nilu Rimal, Ilka Rondinelli, and Leine Stuart.

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AHD	Adolescent Health Department
AHRQ	Agency for Health Care Research and Quality
AIDS	Acquired immunodeficiency syndrome
CO	Country office
HIV	Human immunodeficiency virus
HSS	Health Systems Strengthening
HQ	Headquarters
IEC	Information, education, and communication
IMCI	Integrated Management of Childhood Illnesses
JCI	Joint Commission International
NGO	Nongovernmental organization
NICE	National Institute for Health and Clinical Excellence
NLH	National Library for Health
QA	Quality assurance
QI	Quality improvement
RO	Regional office
SOP	Standard operating procedure
STI	Sexually transmitted infection

FHI responds to the public health needs of resource-poor countries throughout the world. Directly and through local implementing partners, we support local health systems to design, deliver, and evaluate programs that combat HIV/AIDS, tuberculosis, malaria, and other infectious and chronic diseases, and that address reproductive health issues. This support includes technical assistance in developing and implementing standards for care and support services as well as for program management. Creating an effective process to develop meaningful standards is an important and challenging task for international health development organizations.

FHI has a cadre of health care professionals who provide technical assistance to countries in need. Each health care professional has a different knowledge base and a different set of experiences and skills, which often results in different approaches to helping countries set and implement program standards. Although individuality and creativity are part of the flexibility that is necessary to respond to specific contexts, the lack of a common approach to developing service and management standards can be problematic and might result in standards that do not achieve the expected outcomes. As a result, FHI decided to review existing practices for developing standards and then to establish a standards development model.

Goals of the FHI Standards Guide

The goals of the FHI Standards Guide are (1) to help staff members create standards for more efficient service and management processes and (2) to guide professionals assisting countries to establish and implement health care standards. To achieve these goals, the guide sets forth a process for developing, communicating, implementing, and monitoring standards for FHI-supported programs to assure the quality of services and the correct performance of programs and systems.

The Role of Quality in Standards Assurance

Because each individual could have a different idea of what constitutes quality, it needs to be explicitly defined through standards. The Quality Assurance Triangle illustrates the three parts of a quality assurance (QA) process: defining, measuring, and improving quality.

- *Defining quality* refers to (1) setting the administrative and clinical standards for processes and services—that is, the expectations for quality; and (2) communicating and implementing the standards. When standards are defined, measurements can determine if the standards have been met.
- *Measuring quality* refers to collecting data to determine whether standards are being met, processes are being carried out as planned, and services are being delivered as defined—that is, identifying any gaps between the standards and their implementation. Gaps become opportunities for improvement.
- *Improving quality* refers to staff members and their supervisors working together (1) to understand the identified gaps; and (2) to develop and implement strategies and methodologies to close the gaps and meet the standards—that is, to improve the quality of processes and services.

Quality Assurance Triangle*



Scope of the FHI Standards Guide and Its Users

The FHI Standards Guide is designed for FHI employees to use as they develop and implement standards both within the organization and in the field. Thus, the process it describes is equally applicable to the development of administrative, management, technical, and service standards.

Terms and Definitions

Part of the requirement for effective standards, and therefore a goal of this document, is to establish a consistent terminology to describe standards. The participants in the standards development workshop established the following terms and definitions:

1. *Algorithm* refers to a tool that is designed to direct decision making, such as a flow chart, decision tree, or decision grid.
2. *Guidelines* refers to a set of recommendations that are based on scientific evidence or expert consensus to assist in making appropriate decisions about health care and treatment and for program management.
3. *Job descriptions* refers to a document that outlines the qualifications (education, experience, skills, and licensure) that are needed to fill a particular position as well as the roles and responsibilities of that position.
4. *Policy* refers to a statement of expectations that is designed to influence and determine decisions and actions and that is approved by the management of an institution.
5. *Standard* refers to an explicit statement of expected quality.
6. *Standard operating procedures (SOPs)* refers to the chronological steps for carrying out a task or function.

*Franco LM, Silimperi D, Veldhuyzen van Zanten T, MacAulay C, Askov K, Bouchet B, Marquez L. Sustaining quality of healthcare: institutionalization of quality assurance. QA Monograph Series 2(1). Bethesda, MD: Published for the United States Agency for International Development by the Quality Assurance Project; 2002.

The purpose of standardization is to streamline a process or activity to ensure that all participants know what is expected and how to meet the expectations. Accordingly, most organizations have policies and SOPs to achieve this end. The definition of standard adopted by FHI is an explicit statement of expected quality. Explicit means that the expectation is written out so that it is unequivocal. Written standards can serve as a keystone for other processes and functions such as quality improvement, staff orientation, and performance appraisals.

A critical component of nearly all current standards-setting efforts is a commitment to forging a consensus between the community (the beneficiaries), the political bodies, and professional organizations. If these standards are to be accepted by the community for which they are intended, then they have to reflect shared values and commitments of the community. But if change is desired, then these standards need to do more than reflect current practice. A systematic process for developing and implementing standards that are based on sound change-management strategies will increase the acceptance of the standards and the likelihood of their implementation. The seven-step standards development process that is outlined in the FHI Standards Guide will assist you in developing and implementing standards. An example of the implementation of adolescent-friendly clinic service standards is used to illustrate each step.

The development of standards begins with the perception that standards need to be developed. Whether this is an individual's perception or a group's, the steps will be the same. Step one will assist you or your group in thinking through the value of developing standards. And if you and the group decide to proceed, the steps that follow will guide you through the process.

Developing standards takes time and money, and it therefore makes sense to question what value the intended standards would bring to the activity, process, or conditions for which the standards are being considered. The value is typically considerable in situations that could be described in the following ways:

- High-volume: activities, processes, functions, or conditions that occur frequently
- High-risk: activities, processes, or conditions that pose a risk to the organization or to an individual; for example, activities that are dangerous or unsafe
- Problem-prone: processes that have been identified as problematic because of inconsistent practices or outcomes, duplication of effort, redoing, and complexity of tasks
- New: new activities, practices, or processes that require guidance (See Example 1 on page 3)

Step 1. Define the Topic

If you think that standards would be useful for activities or programs in which you are involved, you must first define the topic and the goal of the standards. What will be different as a result of developing these standards? You should do some background investigation to determine if standards already exist, either within FHI or through another source. And you should determine if the standards are being developed for FHI as an organization or for countries. If you are proposing the development of technical standards for a program—for example, palliative care—you should question whether these standards are intended for implementation at the national or facility level. The importance of this distinction is that national standards are typically broad policy statements, whereas facility-level standards guide patient care activities. Technical staff from the Health Systems Strengthening unit could facilitate this step. After careful consideration of the value of

Example 1. Adolescent-friendly service standards

In a given country, at least two in ten teenagers are infected with the HIV virus (high volume). For the majority of young people, sexual activity starts in the mid-teens (high risk). A substantial number of teenagers indicated that they needed more information on matters such as pregnancy, sexually transmitted diseases, sexual intercourse, and relationships. It was also identified that the public health facilities were failing to provide adolescent-friendly health services (problem-prone). Out of this insight, an Adolescent Health Department (AHD) was conceived, with the goal of developing service standards for this particular group.

developing standards, you and/or your group should be ready to write a short concept paper on the purpose of the standards.

Let's assume that a standards committee has been established to facilitate the standards-development process. When you are clear about the topic and purpose of your standards, submit your ideas to the committee. After the committee gives the go-ahead to proceed with the development of the standards, you will need to include this work in your operational plan.

Step 2. Identify Participants and End Products

Developing standards is not a one-man job. You need to consider all aspects of the process for which you are developing standards and include the stakeholders. The stakeholders are the people who will be involved in implementing the standards or impacted by them. If you are developing SOPs for FHI, staff members at all levels need to be included in the process. If, for instance, you are developing a procedure for conducting FHI workshops, think of each step of the process—organizing the event, preparing the educational materials, setting up the technology—that will be used, making accommodations for participants, training, and so forth. People involved in each aspect of this process should be included in developing the standards.

If the standards are being developed for country programs, then you want to invite representatives from the country to participate. You should include experts on the subject and possibly an expert in standards development (Example 2). Approaches to balancing representation differ significantly across various local, regional, and national efforts. Some emphasize grassroots involvement, some stress professional participation, and others rely on a blend of strategies at different stages of the process.

Writing the standards takes a concerted effort that includes the following:

- Identifying a core group (task force) to work on the standards, other participants for ad hoc activities, and a team leader for the task force
- Outlining lines of authority and communication
- Identifying resources, funds for travel (if any), and approval processes that will be required (The approval process should be described in a policy or procedure.)
- Defining the most appropriate communication channels and processes (on-site or on-line)

The task force needs to think about creating linkages across the subject matter to ensure that, as a collective, the standards are complementary, not contradictory or redundant within FHI. This approach acknowledges the shared subject and the need to promote standards that interrelate. Encouraging cross-disciplinary and subject discussions during the standard-setting process might improve the prospects for developing multidisciplinary teaching and learning.

The task force must agree on an end product—for example, a set of standards, a guide to describe implementation, and assessment tools—and then create a written action plan that identifies the activities, the responsible parties, and the time frame to keep everyone on task.

Example 2. Adolescent-friendly services conference

A panel of national and international experts in adolescent and sexual reproductive health was convened to initiate the program. The question posed was “What constitutes adolescent-friendly services?” Experts in the area of adolescent health and quality improvement were invited to design an approach based on quality concepts. In addition to the input provided by the experts, focus groups were held to talk with young people regarding their needs and expectations of clinic services.

Step 3. Gather Information

Good decisions depend on having good information. During the meetings, the task force can use collected data and materials and quality-improvement (QI) tools (as described below) to consider the elements that they want to build into the standards.

Preparatory Materials

Prior to the first meeting with the task force, the person selected to lead the standards development process should gather information regarding the topic. Careful research into the background of each subject area can help the developers assure representation that crosses divisions within a field. The task leader should invite the members of the task force to provide articles or data that they have regarding the subject. This information will prepare the members for their discussions. The leader, or a member of his or her unit, should collect data regarding the following:

- Existing standards
- Laws and regulations
- Current practices
- Clinical evidence
- Technology

Health care providers are routinely barraged with different sets of standards promoted by various organizations. Most of these standards are similar in content, but the slightest variance can confuse

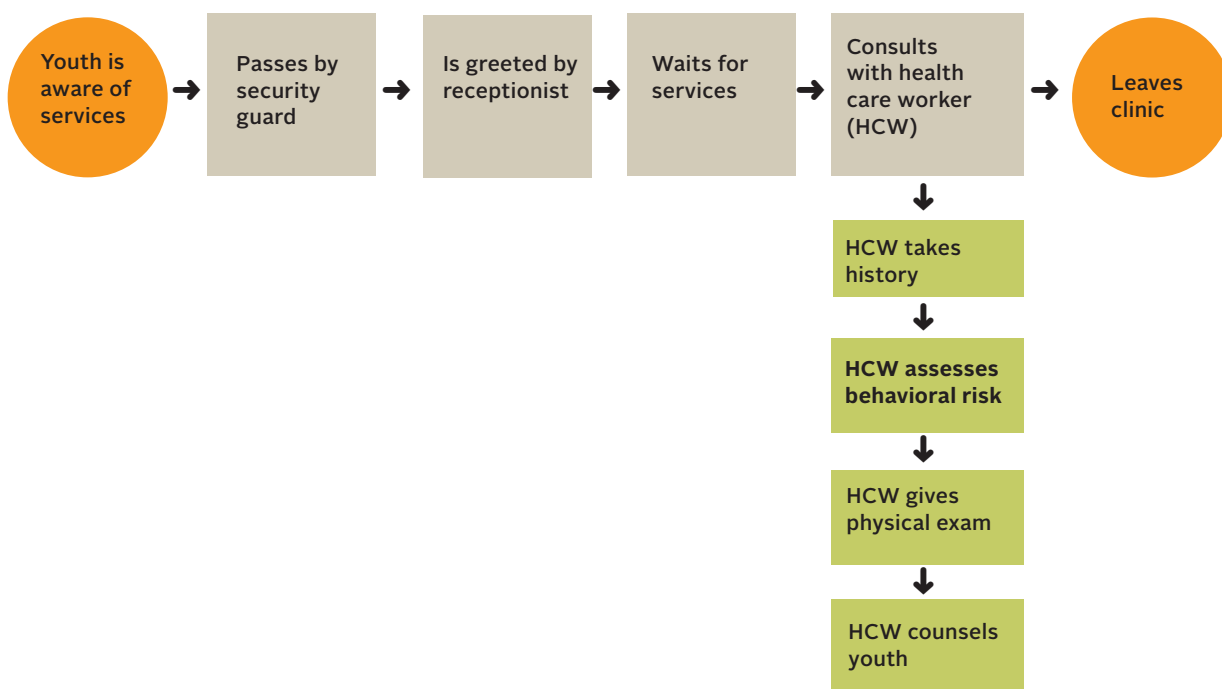
the end user. Standards-setting efforts need to focus on more coordinated efforts between organizations and build on standards that have already been developed. Some of the experts may be invited to make presentations to provide the task force with the most recent information and experiences regarding the topic.

Use of Quality-Improvement Methods and Tools

You can also use QI methods to investigate the issues related to the topic. A flow chart can be used to plot out the steps of the process. Standards should be developed based on a systems approach. This means you should consider each activity, process, and so forth, within the context of the whole system. The adolescent-friendly clinic standards were not focused solely on improving interpersonal relationships, but also took into account each piece of the system that would impact the quality of reproductive health services for adolescents. The logic is that young persons might be treated in a friendly manner, but if the drugs are not available to treat their problems or the counselors do not have the skills to counsel them properly, the quality of the service remains poor. Thus, a young person who comes in for services needs to encounter a clinic equipped with competent staff, educational materials, drugs, supplies, and equipment. Each of these elements can be organized into inputs (resources needed to carry out the activity), processes, and outcomes. You can then develop standards for each one of them.

The first row of Example 3 shows a high-level flow chart of a young person accessing and receiving adolescent-friendly services. The task force decides when to begin and end the flow; the beginning and ending of a process are depicted with circles. The steps between the circles are agreed upon by the task force.

Example 3. Adolescent-friendly services flow chart



For each step, a secondary flow chart is made, as shown under the Consults with HCW step. Each box shows a process, and each process has inputs. Take, for example, the process of consultation: What is needed to perform a consultation?

Inputs for conducting a consultation

History-taking	Behavioral risk assessment	Physical exam	Counseling
<ul style="list-style-type: none"> • Trained staff • Form to document history • Policy/procedure regarding expectations for history-taking 	<ul style="list-style-type: none"> • Trained staff • Form to document risk assessment • Policy/procedure regarding expectations for performing risk assessment 	<ul style="list-style-type: none"> • Trained staff • Form to document exam • Policy/procedure regarding expectations for performing physical exam 	<ul style="list-style-type: none"> • Trained staff • Form to document counseling • Policy/procedure regarding expectations for providing counseling • Anatomical model of penis • Condoms • Job aids

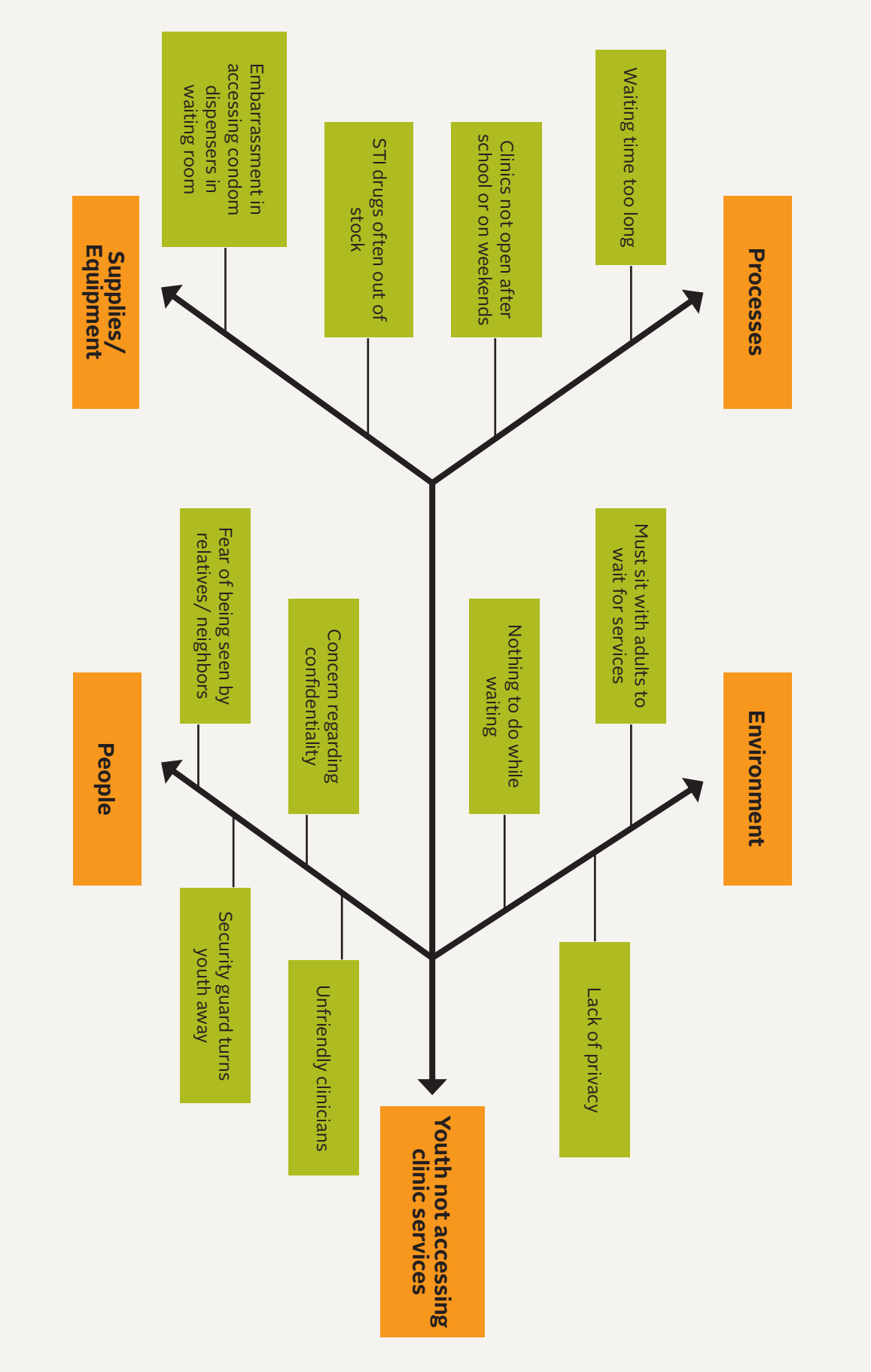
Using a grid that shows the processes for each step and lists the required inputs ensures that the group writes down the standards for each process of the system. Note that the table shows the inputs that are required for each process under consultation, but it does not require a separate form for each process. One form could include all the necessary information. These decisions can be left to the facility. Standards also do not specify the types of job aids, but there would be a standard stating that job aids are needed to provide effective counseling. This exercise provides a systematic approach to determining the processes involved and the inputs required. Standards are then developed for each of these processes as well as for the required inputs.

A cause-and-effect (fishbone) diagram also can be used to explore the problems related to the subject. The object of this exercise is to identify issues that the task force will want to address as they develop the standards. You might ask, “What is the worst thing that could happen to a client in this situation?” Develop your standards to address these potential issues. In the case of adolescent-friendly services, the question was, “Why are youth not accessing public health clinic services?” Example 4 uses a fishbone diagram to show the potential causes. As was done with adolescent services, the potential causes were identified through the knowledge that was gained through research (literature reviews) and professional experience.

The information gleaned from this exercise suggests that standards should be written to avoid these types of problems. For instance, standards for adolescent services need to be written down to promote privacy and confidentiality and to assure the availability of adequate drugs and responsive and friendly personnel at the clinic.

These quality tools help the task force consider the system that provides the care or service. Even though the examples given are clinical in nature, these tools are routinely used to study organizational systems and processes. Using these tools results in a more complete set of standards to improve the quality of care and performance of programs.

Example 4. Fishbone diagram of potential reasons why youth are not accessing clinic services



Step 4. Draft the Standards

The task force will draft the standards using the information that was collected from their literature reviews, discussions, presentations, and QI exercises. Decisions need to be made regarding categories for the standards and the most effective format for the intended end users. Healthy debates should be encouraged in the process in order to develop good standards.

Determine Key Functions

The task force can use an affinity diagram to sort the ideas. The affinity diagram is a process for gathering large amounts of data (ideas, opinions, issues, etc.) and organizing them into categories based on their natural relationships. The leader of the task force can take these steps:

- 1) Ask all task force members to write down issues that they would like to see as a standard on a note card (self-adhesive notes are best). Each member can write up to five issues (each on a separate card or note).
- 2) Without discussing the cards, post all of them on a wall.
- 3) Pick cards and relate them to other cards, asking permission of the members to link the issues, or if preferred, allowing the members to move the cards themselves. This exercise results in cards lined up into categories.
- 4) Create a header for each category that was formed.

Now you have the key functions for the standards. The adolescent-friendly standards were categorized into 10 key functions and each function was then written into a standards statement (Example 5).

Example 5. National adolescent-friendly clinic standards

National Adolescent-Friendly Clinic Standards

1. **Management systems** are in place to support the provision of adolescent-friendly services.
2. The clinic has **policies and processes** that support the rights of adolescents.
3. Clinic **services** are available, accessible, and appropriate for the needs of adolescents.
4. The clinic has a **physical environment** that is conducive to providing adolescent health services.
5. The clinic has **drugs, supplies, and equipment** to provide an adolescent-friendly package of essential services.
6. The clinic provides **information, education, and communication** (IEC) that is consistent with the essential service package.
7. Systems are in place to **train staff** to provide adolescent-friendly services.
8. Adolescents receive an accurate **psychosocial and physical assessment**.
9. Adolescents receive **individualized care** based on standard service delivery guidelines.
10. The clinic provides **continuity of care** for adolescents.

Select a Format

Standards that are written at an international or country level are typically high-level standards (as shown in Example 5), which are cast as a statement and followed by criteria describing how to meet the standard, as shown in Example 6.

Example 6. Standards statement and criteria

Standard: The clinic has a physical environment that is conducive to providing adolescent-friendly health services.

Criteria

1. Consultations with clients occur in a place that assures privacy.
2. The clinic is clean and comfortable for adolescents.

The task force writes more detailed standards to outline specific expectations at the level of service delivery. For the standard above, an SOP might be written to detail the cleaning procedure: who cleans the clinic, when, and how. If the task force is developing standards at the facility level, it will make the decision regarding the format to be used (refer to Terms and Definitions). Algorithms are best suited to situations that call for making decisions, whereas SOPs are used when the steps are clear. You can use these formats for the same subject matter. For instance, the standards for Integrated Management of Childhood Illnesses (IMCI) include algorithms for making differential diagnoses for children presenting with various conditions—for example, diarrhea. Within the same set of standards, there are instructions for the mother on how to give oral drugs at home, which are written as SOPs (as defined by FHI).

Do not write a textbook-type rationale into the content; algorithms and SOPs should be limited to specific directives for essential actions. The key is choosing a format that suits the purpose and that is user-friendly.

The level of detail outlined by the standards will determine their usefulness in providing ample guidance for implementation. Broadly defined standards require critical-thinking and problem-solving skills, which may not exist in some settings. Such standards are subject to multiple interpretations and could lose their potential to promote high quality. In resource-poor countries, clearly delineated and unequivocal standards with a high degree of specificity often prove to be more user-friendly and measurable than general statements.

Facilitate Debates

Careful research of the subject area will help the task force identify evidence to support the development of the standards. Nonetheless, lobbying of various interest groups over controversial issues inevitably occurs. The very nature of the standards-setting exercise invites debate. But lack of controversy does not mean the standard is good, as too much compromise can produce standards that use imprecise, open-ended language that is subject to multiple interpretations. Vague, agreeable standards are unlikely to change or improve services or practices.

Time often seems to be a crucial precondition for developing consensus, and in most cases, the development of health care standards is approached with some urgency. For example, when research indicated that male circumcision might decrease a man's risk of acquiring HIV, there was a clamor for developing standards to promote safe, quality male-circumcision services. Despite the sense of urgency, it was important to allow sufficient time for a broad review and feedback process so that the resulting standards would, in fact, promote safe, quality services.

Write Good Standards

The task force must be clear about the expectations regarding the elements of a good standard. Standards are useful only when they are written correctly. FHI has defined the attributes of a “good” standard as follows:

- *Valid*: Elements are based on scientific evidence or other acceptable experience—expert consensus at a minimum.
- *Clear*: Elements are understood the same way by everyone and cannot be misinterpreted.
- *Measurable*: Elements are quantifiable and can be assessed with valid instruments.
- *Relevant*: Elements are significant, appropriate, important, and of consequence.
- *Specific*: Elements are explicit and well defined.
- *Reliable*: Elements yield the same results in different settings.

The standards-setting task force should judge each of the standards against this set of attributes, although it is not realistic to expect that all standards meet all attributes perfectly.

Step 5. Test the Standards

You need to test the new standards with end users to determine how the standards operate in practice. Standards that look good on paper do not always play out that way in the field. You can use a QI tool—Plan-Do-Study-Act—for this process. The tool is consistent with the FHI QI model.*

Develop a Plan

The task force should develop a plan to field test the standards—that is, implement them on a small scale.

- a) The plan should outline the goals of the field-testing:
 - To determine the strengths and weaknesses of the standards
 - To determine the limitations of the standards' applicability
 - To allow different people in different settings the opportunity to work with the standards, report their experiences, and influence the final version

*FHI has adapted a generic QI model to its needs, with three steps (identify improvement aim & objectives, develop the improvement measurement system, and generate ideas for changes) followed by the test/implementation of the changes using the Plan-Do-Study-Act cycle.

- b) The field-test plan should include the number of sites involved, the duration of the testing, a description of the data to be collected (questions to be asked), and a process for monitoring the test.
- c) Some questions that might be asked of the site participants are:
- How easy would it be for the facility to meet the standards? (feasibility, achievability)
 - Would they like to meet the standards? (acceptability and relevance)
 - Do they understand the standards? (clarity)
 - Are the standards applicable to the setting? (applicability)
 - How much training would be needed to implement the standards? (cost)
 - What system changes, if any, would be required to implement the standards?
 - What, if any, might be the unintended side effects of implementing the standards?
 - What barriers in implementing the standards might they experience?
 - In what format(s) would they like the standards to be made available?

See Appendix 1 for an example of a questionnaire.

Choose a Site

The selection of the site is often determined by where the need for the standards is the greatest, but this is not always the best criterion. The site or country in the most need might be the least willing or able to implement the new standards. The purpose at this point in the standards development process is to test the standards. Thus it is important to select settings that will achieve this purpose. With this in mind, the task force should find a setting that meets the following criteria:

- The local leaders are interested in working with the standards.
- The local health system leaders recognize the need for new standards.
- The FHI country office is committed to the standards.
- There is an effective facilitator available on-site.

It is also helpful, when possible, to try out the standards in different contexts—that is, in various regions with different languages and country portfolios (Example 7).

Implement the Field Test

Once the site has been selected, the testing plan can be implemented (the “Do” of the Plan-Do-Study-Act tool). The plan should include introducing the standards to the end users, usually through training activities. A representative from the task force should work directly with the end users to help them understand and implement the standards. This support typically requires on-site guidance, at least on an intermittent basis. Throughout this activity, the task force members will study the quality of the standards.

Testing standards can take several months, as some standards might require resources and capacity building for implementation. Communication between the task force and the on-site facilitator is critical to learning from the process. The task force will then act upon the recommendations made after the testing and complete the final revision of the standards.

Example 7. Adolescent-friendly pilot clinics

Ten clinics were selected to pilot the standards for the adolescent-friendly clinic. A district approach for implementation was decided upon to ensure that the standards would be implemented as a sustainable district intervention instead of a stand-alone clinic intervention. Prior to initiating any activities, the task force met with district health managers to discuss the program and ask for their support. District meetings were held and presentations were made to district managers, clinic managers, and some staff. The stakeholders selected the pilot clinics at this meeting. They considered a variety of factors in selecting clinics, including poor use of clinic services by youth, high prevalence of STIs and HIV/AIDs, and high rates of teenage pregnancies in the community. The success of the initiative depended on the managers' support and participation in the process. The pilot study demonstrated that the standards were clear and doable, and only a few revisions were required. But the field test revealed that additional resource tools were needed to implement the standards. Accordingly, several resources were developed: a clinic handbook regarding management of reproductive health diseases and conditions, a standards-implementation guide, a workshop to clarify values, and a guide for local resources that could assist clinics in meeting the standards.

Step 6. Communicate the Standards

After finalizing the standards, the task force must decide how to publish and disseminate them.

- How will the standards be bound? Will there be sheets that the end user can take out and use as a checklist? In this case, a ring binder or a folder with a pocket might be the most effective approach.
- Will an electronic version be produced? If so, will the materials be placed on a CD?
- Will the document need to be translated into different languages?

The FHI task force leader should work directly with the publications department to create the published document, according to the FHI template for standards.

Making the standards operational depends on proper strategy and communication. The task force should review current change-management strategies, because implementing new standards and QI methods represents change and therefore should be incorporated into the communication plan. A key point to remember is that the target population must see the change as relevant to its values and needs. Many times, a standard has found its way to the trash container or hidden on a shelf because the end user did not see its value.

The task force should develop a communication plan (see Appendix 2) that addresses the following:

- 1) Who needs to know about the new standards? (This would include all those who are expected to implement the standards and those who will be impacted by the standards.)
- 2) What is the message? Usually there are several key messages that the task force wants to send. For example, “Standards are important to quality of care” and “There will be changes in the way a procedure is done.” Key messages should also respond to the questions that the target groups will have, such as “How will these standards affect me?” and “Why are these standards important?” and “What process will be used to implement the standards?” These questions should be considered in advance and incorporated into the key messages.
- 3) What is the purpose of the communication? The strategy is to persuade the target population that there is a problem, that the problem can be solved with the use of standards, and that these standards are important to their work. Data and statistics describing the magnitude of the issues that were the impetus for developing the standards will prove helpful in convincing the group of the importance of the subject. They will also help the group determine a realistic timeline for the implementation. Presenting a group with a book of standards with no realistic timeline could be overwhelming and stop your communication in its tracks.
- 4) What is the best way to send the message? The message might be the same for various groups; however, the means of communicating the new standards might be different. The most effective approach is to use three or four methods. The least effective methods are to send unsolicited information or give a lecture (Marquez, 2001). A slide show of each standard is neither interesting nor effective. Case studies and other interactive techniques, such as a force-field analysis, will be more successful. A force-field analysis is a method of identifying the pressures for and against a change. For the analysis, you can ask questions such as these: “What are the factors that will be helpful in implementing these standards?” and “What are the expected barriers?” The group will then develop a plan to maximize the facilitating factors and minimize the barriers. This strategy engages the leaders in the implementation process at the onset. Training activities can also be effective vehicles for transferring information.

The most effective communication methods are similar to the ones used to improve performance, such as the following:

- Individual coaching/mentoring
 - Reminders
 - Self-assessment
 - Supervisory and peer review
 - Monitoring and providing feedback
 - External assessment
 - Quality improvement process
- 5) Who will send the message(s)? It is important to select someone who has authority, credibility, and the respect of the group receiving the communication, because social influence cannot be overestimated. Identify the influential leaders and invite them to participate. Influential leaders might be peers, experts, or anyone who is known to be followed by others. These leaders do not always hold official leadership positions.

- 6) When will the message be sent? Set specific dates for each of the communication activities.
This plan will be the guide for the task force to determine if the plan is proceeding as expected.
- 7) How will you get feedback? Design a communication mechanism that will enable users of the standards to convey their issues regarding the implementation of the standards and their understanding of the content of the standards to the developers.

Example 8 illustrates how to complete a communication plan.

Standards that correspond to daily work are more likely to be followed. For instance, medical record forms can be designed to match the requirements of the standards, or job aids can be used to help staff members remember the steps. Incorporating the standards into job descriptions and pre-service programs also helps ensure that standards are successfully implemented.

Example 8. Communication plan for the adolescent-friendly services standards

Who needs to know?	What is the message?	What is the purpose of the message?	What is the best way to send the message?	Who will send the message?	When will the message be sent?	How will you get feedback?
District managers	<p>South African adolescents are dying of HIV/AIDS.</p> <p>Study of adolescents shows that they are unhappy with clinic services.</p> <p>Adolescent-friendly service standards will improve the quality of care and youth attendance at the clinics.</p> <p>Your leadership is important in implementing the standards.</p>	To engage district managers in the process of implementing adolescent-friendly services	Workshop, use current HIV/AIDS statistics to make the point, and conduct force-field analyses to involve managers in identifying the potential barriers and facilitating factors. Each district should develop a plan for overcoming barriers and moving the process forward.	<p>Representative from the ministries of health</p> <p>Respected leader of an NGO focused on youth and reproductive health</p>	June 4-5, 2011	<p>Evaluations during workshops</p> <p>Individual meetings with managers in each district</p>

Step 7. Implement the Standards

Implementation of a standard is defined here as the use of the standard in daily service delivery and program management. Some aspects of standards implementation have been addressed in step six. Although the communication of standards is an essential step for their implementation, the use of the standards requires a more comprehensive strategy, the in-depth description of which is beyond the focus of this guide. The complexity of the strategy depends on the magnitude of the changes that the new standards require in the delivery of services and management of programs.

In some instances, communicating the new standard might be all that is necessary for its implementation. For example, the replacement of one drug with another in the essential drugs list might require only simple communication strategies, such as an official notification from the ministries of health and a series of informational meetings in each facility. In other instances, the new standards might require new knowledge and skills that can be acquired only through a special training event, which can be part of the continuous education system for health providers. For example, the introduction of a new HIV test will be effective only if laboratory technicians are trained and can demonstrate acceptable proficiency. These types of capacity-building strategies usually cannot be limited to a one-time training event but require follow-up and reinforcement.

Sometimes, a new standard requires making many significant changes in the way that services are delivered. In that case, you need a carefully designed plan for their introduction over a period of time. For example, the introduction of a new guideline for child health (such as the IMCI) requires the following:

- The essential drug list must be adjusted.
- A large workforce must be trained.
- Medical records must be redesigned.
- Roles and responsibilities of health providers must be redefined.
- New supervision checklists must be developed.

QA and QI activities are very effective for implementing standards. QA tools allow you to identify the level of implementation of the standards and barriers to their implementation. QI models allow you to focus on the systems changes. Barriers that occur during implementation can be removed and standards implemented consistently within a new system.

Monitoring mechanisms, such as supervisory visits and self-assessment (service providers and managers measuring their own performance) contribute to the implementation of standards by highlighting the parts of the standards that they have more difficulty implementing.

Step 8. Monitor and Evaluate

A great deal of time and effort goes into developing and testing the standards. It is therefore worthwhile for the task force to develop measures to determine the effectiveness of the new standards.

Develop Indicators

The task force should develop indicators prior to implementing the standards and then use these indicators to determine the degree of adherence to the standards after they have been implemented. Collecting baseline data will help you measure the progress toward meeting the standards. Indicators are often written at both the national and facility level. National-level indicators are focused on outcomes of the program, such as the number of facilities that meet the standards. Facility-level indicators look at the overall achievement of the standards, but also measure elements of specific standards. For instance, if you implemented standards for palliative care, you might want indicators that measure how well a patient's pain is assessed and managed. By design, all of the standards should be measurable, but it is not reasonable to measure all of them. The task force should recommend specific indicators or a range of indicators from which the facilities can choose according to their priorities. The FHI Program Monitoring and Evaluation unit and the Health Systems Strengthening unit have excellent resources to assist in the development of indicators.

Establish a Monitoring System

The task force must consider how the indicators will be measured. The process is more likely to be sustainable if the indicators are incorporated into an existing system in the country—for instance, building indicators into the current supervisory system. But this is not always possible. Consequently, the task force may want to develop an assessment tool and should decide the following in the process:

- Will it be a self-assessment or an external assessment tool?
- How will the data be collected? How often and by whom?
- Who will aggregate the data?
- What is the recommended sample size?

Some organizations develop the standards and leave the decisions regarding measurement to the implementing site. (See Example 9 and Appendixes 4 and 5 for other examples.)

Example 9. External assessment process

The youth-friendly service program adopted self-assessment and external assessment approaches. A facility guide was created that included the standards and the self-assessment tool. Clinic staff members were trained to use the tool and were assisted with the baseline assessment. Thereafter, the clinic staff conducted the assessment at intervals to mark progress. When the clinic team felt that they had met all of the standards, they requested an external assessment, which was conducted by a team trained in external assessments. Staff members were awarded a bronze, silver, or gold star based on how well they had met the standards.

Use the Data

Much of the data that is collected never gets analyzed or used, because service providers or program managers typically need assistance in looking at and making sense of the data. Sometimes the site/facility teams encounter a barrier and conclude that the standard is not achievable. QI methods can be very useful at this juncture. When facilities are having difficulty implementing standards, they might need to step back and do some problem solving. For instance, a team implementing male-circumcision services in southern Africa noted that the clients were not returning for their follow-up visits. The team used a cause-and-effect diagram to consider the potential causes to this problem and then developed a plan to increase follow-up visits.

Revise the Standards

Standards need to be revised on a regular basis, every two years at a minimum. Review the current literature to assure that the standards remain up-to-date. Expert consensus on the review and updates will be necessary. If the standards are still current, you can sign off on them without further action. If standards need to be revised, follow the process described in this guide, starting with step three.

The decision to initiate a revision of the standards can be either systematic (following a scheduled revision plan) or triggered by a request from a technical expert as a result of changes in scientific knowledge. The technical expert will then submit a request to the standards committee for review based on new research and best practices. The standards committee convenes a subgroup of members and organizes a review of the new literature or data pertinent to the standard(s) to be revised, following the process described in this guide.

Conclusion

This document provides steps and examples for developing, communicating, implementing, and monitoring standards within FHI at all levels. To summarize, the steps for this process are provided below:

- Survey each content area and its issues in advance of setting standards.
- Develop iterative processes for including professional and community participation.
- Construct reasonable timetables for the completion of the standards.
- Select a format that meets the needs of the end user.
- Develop activities to link subjects and disciplines.
- Use QA/QI tools to develop the standards.
- Develop a communication plan and implement it.
- Develop measures to evaluate the effectiveness of the standards.
- Support continued capacity building.
- Plan for future revisions.
- Embed the process in a QA approach that includes a QI process.

Appendixes 1 to 5 provide tools and examples that can be easily adapted to guide the development, communication, implementation, and monitoring of standards.

Ashton J. *Health manager's guide: monitoring the quality of hospital care*. Bethesda, MD: published for the U.S. Agency for International Development (USAID) by the Quality Assurance Project. 2005. Available from <http://www.qaproject.org>

Berwick DM. *Disseminating innovations in health care*. *Journal of the American Medical Association*. 2003;289 (15):1969–75.

Green PL, Plsek PE. *Coaching and leadership for the diffusion of innovation in health care: a different type of multi-organization improvement collaborative*. *Journal on Quality and Patient Safety*. 2002;28 (2):55–71.

Institute for Healthcare Improvement. *The Breakthrough Series: IHI's collaborative model for achieving breakthrough improvement*. Innovation Series Paper. Boston. 2003. Available from <http://www.ihl.org>

Jaffe DT, Scott CD. *Getting your organization to change: a guide for putting your strategy into action*. Menlo Park, CA: Crisp Publications; 1999.

Marquez L. *Helping healthcare providers perform according to standards*. Operations Research Issues Paper 2 (3). Bethesda, MD: published for the U.S. Agency for International Development (USAID) by the Quality Assurance Project. 2001. Available at www.qaproject.org

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McLagan, PA. *The change capable organization*. Training & Development. American Society for Training and Development. 2003.

Evidence-based organizational change and development in a resource-constrained setting. Population Council. 2003; Working Paper No.180.

Rogers EM. *Diffusion of innovations*. New York: Free Press; 2003.

Senge PM. *The fifth discipline: the art and practice of the learning organization*. New York: Currency Doubleday; 1990.

Web site resources for evidence-based guidelines:

National Library for Health (NLH): <http://www.library.nhs.uk>

National Institute for Health and Clinical Excellence (NICE): <http://www.nice.org.uk>

eGuidelines: <http://www.eguidelines.co.uk>

Centre for Evidence Based Medicine: <http://www.cebm.net>

Health Information Research Unit: <http://hiru.mcmaster.ca/hiru>

Agency for Health Care Research and Quality (AHCPR): <http://www.ahrq.gov>

National Guideline Clearinghouse: <http://www.guideline.gov>

Elsevier Clinical Decision Support: <http://www.ClinicalDecisionSupport.com>

New Zealand Guidelines Group: <http://nzgg.org.nz>

Standards Pilot Test Facility Questionnaire

1. Do you understand the standard?*

not at all somewhat yes

2. Would you like to meet this standard?

not at all somewhat yes

If not, why not?

3. How easy will it be to meet this standard?

difficult reasonable easy

If difficult, what makes it difficult to meet this standard?

4. Does this standard apply to your facility?

not at all somewhat yes

If not, why not?

5. How much additional training will be necessary to implement this standard?

none some a lot

If training is required, what type of training is needed?

6. What system changes, if any, were required to implement this standard?

7. What, if any, were the unintended side effects of implementing this standard?

8. What barriers did you come up against while implementing this standard?

*This question can relate to one standard at a time or a set of standards.

Communication Plan

Use these directions and the form below to create a communication plan.

- First, identify the various populations with whom you need to communicate regarding the standards.
- Decide what message you want to send. This should be more than information. Think about the action you want the individual or group to take to assist in implementing the standards (support, implementation, etc.) and how best to request that action.
- What is the purpose of the communication, and what is the best way to send the message to this audience? Consider the usual patterns of communication for this individual or group, but also be creative.
- Identify who will send the message. This should be someone who is respected by and appropriate for the individual or group. (For example, it is often best for physicians to communicate directly with other physicians.)
- Establish the time for the delivery of the message. Address sequencing and coordination as appropriate. Without a set time, plans often do not get carried out.
- Identify how you will get feedback about both the standard and the communication process.

What is the target population?	What is the message?	What is the purpose of the message?	What is the best way to send the message?	Who will send the message?	When will the message be sent?	How will you get feedback?

Standards Development Checklist

Activity	Responsible person	Done
<p>Step 1: Define the Topic</p> <p>Consider the following questions:</p> <ul style="list-style-type: none"> • Why does FHI need these standards? (high-volume, high-risk, problem-prone, or new situation or behavior) • What is the goal? • What will be different as a result of these standards? • Are you developing the standards for FHI as an organization or for countries? • Are these standards targeted for national- or facility-level implementation? <p>Develop a concept document describing the need for developing standards and submit your ideas to the FHI Standards Committee.</p>		
<p>Step 2. Identify Participants and End Products</p> <p>Identify the stakeholders.</p> <p>Establish a task force.</p> <p>What is the end product—a set of standards, a guide for implementation, an assessment tool, or all three?</p>		

Activity	Responsible person	Done
<p>Step 3. Gather Information</p> <p>Prepare for the first meeting (gather and distribute materials):</p> <ul style="list-style-type: none"> • Existing standards • Laws and regulations • Current practices • Clinical evidence • Technology <p>Hold the first meeting:</p> <ul style="list-style-type: none"> • Introduce the need for standards. • Describe the goal and the current state of the subject (expert presentations). • Develop a flow chart (determine processes and inputs required). • Conduct a cause-and-effect analysis (identify potential problems). 		
<p>Step 4. Draft the Standards</p> <p>Determine key functions (use affinity diagram).</p> <p>Write standard statements.</p> <p>Develop criteria for each standard.</p> <p>If facility-level standards are desired, develop SOPs or algorithms.</p>		
<p>Step 5. Test the Standards</p> <p>Develop a plan to field-test standards:</p> <ul style="list-style-type: none"> • Define the objectives of the field test. • Select sites. • Develop pilot test tools. <p>Test the standards.</p> <p>Finalize the standards.</p>		

<p>Step 6. Communicate the Standards</p> <p>Publish the standards.</p> <p>Develop a communication plan.</p> <p>Implement the plan.</p>		
<p>Step 7. Monitor and Evaluate</p> <p>Develop indicators.</p> <p>Develop a monitoring system.</p> <p>Use data for improvement.</p> <p>Revise standards at regular intervals.</p>		

Example of a Standards and Criteria Template

FHI Essential Standards and Criteria

AREA: Youth-Friendly Programs

Standards	Criteria	Means of verification
<p>1. Management systems are in place to assess the quality and effective provision of adolescent-friendly services.</p>	<p>Systems are in place to collect data on youth-friendly services.</p> <p>A system is in place to assess the quality of youth-friendly programs.</p>	<p>Review data-collection methods and data analysis (how the data are used for programmatic decisions).</p> <p>Review QA processes and reports.</p>
<p>2. There are up-to-date policies, protocols, and processes in place that support the implementation of youth-friendly services.</p>	<p>The program has up-to-date national norms and protocols for comprehensive youth-friendly services.</p> <p>The program has an evaluation process to assess adherence to policies and protocols.</p>	<p>Review existing protocols and assess consistency with up-to-date, evidence-based, scientific information.</p> <p>Review the evaluation process that is in place and assessment reports.</p>
<p>3. An effective logistic system is in place to guarantee availability and distribution of essential drugs, supplies, and equipment for adolescent-friendly services.</p>	<p>The purpose of good management and logistics systems is to ensure consistent availability and distribution of essential drugs, supplies, and equipment for youth-friendly services. These include:</p> <ul style="list-style-type: none"> • Establishing supply priorities • Forecasting commodity needs at all levels of the service-delivery system • Requesting or purchasing goods in a timely manner • Storage • Distribution • Use before deterioration 	<p>Review the structure of the logistics system.</p> <p>Make sure tools are in place for the purchase and distribution of commodities and supplies.</p> <p>Audit storage using a checklist.</p>

Example of a Self-Assessment Form

Standards Self-Assessment Form

Contents

Instructions for Completing Self-Assessment

1. This form is to be completed entirely by the FHI country office (CO). Its purpose is to guide the CO in providing the following:
 - (a) The necessary evidence showing that the CO or program is in compliance with each and every FHI Essential Standard
 - (b) The evidence showing why a standard is considered to be not applicable to the CO or program
 - (c) Where the CO or program is not in compliance, an explanation as to why it cannot comply with a particular standard and what action should be taken (see also paragraphs three and four below)
2. The instructions that accompany this form are intended to help the CO or program complete the self-assessment by setting out the different issues that the CO or program needs to take into account when answering Yes, No, or Not Applicable to each standard. If the CO is in any doubt as to whether it complies fully with a standard, the answer should always be No.
3. If a No answer is given, then an explanation for the noncompliance should be entered in the Supporting evidence column. If the issue is one that is currently being dealt with by the CO, then this should be stated in the Action required column. An indication of when compliance is expected should be entered in the Target date column. If the issue is one where local context or other considerations make it impossible for the CO to comply with a standard, then the reasons should be given. A separate sheet should be used if the explanation is lengthy.
4. It should be noted that a No answer does not mean that a program or CO will be penalized. It means that actions will be taken, according to a timetable, to ensure compliance.
5. If the answer is Yes or Not applicable, then the evidence to support this claim should be noted in the column for Supporting evidence. This will come from a variety of sources—probably one (or more) of the following:
 - (a) The CO procedural regulations
 - (b) The country policies
 - (c) The CO's plans, annual program budget, or other reports
 - (d) Internal operational regulations or manuals
6. Once the self-assessment has been completed to the satisfaction of the CO's director, it should be shared with the program's managers and staff members and with FHI/RO and FHI/HQ.

Youth-Friendly Programs Standards

Standards	Yes	No	N/A	Supporting evidence*	Action required**	Target date
1. Management systems are in place to support the effective provision and monitoring of adolescent-friendly services.						
2. There are policies and processes in place that support the implementation of youth-friendly services.						
3. An effective logistic system is in place to guarantee availability and distribution of essential drugs, supplies, and equipment for adolescent-friendly services.						

Please check **Yes** if you judge that the program or CO complies with this standard, **No** if it does not comply, or **N/A** (not applicable) if this standard does not apply to the program or CO.

*Supporting evidence: Please enter details of the relevant document or other evidence as to why the program or CO does or does not comply with the standard, or the standard is considered not applicable.

**Action required: For action that needs to take place to ensure compliance, please complete the last two columns.