Developing, Implementing, and Monitoring the Use of Standard Treatment Guidelines

a SIAPS How-to Manual

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SIAPS
Systems for Improved Access to Pharmaceuticals and Services

Developing, Implementing, and Monitoring the Use of Standard Treatment Guidelines:

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August 2015

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ABOUT SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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KEY WORDS

Standard treatment guidelines, rational medicine use, health systems strengthening, continuous quality improvement, quality assurance

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Acronyms

AGREE	Appraisal of Guidelines Research and Evaluation [tool]
AHCPR	Agency for Health Care Policy and Research
AMR	antimicrobial resistance
BMJ	British Medical Journal
COI	conflict of interest
CPG	Clinical Practice Guidelines
DOI	declaration of interest
CQI	continuous quality improvement
DOP	Department of Pharmacy [Kenya]
DPML	Department of Pharmacy, Medicine, and Laboratories [Burundi]
DTC	drug and therapeutics committee
ECSA HC	East, Central, and Southern African Health Community
EML	Essential Medicines List
EPN	Ecumenical Pharmaceutical Network
FMHACA	Food, Medicines, and Health Care Administration and Control Authority [Ethiopia]
GRADE	Grading of Recommendations, Assessment, Development, and Evaluation [tool]
JMS	Joint Medical Stores [Uganda]
KEML	Kenya Essential Medicines List
KTA	knowledge-to-action [process]
LMIC	low and middle income country
MEDP	Malawi Essential Drugs Program
MEMS	Mission for Essential Medical Supplies [Tanzania]
MOH	Ministry of Health
MOHSS	Ministry of Health and Social Services [Namibia]
MOHSW	Ministry of Health and Social Welfare [Liberia]
MOPH	Ministry of Public Health
MSH	Management Sciences for Health
NACP	National AIDS Control Program [Malawi]
NGO	non-governmental organization
NTG	National Therapeutic Guidelines [Liberia]
PNLIP	National Malaria Program [Burundi]
RCA	root cause analysis
RPF	Regional Pharmaceutical Forum [East, Central, and Southern Africa]
RPM Plus	Rational Pharmaceutical Management Plus [program]
SCG	Standard Clinical Guidelines [Kenya]
SEP/CNLS	Permanent Executive Secretariat/ National Council for the Fight Against AIDS [Burundi]
SIAPS	Systems for Improved Access to Pharmaceuticals and Services [program]
SIGN	Scottish Intercollegiate Guidelines Network
SPS	Strengthening Pharmaceutical Systems [program]
STG	Standard Treatment Guidelines
STGWG	Standard Treatment Guidelines Working Group [Afghanistan]
TOR	terms of reference
TOT	training of trainers
USAID	United States Agency for International Development
WHO	World Health Organization

CHAPTER 1 Introduction

Aim and objectives of this manual

This manual is a practical guide on how to develop, implement, and monitor the use of evidence-based standard treatment guidelines (STGs). It is a one-stop reference for busy health care practitioners and other stakeholders and is oriented to the needs and realities of resource-limited settings.

The goal of standard treatment guidelines is to promote standards of practice and improve the quality of health care.

Treatment guidelines are designed to assist health care professionals in making decisions about appropriate, effective patient care. However, guideline developers and implementers often fall short of meeting standards for high quality. Stakeholders have expressed concern over issues such as strength of evidence, transparency, conflict of interest, and effective implementation.[1] Ineffectual processes are likely to be an even greater issue in resource-limited settings where constraints related to management, know-how, and resources are common. This manual attempts to fill this gap.

The objectives of this manual are to—

- Provide guidance on STG management that is based on international evidence, recommendations, and experience
- Outline a systematic and well-planned process that supports key players in creating, implementing, and sustaining STGs as a key tool to enhance pharmacotherapeutic practice
- Fill the gap for developing a guideline that is closely aligned with the needs, circumstances, and realities of resource-limited settings by contextualizing to these settings as much as possible
- Provide practical approaches, techniques, examples, success stories, references, and hyperlinks that guideline developers can learn from and use to create and implement credible STGs

This manual draws from a large pool of international resources, including the World Health Organization (WHO) Handbook for Guideline Development.[2] While the aim of the WHO document is to provide standard steps and procedures for the development of guidelines that are produced specifically by WHO, this manual provides more generic and comprehensive guidance not only for developing guidelines, but also for implementing and monitoring them, with a particular focus on and multiple practical examples from low- and middle-income countries (LMICs).

Who this manual is useful for

This manual is intended for a variety of health professionals and other stakeholders involved in organizing and delivering patient care. These include—

- National, regional, or facility level organizations and technical committees responsible for developing or implementing STGs
- Clinical champions, opinion leaders, implementation facilitators, and others interested in or supportive of STGs as a key tool to improve medicine use and treatment outcomes
- Health care providers or practitioners (e.g., physicians, pharmacists, nurses, public health professionals), including those belonging to specialty groups
- Professional associations
- Academics
- Health care management groups, insurance schemes managers, health planners, health care policy-makers, health care administrators, and supply chain managers
- Students of pharmacy, nursing, medicine, public health, and other allied health professions
- Stakeholders interested in practice change in health care, best practices, continuous quality improvement, translating knowledge into practice, and system-based practice

This manual combines principle with practice, making it easy for the reader to appreciate concepts alongside practical implementation approaches. It is organized according to the steps required to develop, implement, and monitor treatment guidelines. To benefit from a comprehensive understanding of the overall guideline implementation process, it is recommended that the reader become familiar with all sections of the manual before initiating STG support activities.

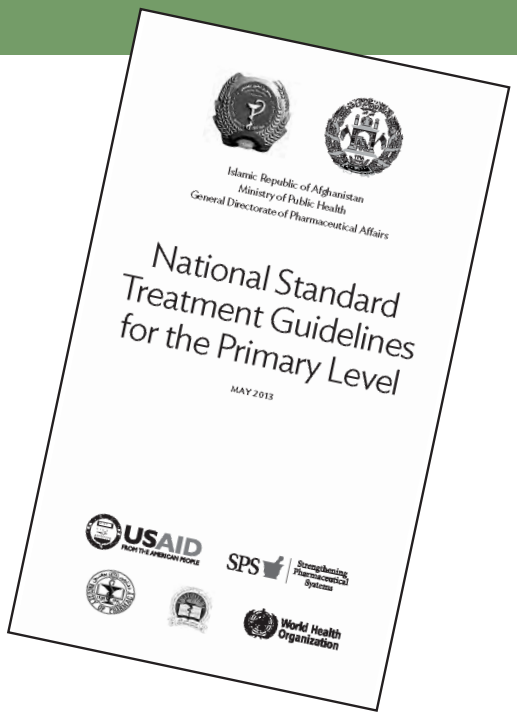
Rationale for treatment guidelines

Treatment guidelines are a powerful tool for promoting rational medicine use. There is a serious and widespread problem of quality in medical practice. The medical literature has demonstrated unexplained variations in clinical practice and health outcomes, significant rates of inappropriate care, inconsistent involvement of patients in decision making, and high health care costs.[3] In a health care system where new treatments and technologies are continually emerging, the systematic development and implementation of treatment guidelines is an important strategy for ensuring that medicines are used safely, appropriately, effectively, and at the lowest cost to patients and health facilities.

Clinical guidelines can help your health facility focus on putting the necessary staff, information systems, and clinical and administrative processes in place so that patients receive high-quality evidence-based care.[4]

Treatment guidelines are a valuable link between evidence and sound clinical practice.[5] Systematically developed guidelines are supported by the best available evidence from scientific findings, clinical expertise, and patient preferences to provide proven and practical treatment recommendations.[6] A rigorous development process gives health care providers the confidence that they are providing the best possible care to their patients.

Together, standard treatment guidelines and essential medicines lists form the major basis for supplying and prescribing pharmaceuticals and training health


Islamic Republic of Afghanistan
Ministry of Public Health
General Directorate of Pharmaceutical Affairs

National Standard Treatment Guidelines for the Primary Level

MAY 2013

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SPS Strengthening Pharmaceutical Systems
World Health Organization

workers. STGs and essential medicines lists (EMLs) are complementary and interdependent reference documents. EMLs are intended to guide medicine procurement, supply, and use in the public and private sectors; medical reimbursement schemes; medicine donations, and local medicine production.[7] STGs and EMLs should be consistent to support the availability of appropriate medicines, provide cost-effective treatments for common diseases, and encourage consistency in prescribing practices. Both of these important publications should be used for pre-service and in-service training, supervision, and medical audit.[8]

Treatment guidelines are a useful tool for supporting health systems and improving the quality of health care. Clinical care gaps, or disparities between evidence-based knowledge and daily clinical practice, are all too common in the health care system. Providing quality health care means minimizing clinical care gaps to deliver the best possible care and attain the best possible health outcomes when people access health services. By definition, quality health care ensures effective, efficient, accessible, patient-centered, equitable, and safe care.[9]

Definitions, benefits, and limitations of STGs

Definitions

Standard treatment guidelines, clinical practice guidelines, treatment protocols, and practice policies are closely related terms that provide "recommendations intended to optimize patient care...informed by a systematic review of evidence and an assessment of the benefits and harms of alternatives."[10] To be considered credible, guidelines should—

- Be based on a systematic review of existing evidence
- Be developed by a knowledgeable, multidisciplinary group of experts and representatives from key affected groups
- Consider important patient subgroups and patient preferences, as appropriate
- Be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest
- Provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations
- Be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations

Clinical algorithm and clinical pathway are related terms, but differ from treatment guidelines in their functions.

A clinical algorithm presents a set of rules for solving a problem or accomplishing a task. Through the use of if/then statements, an algorithm illustrates a treatment guideline in a step-by-step flow chart,[11] providing a visual decision tree for a specific patient care problem. Algorithms are useful, but not as comprehensive as treatment guidelines.[12]

A clinical pathway is a quality assurance tool that organizes, specifies, and sequences the major flow of services and interventions of an entire interdisciplinary team for a particular diagnosis or procedure. Unlike treatment guidelines, a pathway focuses on the quality and efficiency of care after decisions have been made about what procedures or services to perform.[13]

Benefits of STGs

STGs are developed, implemented, and evaluated by those responsible for patient care,[14] and thus have the best interest of the patient in mind. The benefits of STGs are multifaceted (table 1.1). When properly developed and implemented, STGs may enhance rational medicine use, prevent the development of antimicrobial resistance (AMR), and improve the quality and safety of health care.

Beyond the stated benefits for practitioners, patients, and supply managers, treatment guidelines also carry advantages for payers and policy makers. The systematic use of treatment guidelines reduces health care costs by minimizing the excessive use of interventions and allocating care resources judiciously.[19] In addition, the involvement of local prescribers, pharmacists, and health care administrators in the guideline development process enhances their level of credibility and authority. Treatment guidelines make it easy to provide focused information and training, and to integrate special program recommendations (e.g., HIV and AIDS, tuberculosis, malaria, and maternal and child health) into a single document.

To understand the role of treatment guidelines in clinical care, it is important to know what they are *not* intended to do. They are not intended to serve as a cookbook approach to medicine or as guidance in all circumstances and for all patients.[20, 21]

Limitations of STGs

Inaccurate guidelines provide the wrong information. Often times, guidelines are improperly developed because they are based on existing practices rather than evidence-

TABLE 1.1
The benefits of standard treatment guidelines[15, 16, 17, 18]

CATEGORY	BENEFITS
Practitioners	• Provide evidence-based guidance, improve diagnostic accuracy, and promote effective and safe therapy • Provide standardized information to give to patients • Provide a basis for measuring, monitoring, evaluating, and improving performance and quality of care • Support evidence, protection, or defense against malpractice
Supply Managers	• Improve availability of medicines • Provide a standardized basis for quantifying, ordering, and pre-packaging medicines, where possible and appropriate
Patients	• Improve availability of medicines due to consistent usage patterns • Enable consistent and predictable treatment from various levels of providers and locations • Enhance treatment outcomes (cure or alleviation) • Increase satisfaction with care • Reduce health care costs

based medicine.[22] Promoting faulty treatment guidelines can encourage the delivery of ineffective and unsafe medical interventions.

Guidelines are only as good as the evidence on which they are based.[23] Science does not have all the answers to questions related to clinical care—there are gaps and limitations. Poor study designs and limited generalizability can produce misleading data.[24] Guidelines can quickly become outdated unless a functioning system exists to update them regularly to keep up with evolving scientific data and best practices.

Guideline development and maintenance requires much time and effort. Guideline development and maintenance is a resource-intensive process that requires a system and budget, as well as the necessary skills and time to thoroughly analyze scientific evidence.[25]

Guidelines may give health care practitioners a false sense of security. A guideline should be viewed as a resource to guide clinical decision making, not as a prescriptive document. Viewing treatment guidelines as a dictate may give health care practitioners a false sense of security and discourage ongoing critical thinking.[26] Since each clinical situation is unique, clinical judgment and patient preferences should be considered when making medical decisions.

Treatment guidelines are only useful when implemented properly.[27] Developing a guideline is relatively easy compared to implementing one.[28] Guidelines are not automatically implemented merely because they exist; rather, proactive and effective strategies are required to ensure their routine use.[29] Implementation should be taken into account at the start of the development process (see chapter 7).[30]

CHAPTER 1

TAKE-HOME MESSAGES

- Treatment guidelines are designed to assist health care professionals in making decisions about appropriate and effective patient care. Treatment guidelines are not intended to serve as a cookbook approach to medicine or as guidance in all circumstances and for all patients.
- Treatment guidelines are a valuable link between evidence and sound clinical practice.
- Standard treatment guidelines and essential medicines lists form the major basis for supplying and prescribing pharmaceuticals and training health workers.
- When properly developed and implemented, standard treatment guidelines may enhance rational medicine use, prevent the development of antimicrobial resistance, improve the quality and safety of health care, and reduce health care costs.

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CHAPTER 2 Planning for Guideline Development

STEP 1.
Assess existing practices, identify need, establish objectives, and obtain approval

The process for developing, updating, disseminating, and evaluating treatment guidelines varies from country to country. The Ministry of Health (MOH), international health organizations, and health professional associations represent some of the various entities that may lead the guideline development and dissemination process. Regardless of which stakeholders develop the guidelines, the process generally remains the same,[31] requiring ample time, skills, and resources. Proper planning is the best way to ensure useful treatment guidelines.

A. Determine the need for the guideline and its objectives

To determine whether there is a demand for the guideline and what objectives it will meet, consider the following points.

Is the guideline really needed?
Treatment guidelines should meet a defined health care need, for example, when[32]—

- There is wide variation in practice or health outcomes
- There is a proven treatment for a condition and mortality or morbidity can be reduced
- There is a need to bring together scientific knowledge and expertise on a subject
- There are iatrogenic (of or relating to illness caused by medical examination or treatment) diseases or interventions that carry significant risks or costs

Are there existing guidelines? If so, what is their quality?
Treatment guidelines should not be duplicative. If there is an existing guideline that meets a defined need, then developing a new guideline may not be necessary.[33] To avoid duplicating guidelines, consult with other stakeholders. There must be justification for producing a new guideline.

If existing guidelines are out of date or of poor quality, then you may consider updating them.[34] To check for quality, use a valid tool such as the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument (see chapter 5).

Why is the guideline needed now and who needs it?

The guideline must be driven by clear, practical public health-oriented objectives. Think about why the guideline needs to be developed now and the existing need that it will respond to. What is the purpose of developing the intended guideline?[35] To keep your guideline as clear and direct as possible, think about who your target audience is. Also think about how to strategically fit the new guideline into suitable programs or projects.

Who is likely to implement the new guideline?

Consider the type of health care providers and patients for whom the guideline is intended.[36] Think of key organizations, experts, and stakeholders who will be involved in implementing the guideline. If you cannot identify stakeholders, then you are not ready to proceed. Once you have determined that a guideline is needed, you are ready to proceed with planning.

B. Submit a proposal and obtain approval

Submit a proposal that outlines your target audience, type of guideline, timeline, budget, resources and skills, partners, plans for peer review, plans for editing and production, dissemination strategy, and evaluation of impact.[37] To ensure smooth operations, wait to receive formal approval before proceeding. In the case of a national STG, the MOH is the authoritative structure that is likely to approve the proposal. In the case of a facility-level STG, hospital management is likely to grant approval.

C. Build awareness, advocacy, and commitment for the guideline

A key initial step to ensuring that guidelines are effectively implemented is to develop visible, high-level support. Actively engage with care providers, other users, and patients to expand the base of committed stakeholders and ensure that guidelines are supported and integrated into the health system. To raise awareness, consider delivering presentations or short seminars to stakeholders.[38]

STEP 2.
Map key steps and plot a tentative timeline

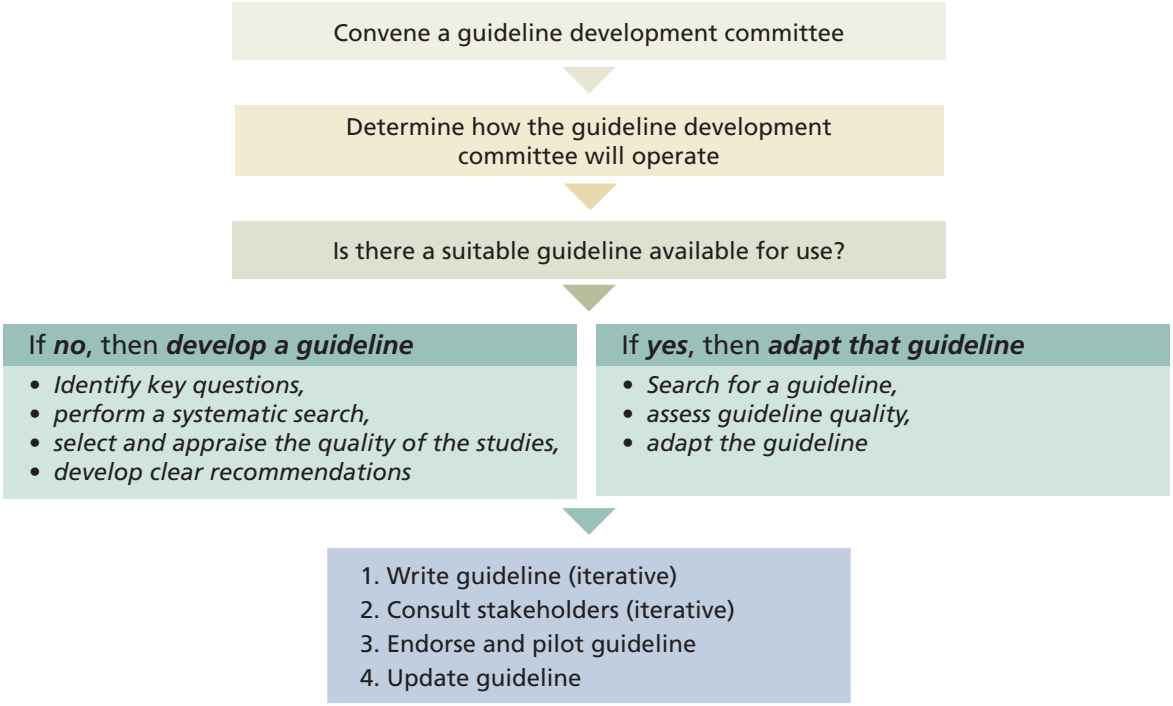
Once you have determined that a guideline is needed and obtained the necessary approval, map out the key steps for its development or adaptation. Figure 2.1 illustrates these key components.

Formulate a simple plan that clearly plots out what activities to carry out and when. Table 2.1 shows the major elements required to develop a selective or comprehensive treatment guideline, along with the estimated time required to complete each step. The development of a comprehensive guideline, from start to implementation, may take up to 12 months to complete. The development of a single protocol may take between 3 and 6 months.[40] Timelines largely depend on the availability of committee members, many of whom have busy schedules as clinicians or health practitioners.

STEP 3.
Plan for resources proactively

A critical aspect of planning the guideline development process is assessing and acquiring the resources necessary to develop the guideline and implement associated activities.[44] Being proactive in your planning, and doing so in advance will help you get the support you need.

FIGURE 2.1
Steps for developing or adapting treatment guidelines[39]



Guideline development and implementation require three types of resources: human, financial, and in-kind.[45]

Human resources are the individuals with the expertise needed to develop the guideline. Finding the appropriate human resources often requires a careful and wide search, especially in resource-constrained countries, to identify the right experts to develop various sections of the guideline.

Financial resources comprise the funding needed to cover the financial costs of guideline development and implementation. Expenses include committee meetings as well as drafting, finalizing, printing, disseminating, and monitoring the guideline.

In-kind resources are non-cash forms of support, such as access to goods and services. A plan that sets priorities through clearly defined steps and activities will help you determine how to allocate resources in a way that enhances quality and efficiency in the process.[46] You should seek support from stakeholders who can help estimate or mobilize the necessary resources. When presenting your case, note[47]:

- The specific goals of guideline implementation
- A description of the target population
- Planned implementation strategies
- Why the guideline is unique and important
- Possible research and development opportunities
- Potential cost savings
- Timelines
- Budget

Lobbying for resources requires a detailed and convincing argument that explains the benefits and risks of the initiative. How will treatment

TABLE 2.1
Major elements of the guideline development plan[41, 42, 43]

STEPS	OBJECTIVES OF EACH STEP	ESTIMATED TIME REQUIRED (in months)
Appoint a guideline development committee	• Establish a multidisciplinary committee • Institute a clear terms of reference • Protect against conflicts of interest	1
Determine the scope of the guideline	• Define the purpose, timeline, and scope • Identify the type of guideline, end users, and levels of use • Ask an external review group to review the scope • Recruit contributors, writers, reviewers	1
Identify diseases that the guideline will cover	• Review morbidity and mortality patterns • Consult medical specialists and practitioners to identify and confirm the most prevalent conditions	1
Review existing literature	• Identify scientific evidence and review international recommendations (i.e., those from WHO)	2
Assess scientific evidence	• Determine appropriate treatment options • Explicitly link recommendations to evidence • Choose cost-effective treatment • Ensure the STG and national EML are aligned	2
Hold a consensus workshop and draft guideline	• Determine what information to include in the guideline • Draft the guideline for comments and pilot testing	3
Review and edit draft guideline	• Obtain feedback regarding guideline clarity, quality, and ease of implementation • Revise the guideline	1
Field test	• Field test and have the guidelines edited to ensure consistency and accuracy	3
Publish guideline	• Publish the guideline in a user-friendly layout and format	1
Launch and disseminate guideline	• Hold an official public launch covered by the press and broadcast media with high-level representation	1
Disseminate guideline and conduct training	• Distribute the guideline widely to health facilities and key stakeholders (include posters and training materials) • Train students and health care personnel on how to use the guideline (pre-service, in-service, and reinforcement trainings)	Ongoing
Monitor guideline and medicine use	• Monitor prescribing compliance for high-priority health problems • Use monitoring data to establish medicine use evaluation programs • Provide supportive supervision and incentives to enhance prescribing compliance to the guideline	Ongoing

guidelines address challenges? What will be required for their successful implementation? Your goal is to persuade decision makers that the initiative is a sensible investment.

Once you have mapped out the key steps of the development and implementation process, as well as the resources required to support the initiative, you are ready to determine the associated costs.

STEP 4. Budget for guideline development and implementation

A. Determine an accurate and presentable budget

Estimating the costs associated with guideline development and implementation can be tricky. The costs can be considerable, depending on the approaches taken during the process.[48] Consider consulting with stakeholders to assist you in determining a suitable budget that covers all planned activities in the local context. Expenses can be determined by research, experience, and advice.[49]

B. Seek multi-source funding

Efforts should be made to mobilize resources and secure funding from multiple in-house and external sources to reduce the burden of cost on any one department or program, and to support sustainability.[50] Groups that commonly provide funds for guideline development and implementation include the MOH, local and regional patient advocacy organizations, medical specialty societies, and hospital administration. Donors may also provide funding for work on treatment guidelines.

Box 2.1 briefly describes how the Malawi Essential Drugs Program benefited from multi-source funding to print the standard treatment guidelines.

When soliciting funders, be wary of potential conflicts of interest. Engage in complete and transparent disclosure of all financial, personal, and professional relations with the industry (see chapter 3).

BOX 2.1 Co-funding covers printing costs for Malawi STG[51]

Following an 11-month systematic process of preparation and review, the second edition of the Malawi standard treatment guideline was ready for printing. Three quotes were collected from pre-selected printers based on the quality of their previous work. Printing costs were budgeted under Malawi Essential Drugs Program (MEDP) project funds, and the program subsequently sought multiple sources of funding to cover these expenses. Nine thousand copies of the guideline were printed, at a unit cost of 1.45 US dollars. Since the guideline devotes considerable text to the treatment of clinical presentations in people living with HIV and AIDS, the National AIDS Control Program (NACP) committed to funding one third of the costs.

This co-funding model had the benefit of reducing the burden of cost borne by the MEDP and also promoted the interests of the NACP.

C. Build partnerships and pool resources

Building partnerships with key stakeholders that have a vested interest in treatment guidelines is valuable. You can add a significant amount of visibility, credibility, and clout to your initiative if you partner up with stakeholders that carry a high level of influence. Align yourself with key people and organizations with which you can pool resources.

CHAPTER 2
TAKE-HOME MESSAGES

- Treatment guidelines should meet a defined health care need.
- Developing treatment guidelines requires a lot of time, skills, and resources.
- Proactive and advanced planning will help you get the support you need. A plan that sets priorities through clearly defined steps and activities will help you determine how to allocate resources in a way that enhances quality and efficiency in the process.
- Consider consulting with stakeholders to assist you in determining a suitable budget that covers all planned activities in the local context. Where possible, mobilize resources and secure funding from multiple sources.
- Building partnerships with key stakeholders that have a vested interest in treatment guidelines is valuable. Developing visible, high-level support is a key step to ensuring that guidelines are implemented effectively.

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CHAPTER 3 Setting Up a Guideline Committee and Establishing Procedures

STEP 1. Set up the guideline committee

A. Form a committee in the beginning of the process

For a national level guideline, the MOH is typically responsible for appointing and overseeing the guideline development committee. The guideline development committee can also be a subcommittee of the national drug and therapeutics committee (DTC) (also referred to as a medicine and therapeutics committee or a pharmaceutical and therapeutics committee).[52]

For a facility-based guideline, the facility DTC is the most appropriate body to appoint the committee. Facilities that do not have a DTC can pull together an ad hoc committee to catalyze the process.

For disease-specific guidelines, public health programs may take the lead in convening a committee to support their development. Regardless of the type of guideline, consider making a call for nominations with submission of curricula vitae and conflicts of interest before forming a committee.

B. Set goals for the guideline committee

The primary goals of the guideline committee are to improve the quality of medical care for the population and to build an efficient and quality-assured guideline development and maintenance process that increases satisfaction among patients and health care workers. The committee's objectives are laid out in the terms of reference, which is discussed in the next section of this chapter.

C. Ensure an appropriate composition and mix of the guideline committee

A guideline committee should be multidisciplinary, comprising both clinical and non-clinical staff involved in health care delivery. Members should represent various disciplines with relevant backgrounds and experience in different specific clinical areas or programs. Membership should also be balanced through appropriate gender and geographical representation.

Research has consistently shown that the make-up of the guideline committee

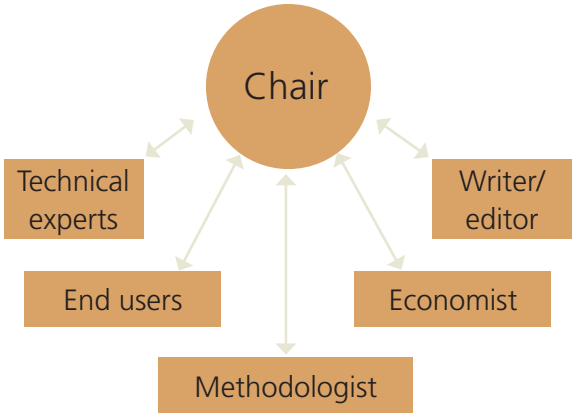
has considerable influence on the recommendations produced.[53] To ensure that the most effective standards of care are identified, assessed, and implemented, committee members' technical interests, skills, expertise, values, and knowledge should be balanced and complementary.[54]

Establishing a multidisciplinary committee that explores a range of ideas from representatives of key affected groups and disciplines ensures that[55]—

- All relevant groups are represented
- All relevant scientific evidence will be identified and evaluated critically
- Practical problems related to guideline use will be identified and addressed
- Stakeholders will consider the guideline credible and actively participate in its implementation

Ideally, a guideline development committee should include a chair, technical experts, end users, a methodologist, an economist, and a writer/editor. Such diverse and complementary skills aid the guideline development process.[56] In some settings, especially in LMICs, all of these specialized categories of experts may not be easily available. Efforts should be made, however, to include as many of the above categories as possible.

Guideline Development Committee



Chair

The committee must be led by an expert group facilitator with previous experience in developing evidence-based guidelines. The chair should be committed and efficient, with strong interpersonal skills. Avoid appointing a content expert with strong views about particular interventions[57] and instead select a neutral leader who will foster a spirit of collaboration.

Technical experts

Technical experts must have relevant expertise and experience in the clinical subject areas under consideration. Major technical areas include primary care, nursing, and allied health.[58]

End users

End users represent those groups most affected by the guidelines. This includes patients (e.g., people living with HIV) and representatives of groups responsible for implementing the guidelines (e.g., health professionals, program managers). Involving consumers in the development process ensures that a relevant, appropriate, and well-understood guideline will be produced.[59]

Methodologist

Methodologists (e.g., health economists, biostatisticians) are well-versed in assessing evidence and developing guidelines. The advice provided by a methodologist complements the contributions of subject-matter experts.[60]

Economist

An economist identifies and interprets evidence related to the economic costs and benefits of the recommendations.

Writer/editor

The writer must be involved throughout the entire process of planning and

development. The writer/editor should document the process and either write or edit the guidelines clearly. Involving a strong writer/editor from beginning to end will ensure intelligible, accurate, and consistent recommendations.[61]

Guideline development committees vary in size depending on the scope of the guideline in question. Experience suggests that the committee should consist of 6 to 10 members. This comfortable size allows for an appropriate mix of representatives with the necessary expertise and experience, without compromising effective group interactions.[62]

STEP 2.
Address conflicts of interest

A conflict of interest (COI) exists when a committee member or his/her affiliating organization has financial or personal relationships with other people or organizations that may inappropriately influence his/her actions.[63]

Conflicts of interest may exist with organizations that fund guideline development initiatives. These include pharmaceutical companies, medical associations, local and regional patient advocacy organizations, hospital administrations, and health ministries.[64]

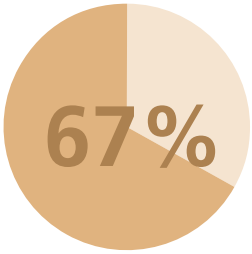
It is highly advised that guideline committee members fully disclose financial, personal, and professional relations to avoid compromising the integrity of their work. Ideally, the chair and a majority of the guideline committee members should not have any conflicts of interest.[65] This section describes who should declare interests, how interests should be declared, and how interests should be managed during the guideline development process, as this poses a major governance issue.

A. Examples of conflict of interest

Conflicts of interest may stem from financial relationships, personal relationships, academic competition, or public position. Financial conflicts are easiest to identify and include personal financial gain, proprietary interests, patents, grants or fellowships, stock ownership, employment, and consultancies.[66] Academic conflicts and public positions, on the other hand, are harder to recognize. The general rule of thumb is to consider whether an interest could affect an individual's ability to behave in an objective and independent manner during the guideline development process.[67]

B. Examples of evidence of conflicts of interest

Increasingly, guideline developers are enforcing policies to address financial and intellectual COI. Management and reporting of COI, however, needs improvement. An assessment revealed that 67 percent of 431 guidelines developed by specialty societies failed to disclose information about committee members, preventing any attempt to even evaluate potential COI. Similarly, more than 50 percent of guidelines within the National Guidelines Clearinghouse, a publicly available database of evidence-based clinical practice guidelines and related documents in the United States, included neither information about financial conflicts among committee members nor about financial sponsors.[68]



of 431 guidelines developed by specialty societies failed to disclose information about committee members.

Box 3.1 presents an example of how issues of COI persist among developers and sponsors of treatment guidelines.

BOX 3.1

Biased guidelines: a growing concern among medical professionals[69]

High dose steroids became the standard of care for acute spinal cord injury in the United States in the early 1990s. This drew skepticism among neurosurgeons, many of whom shared concerns about the association between high dose steroids and infection, lengthy hospital stays, and death. According to a poll, only 11 percent of neurosurgeons (*N* = 1,000) believed that high dose steroids were safe and effective in treating acute spinal cord injury. The same poll, however, revealed that 60 percent of neurosurgeons would continue prescribing high dose steroids despite their potential harm.

As it turns out, the sole reviewer of a key Cochrane review on this topic had provided consultancies to steroid manufacturers. Two decades later, new guidelines warn about the serious dangers of prescribing high dose steroids for acute spinal cord injury. This case highlights one of the several examples mentioned by an investigative medical journalist in a 2013 issue of *British Medical Journal* (BMJ) that explores the ethical challenges faced by physicians when biased standard treatment guidelines are promoted.

In theory, treatment guidelines are developed according to strict standards concerning conflicts of interest. In reality, however, bias is widespread. A recent survey in the United States shows that 71 percent of clinical policy committee chairs and 90.5 percent of co-chairs held financial conflicts.

When promoted by reputable bodies, biased guidelines are accepted as credible standards of care. Biased guidelines directly affect physician performance, medicine selection, and may, in some cases, be used as evidence in malpractice suits. According to the BMJ article, even when doctors believe a guideline is potentially harmful, a considerable number follow it. Eighty-four percent of American doctors are concerned about the influence of the pharmaceutical industry over treatment guidelines, yet they follow recommendations for fear of putting their careers at risk.

C. Who needs to declare?

Potential members of the guideline development group, the external review group, and any other experts or advisors invited to participate in guideline development meetings must declare any affiliations and relationships with interest groups before invitations are issued.[70] Declaring COI is the best way to ensure that the guideline committee member selection process is transparent and legitimate.[71]

D. What needs to be declared?

Individuals should declare financial conflicts, academic conflicts, and public positions. Together, the guideline committee should ultimately determine if a conflict of interest exists and whether the nature and extent of the conflict excludes an individual from participating in the guideline development process.[72] Consider using explicit criteria to aid with decision making.[73] Table 3.1 provides criteria to determine potential sources of conflict of interest.

E. Ensure a documented process for declaring COI

A clear, detailed declaration of interests (DOI) form should be developed that requests as much information as possible on the nature and extent of potential COI.[75] A sample DOI form is presented in box 3.2. This simple generic form is adapted from a DOI

BOX 3.2

Sample declaration of interest form[76]

DECLARATION OF INTEREST FORM

Name _____

Position _____

Have you, or anyone in your family, any financial or other interest in any pharmaceutical manufacturer or supplier, and which may constitute a real, potential or apparent conflict of interest?

Please tick ☐ Yes ☐ No

Have you had, during the past four years, any employment or other professional relationship with any organization that is a pharmaceutical manufacturer or supplier or represents such organizations?

Please tick ☐ Yes ☐ No

If you answered 'yes' to either question, please give details in the box below.

Type of interest, for example patents, shares, employment, association, payment*	Name of commercial entity	Belongs to you, your family, or work unit?	Current interest? Or year that interest ceased

*amounts do not have to be declared

Is there anything else that could affect, or be perceived to affect, your objectivity or independence in carrying out your duties in the STG guideline development committee?

_____

_____

_____

I hereby declare that the disclosed information is correct and no other situation of real, potential, or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances.

Signature _____

Date _____

TABLE 3.1
Declaration of potential sources of conflicts of interest[74]

INTEREST	EXAMPLE
Personal, specific	• Personal consultancy held by committee members on the specific drugs or diagnostic tests being discussed/evaluated
Personal, non-specific	• Personal shares, consultancy held in drug or diagnostic companies
Non-personal, specific	• The department/unit in which the committee member works supports the specific drugs or diagnostic tests being discussed/evaluated
Non-personal, non-specific	• The department/unit in which the committee member works supports drug or diagnostic companies

form included in a Drug and Therapeutics Committee manual produced by WHO and Management Sciences for Health (MSH).

Each individual participating in the guideline committee should be requested to complete a DOI form prior to the first meeting. The DOI should be assessed, summarized, and openly presented to the entire group at the first meeting.[77] The disclosure list needs to be distributed to committee members for verification. Any previously declared conflicts should be updated, as needed, during the course of the guideline development process.[78] If the revised declarations constitute a potential conflict, the appointing body should manage the declared conflicts.

F. Assess the significance of the declared COI

According to WHO, there are some interests that should clearly exclude participation in the guideline development committee or expert review panel. These include[79]—

- Owning shares in a company that manufactures a product that may be recommended in the guidelines
- Holding a patent on a product that may be recommended in the guidelines
- Having a family member who works for a company that manufactures a product that may be recommended in the guidelines
- Current or past involvement in a major academic program of work (e.g., trials, systematic review) that concerns a product that may be recommended in the guidelines
- Receiving funding from, being or have recently been employed by, consulting for, or acting as an advisor to, or paid speaker or opinion leader for a company with an interest in a specific product related to the guidelines

The entity that appoints the guideline development committee and expert review panel decides, on a case-by-case basis, whether and to what extent individuals can participate in guideline development. If a potential participant declares significant personal financial interests with a single company that has a commercial interest in the guideline, then she or he should not participate in the guideline development process at all. If a potential participant has links with multiple companies or has received research funding from companies with commercial interests in the outcome of the guideline, then she or he may be included

Eighty-seven percent of authors of guidelines published between 1991 and 1999 had some form of interaction with the pharmaceutical industry. Fifty-eight percent had received financial support to carry out research, and 38 percent had been employed by a pharmaceutical company.[80]

in the discussion but should be excluded from participating in guideline development.[81]

Decisions on how to manage declared interests must be documented before the initial guideline committee meeting and included in the final guideline. Every member of the guideline development committee should know how conflicts of interest will be managed for individual members. Figure 3.1 provides examples of how to manage declared interests.

FIGURE 3.1
Possible decisions for managing declared interests[82]

DECISION 1

The COI requires no action beyond declaration at the meeting and reporting in the final guideline.

DECISION 2

The COI is significant but related to only some areas of the guideline development committee's work. The participant cannot participate when the group considers these areas and will not have access to relevant documents.

DECISION 3

The COI excludes participation.

DECISION 4

The COI is such that participation in the discussion is appropriate but the member cannot participate in the development and approval of recommendations.

G. Ensure all COI declarations are transparently documented in the guideline

The final guideline document must include a summary of how COI declarations were collected. It must also include declared conflicts and a concise explanation of how they were managed. Where no conflict was declared, the guideline committee should indicate as such.

H. Balance financial support and COI

Evidence-based research shows that COI exists in practice. Research has shown an association between the financial interests of a guideline development committee and the recommendations that support those interests.[83] The need for financial support must be balanced with the potential bias of recommendations. The best way to achieve this balance is to authorize the complete disclosure of financial, personal, and professional relations.[84] Use detailed DOI forms, consider explicit criteria for COI, and manage COI on a case-by-case basis.

STEP 3.
Establish guideline committee procedures

Once the committee has been established, its members will be ready to set timelines, outline responsibilities, establish a clear terms of reference (TOR), decide on methods of consensus, and agree on how to deal with issues. The committee must develop a code of practice for maintaining a constructive balance between confidentiality and transparency. The committee should also develop a matrix that includes disclosed COIs for all members of the committee.

A. Establish a clear terms of reference

Producing a treatment guideline requires a substantial amount of time and effort. As such, the roles and expectations of committee members should be made clear at the time of recruitment.[85] The committee will agree on a

TABLE 3.2
Sample TOR for Guideline Development Committees[87]

Functions of committee chair	The purpose of the chair is to ensure that the guideline development committee adheres to its agenda and achieves its goals using appropriate methodological standards. Specifically, the chair is required to— • Assist staff in planning conference calls and meetings • Guide discussion according to agenda • Encourage all committee members to actively contribute their opinions and ideas • Remain aware of small group processes • Establish a climate of trust and mutual respect among members • Maintain a balanced, unified group discussion • Encourage constructive debate and summarize main points and key decisions • Delegate writing assignments • Integrate group work into the draft guideline
Functions of committee members	Committee members are responsible for developing a relevant, appropriate, and well-understood STG. Specifically, they are required to: • Fully disclose any potential conflicts of interest • Participate in all conference calls • Attend all meetings • Show a commitment to teamwork • Communicate clearly • Conduct a review of the medical literature • Read all relevant materials and provide constructive contributions throughout • Develop treatment recommendations that are explicitly linked to the evidence • Maintain regular communications • Complete personal assignments on time • Maintain confidentiality
Frequency of meetings	• Schedules, meetings, and venues are arranged by support personnel. The committee should meet on a regularly scheduled basis and a set minimum of members should be present at any meetings.
Record of meetings	• Meeting minutes will be recorded by support personnel.

number of roles, and some members may fill more than one.[86]

The TOR describes the purpose and structure of the guideline development committee. It should define the role of the committee chair and committee members, as well as the goals and objectives of the committee. Table 3.2 presents a sample TOR for a guideline development committee.

Note that ideally one or more patient representatives should participate in the guideline committee to ensure that issues that matter to patients are reflected in the guidelines and to identify areas where patient preferences may need to be considered.[88]

B. Plan and run meetings effectively

Advance planning is the greatest guarantee of success during the guideline development process,[89] as committee meetings cover a lot of information in a short amount of time. Plan for effective meetings by providing clear

information about the scope of the meeting, the role of committee members, and the objectives and processes of the committee.[90] Consider the following—

- How can participants prepare for the meeting?
- What needs to be achieved during the meeting?
- What can be done afterwards?
- What follow-up will take place with meeting participants?

Following a timetable will keep the committee on track. Meetings should be planned early in the process so that committee members can confirm their availability. Consider engaging administrative and clerical support to help arrange meetings, facilitate communications, record minutes, and prepare documentation.[91]

Research has shown that decision making is best achieved through formal consensus development. This method, which provides for both group discussion and private consideration, "involves the generation of group judgments based on explicit aggregation of individual participants' judgments and allows participants to revise their judgments in private following structured interaction and formal feedback of group views."[92]

C. Map relevant stakeholders

Once the goals and objectives of the committee have been set, members should map out additional relevant stakeholders to form an external review group. The external review group will be asked to review the scope of the guideline early in the development process. They will also be asked to review the draft guideline once it has been prepared. Much like the guideline committee, the external review group should be balanced with regards to technical expertise, gender, and geographic location.[93]

CHAPTER 3

TAKE-HOME MESSAGES

- The guideline committee goals are to improve the quality of medical care for the population and to build an efficient and quality assured guideline development and maintenance process that increases satisfaction among patients and health care workers.
- The make-up of the guideline committee has considerable influence on the recommendations produced. A guideline committee should be multidisciplinary, comprising both clinical and non-clinical staff involved in health care delivery. Experience suggests the committee should consist of 6 to 10 members.
- Declaring conflicts of interest is the best way to ensure that the guideline committee member selection process is transparent and legitimate. Conflicts of interest may stem from financial relationships, personal relationships, academic competition, or public position. Full documented disclosure of financial, personal, and professional relations will safeguard the integrity of the committee's work.
- Once established, the guideline development committee must develop a TOR that describes the purpose and structure of the committee.
- The guideline development committee should plan for effective meetings by providing clear information about the scope of the meeting, the role of committee members, and the objectives and processes of the committee.
- Once the goals and objectives of the committee have been set, members should map out additional relevant stakeholders to form an external review group.

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CHAPTER 4 Determining the Scope of the Guideline

STEP 1. Draft the scope of the guideline

Preparing a scope is a challenging, though critical, aspect of guideline development. The guideline scope should clearly state the guideline's objectives, its intended users, and the standard set of information it will include for individual diseases or conditions along with any complementary information on rational medicines use. Most guidelines include a minimum of information on clinical features, diagnostic criteria, treatment of choice, non-drug treatment, and referral criteria for each condition or disease included.

The following sections may serve as a checklist to help you build a scope for the guideline.

A. Determine which health issues the guideline will address

Guidelines can be developed for any of a wide range of topics. Topics should be high-priority and feasible. High-priority topics are based on disease burden, controversy or uncertainty, cost, new evidence, potential to improve health outcomes and quality of life, public or provider interest, and variations in care. Feasible topics are well supported by good quality evidence to guide the formulation of recommendations.[94]

To identify the health issues that the guideline will cover, review morbidity and mortality patterns and consult with medical specialists and practitioners to identify the most prevalent conditions. Specifically, ask key clinicians about the problems or barriers they have experienced in clinical practice. The following parameters can help you decide which health issues to include in the guideline[95]—

- High prevalence condition or high use medical procedure
- High associated cost
- Effects on premature mortality and avoidable morbidity
- Evidence that medical care can make a difference in outcomes
- Knowledge of current variations in practice

B. Identify the type of guideline

A guideline may be one of three types: individual, selective, or comprehensive. When identifying the type of guideline to develop, be sure to consider the capacity and resources available. In an individual guideline, standard treatments are prepared for only one condition (e.g., malaria). In a selective guideline, standard treatments are prepared for a small number of high-priority problems. In a comprehensive guideline, standard treatments are prepared for all of the most

common health problems in a given country.[96] This may include 30, 50, or over 100 common health problems.[97]

C. Determine the primary and secondary target audiences for the guideline

The guideline committee must determine the type of care providers and consumers for whom the guideline is intended.[98] The committee should define the intended primary target users, as well as secondary target users. This decision needs to be made early in the development process, as it influences the orientation and emphasis of the content and the language of the guideline. The committee should clearly define the types of settings in which the guidelines are appropriate for use.
For example—

- The second edition of the Somalia STG is primarily intended for use by health professionals working in maternal and child health and outpatient facilities. Secondary target groups include anyone working with medicines, particularly doctors, nurses, and pharmacists working in hospitals, private clinics, and pharmacies.[99]
- The third edition of the South Africa Hospital Level Adult STG and EML is primarily intended for use by doctors and pharmacists working at district and regional hospitals.[100]
- The third edition of the Ethiopia STG is primarily intended for use at general hospitals in both the public and private sectors.[101]
- The sixth edition of the Ghana STG is intended for use by prescribers (including doctors, medical assistants, and midwives), pharmacists, dispensers, and other health care staff who prescribe at primary care facilities.[102]
- The first edition of the Namibia STG is intended for medical officers, nurses, pharmacists, and all other health care providers involved in the management of patients in the public and private sectors.[103]

D. Check for relevant guidelines that may already exist

Conduct a search for any existing guidelines, particularly those that are available in your local setting or country. An additional search should be conducted to identify systematic reviews, health technology assessments, or economic evaluations that are related to the guideline topics (see chapter 5).[104]

A website called the National Guideline Clearinghouse houses hundreds of treatment guidelines from different health care organizations. Though limited to the United States, this repository of information was created by the federal government to make guidelines on various topics available and accessible to the healthcare community.[105] Visit the website at http://www.guideline.gov.

E. Assess the quality and relevance of existing guidelines

Once you have established that guidelines exist, assess their relevance by examining the quality of evidence, the balance between risks and benefits, and the strength of the recommendations. Are the criteria for assessing the quality of guidelines clearly laid out? Are the references current? Were the studies published in peer-reviewed journals? Are the guidelines up-to-date?

When assessing existing guidelines, you can perform a quality assessment using the Appraisal of Guidelines and Research and Evaluation (AGREE) instrument[106]. The AGREE instrument is used to determine whether a guideline is acceptable, reliable, and of good quality.

TABLE 4.1
The AGREE II instrument: domains and descriptions of key items[107]

DOMAIN	KEY ITEMS
Scope and Purpose	• Objective(s) of the guideline specifically described • Health question(s) specifically described • Target population (patients, public, etc.) specifically described
Stakeholder involvement	• Development committee includes relevant professionals • The target population's views and preferences are sought • Target users are clearly defined
Rigor of development	• Systematic methods are used to search for evidence • Criteria for selecting evidence are clearly described • Strengths and limitations of evidence are clearly described • Methods for formulating recommendations are clearly described • Health benefits, side effects, and risks are considered • Explicit link is made between recommendations and evidence • Guideline is reviewed by external experts before publication • Procedure for updating guideline is provided
Clarity of Presentation	• Recommendations are specific and unambiguous • Different options for managing conditions or health issues are clearly presented • Key recommendations are easily identifiable
Applicability	• Advice and/or tools on how to put recommendations into practice are provided • Facilitators and barriers are discussed • Potential resource implications are considered • Monitoring and/or auditing criteria are presented
Editorial independence	• The views of the funding body have not influenced the content of the guideline • Competing interests of guideline development committee members are recorded and addressed

The original AGREE instrument has been enhanced and further developed into AGREE II, which includes a User's Manual. AGREE II provides a framework to assess the quality of guidelines, as well as a methodological strategy to develop guidelines and inform the type of information and the manner in which it should be reported[108]. Visit www.agreetrust.org for free, downloadable copies of AGREE II and the accompanying User's Manual. The AGREE instrument is included in appendix B of this manual.

Each domain of the instrument reflects a potential source of bias or issues related to clarity and comprehension, as shown in Table 4.1. Potential sources of bias include the type of literature search used, the method used to evaluate evidence quality, and conflict of interest.

F. Determine whether to develop a new guideline or adapt an existing one

In resource-limited settings, adapting a pre-existing clinical guideline from elsewhere to the local context may be more suitable than developing a new guideline, as it requires less money and time. Guideline adaptation makes use of an already developed guideline by appropriately customizing it to fit a unique cultural and organizational context. Like the development process, the adaptation process should be systematic and transparent, and should include an assessment of the quality, content, and adaptability of the guideline, among other factors.[109]

Adaptation of evidence-based guidelines can only be achieved through an in-depth

knowledge of the methodology and a detailed understanding of the local context.[110] The following documents offer detailed guidance on guideline adaptation:

- Adaptation of clinical guidelines: literature review and proposition for a framework and procedure. http://intqhc.oxfordjournals.org/content/18/3/167
- The ADAPTE process: resource toolkit for guideline adaptation (version 2.0). http://www.g-i-n.net/document-store/working-groups-documents/adaptation/adapte-resource-toolkit-guideline-adaptation-2-0.pdf

Sometimes, a country may have multiple, inconsistent guidelines that recommend treatment for the same conditions. Similarly, in some instances, neighboring countries may have widely different treatment guidelines for the same conditions. Such inconsistency can lead to non-standardization, confusion, and variations in practice. Box 4.1 describes how the USAID-funded Rational Pharmaceutical Management (RPM) Plus Program provided technical assistance in conducting a meta-analysis of STGs for HIV and AIDS, TB, and malaria in East, Central, and Southern African countries. What emerged from this review was a set of harmonized STGs for HIV and AIDS, TB, and malaria designed to simplify and standardize treatment and care in the region.

BOX 4.1

Regional harmonization of treatment guidelines for HIV and AIDS, TB, and malaria in East, Central, and Southern African countries[111]

The East, Central, and Southern African Health Community (ECSA HC) is an intergovernmental organization with membership from 10 countries that promotes regional cooperation in health in the ECSA region. With technical support from the USAID-funded Rational Pharmaceutical Management (RPM) Plus Program, the ECSA HC established the Regional Pharmaceutical Forum (RPF) in 2003 to increase the efficiency of pharmaceutical systems in member states. Among other key interventions, the RPF identified the need to simplify and standardize treatment in the ECSA region through the development of regional standard treatment guidelines for HIV and AIDS, TB, and malaria.

In 2005, RPM Plus provided technical assistance in conducting a meta-analysis of STGs for HIV and AIDS, TB, and malaria from ECSA member states. Specifically, the team—

- Gathered and compared information on treatment protocols and regimens
- Developed recommendations for the regional harmonization of treatment protocols and regimens
- Drafted a harmonized set of regional standard treatment guidelines that account for safety, efficacy, and cost-effectiveness

In 2007, a harmonized set of regional treatment guidelines for HIV and AIDS, TB, and malaria was finalized, along with a complementary model medicines formulary to promote rational medicine use and provide a drug information resource for health care providers. The two documents, *Guidelines for the Management of HIV and AIDS, Tuberculosis and Malaria in East, Central and Southern Africa* and *ECSA Model Formulary for HIV and AIDS, TB and Malaria,* serve to simplify drug management processes, enhance information sharing, and foster collaboration in pharmaceutical management activities.

G. Determine whether the guideline is national or local in scope

Guidelines can be developed at either the national or local level. Developing a national level guideline requires a broad pool of expertise and resources. A national guideline is also limited by regional variations in the availability of resources and the lack of involvement of local end-users. These factors may negatively impact uptake. While guidelines that are local in scope have the advantage of increasing ownership and commitment,[112] they require an extensive process and involvement at the local level with fewer opportunities for support from a wider pool of national experts and stakeholders.

H. Address the needs of different levels of care

Consider whether information for all levels of health workers should be presented in one publication, or if different publications should be issued for different levels of care. An example of the latter exists in Ethiopia, where three separate

TABLE 4.2
Conditions and ancillary information featured in a sample of standard treatment guidelines[117]

	Ethiopia STG for General Hospitals 2014	Ghana National STG 2010	Malawi National STG 2009	Namibia National STG 2011	Somalia National STG 2007	South Africa Hospital Adult STG 2012	Swaziland National STG 2012	Zambia National STG 2008	Uganda National STG 2010
Infectious diseases	√	√	√	√			√	√	√
Sexually transmitted infections	√	√	√	√	√		√	√	√
Ophthalmological problems	√	√	√	√	√	√	√	√	√
Ear, nose, and throat problems	√	√	√	√		√	√	√	√
Mouth and pharynx problems	√	√	√		√		√	√	√
Obstetrics and gynecological disorders	√	√	√	√	√	√	√	√	√
Emergency conditions and trauma	√	√	√	√	√	√	√		√
Disorders of the gastrointestinal tract	√	√	√	√	√	√	√	√	√
Disorders of the liver	√	√	√			√			√
Nutritional disorders		√	√	√	√		√	√	√
Problems of the newborn		√							
Disorders of the cardiovascular system	√	√	√	√		√	√	√	√
Disorders of the central nervous system	√	√	√	√		√	√	√	
Psychiatric disorders	√	√	√	√		√	√	√	√
Endocrine and metabolic disorders	√	√	√	√		√	√	√	√
Disorders of the kidney and genitourinary system	√	√	√	√		√	√		√

TABLE 4.2
Conditions and ancillary information featured in a sample of standard treatment guidelines (continued)

	Ethiopia STG for General Hospitals 2014	Ghana National STG 2010	Malawi National STG 2009	Namibia National STG 2011	Somalia National STG 2007	South Africa Hospital Adult STG 2012	Swaziland National STG 2012	Zambia National STG 2008	Uganda National STG 2010
Musculoskeletal disorders	√		√	√		√	√		√
Parasitic diseases			√		√	√			√
Respiratory conditions	√	√	√	√	√	√	√	√	√
Disorders of the skin	√	√	√	√	√	√	√	√	√
Bites, burns, and wounds	√	√	√	√	√	√	√	√	√
Poisoning	√	√	√	√	√	√	√	√	√
Antibiotic prophylaxis in surgery		√				√			
Management of pain		√	√			√	√		√
Palliative care	√		√	√			√		
Common malignancies/ oncology		√		√				√	
Blood and blood diseases	√	√	√	√		√	√		
Pediatric diseases	√	√		√			√		√
Annexes/appendices									
Disease index	√			√				√	√
Medicine index	√		√	√			√	√	
Adverse drug reaction form		√		√			√		
Form to amend the STG				√			√		√
Immunization schedule	√						√		√
Medicine use in pregnancy	√							√	
Feeding problems	√								

STGs were published in 2010. Each guideline caters to a different level of care—general hospitals,[113] primary hospitals,[114] and health centers.[115] Similarly, in South Africa, hospital level STGs have been published separately for adults and pediatrics, and STGs have also been developed for primary health care and tertiary hospitals. Producing separate guidelines for different levels of care has the advantage of recommending only those medicines that are supplied to a particular level. For rural facilities, for example, the language is generally simpler, there are more illustrations, and only those medicines available at the rural level are recommended.

Alternately, one publication can serve as a comprehensive reference for all recommended treatments. The production process is easier and generally less expensive. While information for higher levels of care may not be practical for those at lower levels of care, it can be educational.[116]

I. Determine what information the guideline will include

Comprehensive guidelines are typically wide in their scope and cover several organ systems and disease areas. Table 4.2 presents a matrix

TABLE 4.3

Categories of information to describe conditions or diseases in a sample of standard treatment guidelines

	Ethiopia STG for General Hospitals 2014	Ghana National STG 2010	Malawi National STG 2009	Namibia National STG 2011	Somalia National STG 2007	S. Africa Hospital Adult STG 2012	Swaziland National STG 2012	Zambia National STG 2008	Uganda National STG 2010
Definition or description	√	√	√	√	√	√	√	√	√
Causes	√	√	√	√	√	√	√	√	√
Risk factors	√	√	√	√	√	√	√	√	√
Clinical features (signs and symptoms)	√	√	√	√	√	√	√	√	√
Treatment	√	√	√	√	√	√	√	√	√
Non-pharmaceutical treatment	√	√		√			√	√	
Dose regimens	√	√	√	√	√	√	√	√	√
Important contraindications and side effects	√	√	√	√		√	√	√	√
Clinical investigations or diagnostic criteria	√	√	√	√		√	√	√	√
Prevention	√	√	√	√	√	√	√	√	√
Referral criteria	√	√	√	√	√	√	√	√	√
Health education				√			√		

comparing conditions or diseases and ancillary information included in a sample of treatment guidelines from LMICs. As you can see, guidelines cover a variety of topic areas, from common emergencies to diseases and disorders of various body systems. As the table shows, certain topic areas, such as obstetric/gynecological and ophthalmological problems, are covered by all or most of the guidelines, but certain others, such as malignancies and poisonings, are covered by only a few.

For each individual condition or disease included, treatment guidelines typically present the treatment of choice, along with some additional clinical information to help guide the prescriber. Table 4.3 compares the categories of information that are typically included within each condition or disease covered in the same sample of treatment guidelines from low- and middle-income countries. From the table, it is clear that most STGs cover the following types of information to describe each condition or disease:

- Definition or description
- Causes
- Risk factors
- Clinical features (i.e., signs and symptoms)
- Diagnostic criteria
- Treatment of choice (i.e., choice of medicine, dosage schedule)
- Non-pharmaceutical treatment
- Important contraindications and side effects of the recommended medicine(s)
- Clinical investigations or diagnostic criteria
- Prevention
- Referral criteria (i.e., when to refer patient to a higher level of care)

FIGURE 4.1
Excerpt from 2010 Ghana STG[117]

CHAPTER 3: DISORDERS OF THE LIVER

7. AMOEBIC LIVER ABSCESS

This is a collection of brownish coloured fluid in the liver occurring often as a single mass in the right lobe, as a complication of intestinal infection with *Entamoeba histolytica*. Occasionally, pyogenic abscesses may have a similar clinical presentation, and will require treatment with appropriate antibiotics

CAUSES
- *Entamoeba histolytica*

SYMPTOMS
- Right upper abdominal pain
- Abdominal distension
- Fever
- Cough

SIGNS
- Large tender liver
- Tenderness and or bulging at right intercostal spaces
- Jaundice
- Dullness to percussion on the right lower zones with basal crepitations

INVESTIGATIONS
- Abdominal ultrasound
- Chest X-ray
- FBC
- Stool examination

TREATMENT

Treatment objectives
- To eradicate infection
- To prevent further destruction of liver tissue
- To prevent rupture of abscess into pleural, pericardial or peritoneal space

Non-pharmacological treatment
- Surgical drainage of abscess if indicated

Pharmacological treatment
(Evidence rating: A)
- Metronidazole, oral,

DISORDERS OF THE LIVER

Adults
800 mg 8 hourly for 10 days
Children
7-12 years; 200-400 mg 8 hourly for 10 days
4-7 years; 200 mg 8 hourly for 10 days
1-3 years; 100-200 mg 8 hourly for 10 days
Or
Tinidazole, oral,
Adults
2 g daily for 3-6 days
Children
50-60 mg/kg daily for 5 days

REFER

Patients with abscesses that are large or not responding to treatment will need to be referred to a physician or surgical specialist.

8. JAUNDICE

This is a condition in which the skin, palms and the sclerae become yellow in colour as a result of elevated levels of bilirubin in the bloodstream. The symptoms and signs that accompany jaundice often give helpful clues to the underlying cause.

In adults and children, hyperbilirubinaemia may result in hepatic encephalopathy (See sections on **Chronic Hepatitis, Obstructive Jaundice and Liver Failure).**

Jaundice in neonates can result in kernicterus because of the consequences of hyperbilirubinaemia on the brain of the newborn. Kernicterus causes death in most infants and survivors suffer mental and physical handicaps with cerebral palsy, high frequency nerve deafness, poor memory, low IQ and visual-motor incoordination.

Jaundice appearing in the first 48 hours after birth, or a bilirubin concentration >170 micromol/L in premature infants, or >255 micromol/L in full-term infants, warrants investigation. However, jaundice appearing from the third day after birth onward is usually physiological.

Exchange transfusion is the definitive treatment for Hyperbilirubinaemia that has reached the level where kernicterus may occur.

CAUSES

Adults
- Hepatitis - viral, alcoholic, drug-induced (including allopathic and herbal preparations)

Figure 4.1 illustrates how these categories of information are succinctly laid out in a treatment guideline. This example of information on amoebic liver abscess comes from the 2010 Ghana STG.

The success of a treatment guideline largely depends on how it aligns with the essential medicines list. When determining what medicines the guideline will include, be mindful of establishing consistency between standard treatment guidelines and the national essential medicines list. This will ensure that the guidelines are supported by the supply system.[118] Also keep in mind that selecting medicines that are too sophisticated, too expensive, or not generally available at the relevant level of care will have a negative impact on their acceptance by the health care community.[119]

For example, the Swaziland STG (2012) includes a listing of essential medicines (Figure 4.2). Column 4, Level, describes at which level of care the medicine can be ordered and prescribed:

- Level **A** indicates medicines that are distributed to all health care facilities as part of primary health care services. Both doctors and nurses can prescribe these medicines.
- Level **B** indicates medicines that are distributed to health centers and hospitals. Only medical doctors can prescribe these medicines.

- Level **C** (not pictured here) indicates medicines that are distributed to hospitals only. Only medical doctors working in hospitals can prescribe these medicines, following appropriate diagnosis.
- Level **S** indicates medicines that are distributed on demand by specialist doctors.
- An **asterisk** indicates medicines that are distributed by vertical national programs (e.g., TB, malaria).

Column 5, VEN, describes the various medicines according to the importance of their therapeutic effect: V = vital, E = essential, N = nonessential.

In addition to the typical sets of information discussed above, treatment guidelines are also used to provide relevant and highly useful supplementary information.

- South Africa's third edition of the Adult Hospital Level STG-EML (2012)[121] highlights and promotes adverse drug event reporting. At the end of the documents, users can access an *Adverse Drug Reaction and Product Quality Problem Report Form.* See appendix C of this manual to view the form. Access the publication at http://www.kznhealth.gov.za/pharmacy/edladult_2012.pdf.
- Somalia's second edition of the STG (2007)[122] is a two-part publication. Part 1 features standard treatment guidelines describing treatment options for common diseases in Somalia. Part 2 features a training manual on rational management and use of medicines at the primary health care level. Access the publication at http://www.who.int/selection_medicines/country_lists/som_stg_2007.pdf.
- Zambia's STGs, EML, and essential laboratory supplies list (2008)[123] includes a list of essential laboratory reagents and supplies, guidance on drug use in pregnancy, and guidance on drug use among nursing mothers. Access the publication at http://apps.who.int/medicinedocs/en/d/Js19280en/.
- Ghana's sixth edition of STGs (2010)[124] includes tips on prescription writing. Access the publication at http://apps.who.int/medicinedocs/documents/s18015en/s18015en.pdf.

FIGURE 4.2
Essential Medicines List Section of the Swaziland STG (2012)[120]

ESSENTIAL MEDICINES LIST

Medicine	Strength	Dosage Form	Level	VEN
Rabies (purified Vero rabies vaccine)	—	Injection	A*	V
Tetanus immunoglobulin	250 IU/2 mL	Injection	A*	V
Tetanus toxoid	40 IU/5 mL	Injection	A*	V
Tuberculin, Mantoux test (diagnostic)	—	Injection	A*	E
Tuberculin, TINE test (screening)	—	Dry powder	A*	E
Typhoid	—	Injection	A*	V
Yellow fever	—	Injection	A*	V
ANTINEOPLASTICS AND IMMUNOMODULATING AGENTS				
Cytostatic agents				
Adriamycin	50 mg/5 mL	Injection	S	E
Bleomycin	15,000 IU	Powder for injection	S	E
Cyclophosphamide	25 mg	Tablet	S	E
Cyclophosphamide	500 mg/vial	Injection	S	E
Dacarbazine	200 mg/vial	Injection	S	E
Fluorouracil	50 mg/mL	Injection	S	E
Methotrexate	25 mg/mL	Injection	S	E
Methotrexate	2.5 mg	Tablet	S	E
Vinblastine	10 mg/mL	Injection	S	E
Vincristine	2 mg/mL	Injection	S	E
Endocrine therapy				
Tamoxifen	10 mg	Tablet	S	E
Immunosuppressants				
Azathioprine	50 mg	Tablet	S	E
Cyclosporine	25 mg	Capsule	S	E
Cyclosporine	50 mg/5 mL	Injection	S	E
MUSCULOSKELETAL SYSTEM				
Anti-inflammatory and antirheumatic products (including paracetamol)				
Acetylsalicylic acid (aspirin)	300 mg	Tablet	A	E
Diclofenac	75 mg	Injection	A	E
Diclofenac	1%	Gel	S	E
Diclofenac	50 mg	Tablet	B	E
Diclofenac	25 mg	Suppository	B	E

Remember, a successful guideline is simple and clearly guides the user through the treatment process. Determine the *minimum* amount of information that is appropriate for use in the local setting. Remain focused and resist the temptation to write a textbook.[125]

Once the guideline scope has been drafted by the guideline development committee, it should be submitted to an external review group for feedback, as described in the next step.

STEP 2.
Send the scope of the guideline to reviewers and finalize

Submit the scope of the guideline to an external group of reviewers for feedback. Once the scope has been reviewed, the appropriate feedback should be incorporated.

Box 4.2 provides an example of how an AMR advocacy working group in Zambia collaborated with other local stakeholders to revise the infectious disease components of the national guideline, which were later incorporated into the revised medical curriculum.

After the feedback has been incorporated, take a final look at the revised scope. Are the objectives clear, specific, and measurable? Are the targets achievable? Is the timeline appropriate? Have you mobilized adequate human, financial, and material resources?[131] Make any final adjustments and finalize the scope.

BOX 4.2

Collaboration between the Zambia AMR Advocacy Working Group and other stakeholders to revise the national STG[126, 127, 128, 129, 130]

With USAID support, predecessors of the Systems for Improved Access to Pharmaceuticals and Services Program—Strengthening Pharmaceutical Systems and Rational Pharmaceutical Management Plus—helped national stakeholders implement country-level antimicrobial resistance (AMR) advocacy and containment strategies. A Zambia AMR Advocacy Working Group (AWG) was established, and through its leadership, a high-profile AMR stakeholders meeting was held and a widespread call-to-action was generated. As a part of its containment strategy, the AWG sponsored a workshop for physicians implementing and using STGs for infectious diseases of major public health importance. From this workshop came recommendations for revising the existing national STGs. This inspired the support of the Zambia National Formulary Committee to review the infectious disease components of the national STG to promote rational use of antimicrobials. The AWG continued to collaborate with the Formulary Committee and the Ministry of Health during the review process, leading to the finalization and publication of the revised STGs in 2008. Subsequently, with AWG's continued efforts, the national STGs were incorporated into pre-service medical curriculum.

CHAPTER 4

TAKE-HOME MESSAGES

- The scope of a treatment guideline should clearly state the document's objectives, its intended users, and the standard set of information it will include for individual diseases or conditions, along with any complementary information on rational medicines use.
- Guidelines should be developed for topics that are high-priority and feasible. To identify the health issues that the guideline will cover, review morbidity and mortality patterns and consult local stakeholders to identify the most prevalent conditions.
- There are three types of STGs: individual, selective, and comprehensive. These differ in the number of conditions or individual diseases covered.
- In resource-limited settings, adapting a pre-existing clinical guideline from elsewhere to the local context may be more suitable than developing a new one, as this requires less money and time.
- Most guidelines include a minimum of information on clinical features, diagnostic criteria, treatment of choice, non-drug treatment, and referral criteria for each condition or disease included.
- Once the scope of the guideline has been drafted, submit it to an external review group for feedback. Make any final adjustments and finalize the scope.

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CHAPTER 5 Determining Appropriate Treatment Options

STEP 1. Review the evidence

The first step to determining appropriate treatment options is to follow the proper steps to obtain the best available evidence, and to assess the quality of the evidence once it has been identified.

The importance of evidence-based medicine

Treatment guidelines should be based on the best available evidence. Guidelines that rely solely on group opinion or experience of routine clinical practice are susceptible to bias and may not reflect good clinical practice.

To obtain the best available evidence, the guideline development process must identify and assess national standards, international scientific evidence (e.g., systematic reviews, meta-analyses, randomized controlled trials, and reputable guidelines), international organizations' recommendations (e.g., WHO), and the views of patients and service users (e.g., national surveys of patient experience).[132] Search major bibliographic databases (e.g., MEDLINE, Embase), reference lists from relevant studies, conference abstracts, and other grey literature. In addition, reach out to experts to identify additional studies.[133] The evidence gathered should be triangulated with country-specific best practices.

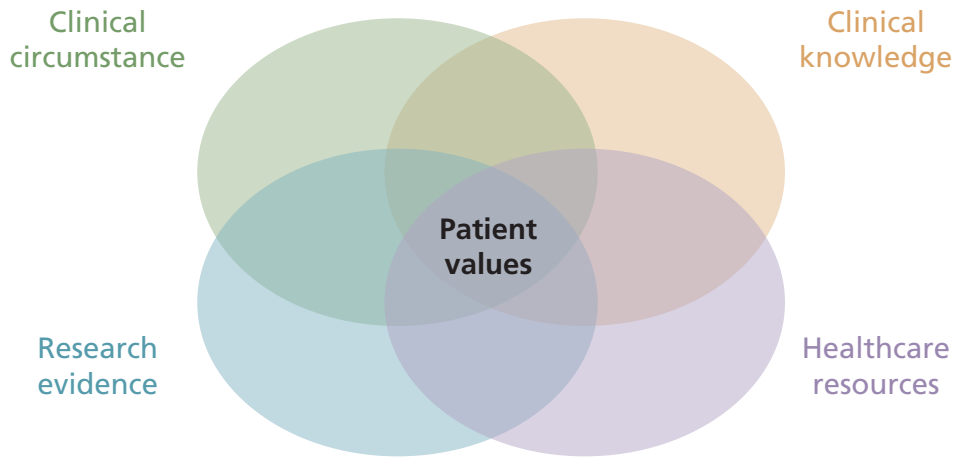
Follow the appropriate steps for gathering evidence

Conduct a search of international and local literature to determine what information already exists. Search for any existing guidelines, individual studies, systematic reviews, journals, and reviews. Also, solicit input from experts in the field. This will highlight any information gaps.

Clinical decision making relies on a variety of information. When gathering evidence, consider patient needs and preferences, clinical circumstances, clinical knowledge, and health care resources. Giving proper consideration to these aspects during the development and implementation process will increase the chances of a successful guideline, as these various types of information are intricately related (Figure 5.1).

Once the guideline development committee has identified the evidence, it must be synthesized. A variety of methods can be used to review and evaluate evidence, ranging from a very formal meta-analysis of randomized controlled trials to a less formal interpretation based on clinicians' knowledge and routine

FIGURE 5.1
Interplay of types of research evidence[134]



clinical practice. The degree of formality is positively associated with the credibility and validity of the guidelines.[135]

Approaches to synthesizing evidence include clinician knowledge, an unsystematic literature review, a systematic review, an ungraded systematic review, and a formal meta-analysis (Table 5.1). Each of these approaches has been used to interpret evidence and arrive at recommendations. You may also combine approaches to interpret the evidence. The downside of combining approaches, however, is the extra time and money required to complete the work.[136]

In the case of a WHO-recommended treatment for a condition, like amoxicillin for pneumonia, the guideline committee is not required to evaluate the evidence to align it with international recommendations. Any recommendation published by WHO has a strong level of evidence attached to it and has already been reviewed by a panel of experts.

A systematic review identifies and summarizes evidence on the effectiveness of interventions, assesses the extent to which research findings are generalizable and consistent, and explores inconsistencies in data.[138] If performed using the proper approach, systematic reviews reduce the risk of reporting bias and improve the reliability and accuracy of recommendations.[139]

A systematic review requires[140]—

- A specific and clearly focused question
- An explicit, reproducible method that includes pre-defined eligibility criteria
- A comprehensive, exhaustive, and systematic search for primary studies
- A selection of studies using clear and reproducible eligibility criteria
- A critical appraisal of included studies for quality
- A systematic presentation and synthesis of the characteristics and findings of the included studies

Conducting a systematic review, however, is not always necessary or feasible.[141] In resource-limited settings, for example, poor access to material resources, time constraints, limited expertise, and cost make it challenging to

TABLE 5.1
Methods of synthesizing evidence[137]

METHOD	DESCRIPTION
Clinician knowledge	• Used when clinical information is lacking • Information may be incomplete, as clinicians may not have the time to research, collate, and interpret data • May reinforce possible prevailing biases and inappropriate practices rather than produce new approaches to care
Unsystematic literature review	• Does not use explicit search strategy, inclusion criteria, or formal method of synthesis • Information of variable quality is collected in a random manner • Information may be difficult to collate and interpret • May result in selection bias due to omission of some studies
Systematic reviews	• Applies search criteria • Search and analysis includes studies deemed methodically correct • Search strategy increases the validity and reliability of the outcome • Cochrane reviews are updated on a regular basis to ensure new evidence is included
Ungraded systematic review	• Reviews only randomized trials • May omit important studies with a different design methodology
Formal meta-analysis	• Pools all the information from multiple randomized trials and summarizes all the reviewed evidence by a single statistic (e.g., pooled relative risk of mortality) • Generally more reliable and yields more valid evidence

conduct systematic reviews. In such settings, guideline developers should maximize what has already been done. Any existing systematic reviews that are current, relevant, and of high quality should be used. Guideline developers should know where and how to access existing systematic reviews and up-to-date abstracted evidence and treatment summaries from reputable bodies and use this information to make decisions. Table 5.2 lists selected organizations that provide clinical information relevant to those involved in STG development or revision.

The Cochrane Collaboration is a large global network that produces systematic reviews. You may consult with the Cochrane Collaboration at http://www.cochrane.org/cochrane-reviews/cochrane-database-systematic-reviews-numbers to identify existing or forthcoming systematic reviews or updates on reviews on guideline topic(s) under consideration.[142] Box 5.1 presents an abstract from a systematic review by the Cochrane Collaboration on the effects of antibiotic prophylaxis in cesarean section.

Assess the quality of evidence

Once the relevant evidence has been identified and synthesized, the guideline development committee must assess its quality, relevance, and strength. There are several different instruments that can be used to assess evidence quality. Assessing the strength and quality of supporting evidence increases the transparency and usefulness of treatment guidelines.

If present on the guideline development committee, the methodological expert would be best suited to serve as the primary person responsible for assessing the level and quality of evidence or reviewing evidence assessments done by other members of the committee.

BOX 5.1

An abstract from a systematic review by the Cochrane Collaboration[143]

- **Background:** The single most important risk factor for postpartum maternal infection is cesarean section. Routine prophylaxis with antibiotics may reduce this risk and should be assessed in terms of benefits and harms.
- **Objectives:** To assess the effects of prophylactic antibiotics compared with no prophylactic antibiotics on infectious complications in women undergoing cesarean section.
- **Search strategy:** We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (May 2009).
- **Selection criteria:** Randomized controlled trials and quasi-randomized controlled trials comparing the effects of prophylactic antibiotics versus no treatment in women undergoing cesarean section.
- **Data collection and analysis:** Two authors independently assessed the studies for inclusion, assessed risk of bias, and carried out data extraction.
- **Main results:** We identified 86 studies involving over 13,000 women. Prophylactic antibiotics in women undergoing cesarean section substantially reduce the incidence of febrile morbidity (average risk ratio (RR) 0.45; 95% confidence interval (CI) 0.39 to 0.51, 50 studies, 8,141 women), wound infection (average RR 0.39; 95% CI 0.32 to 0.48, 77 studies, 11,961 women), endometritis (RR 0.38; 95% CI 0.34 to 0.42, 79 studies, 12,142 women), and serious maternal infectious complications (RR 0.31; 95% CI 0.19 to 0.48, 31 studies, 5,047 women). No conclusions can be made about other maternal adverse effects from these studies (RR 2.43; 95% CI 1.00 to 5.90, 13 studies, 2,131 women). None of the 86 studies reported infant adverse outcomes and, in particular, there was no assessment of infant oral thrush. There was no systematic collection of data on bacterial drug resistance. The findings were similar whether the cesarean section was elective or non-elective, and whether the antibiotic was given before or after umbilical cord clamping. Overall, the methodological quality of the trials was unclear and in only a few studies was it obvious that potential other sources of bias had been adequately addressed.
- **Authors' conclusions:** Endometritis was reduced by two thirds to three quarters and a decrease in wound infection was also identified. However, there was incomplete information collected about potential adverse effects, including the effect of antibiotics on the baby, making the assessment of overall benefits and harms complicated. Prophylactic antibiotics given to all women undergoing elective or non-elective cesarean section is clearly beneficial for women but there is uncertainty about the consequences for the baby.

Endometritis was reduced by two thirds to three quarters and a decrease in wound infection was also identified.

TABLE 5.2
Reputable sources of clinical information for guideline development or revision

SOURCE	WEBSITE
Clinical evidence	http://clinicalevidence.bmj.com/ceweb/index.jsp
Database of Abstracts of Reviews of Effects (DARE)	http://www.crd.york.ac.uk/CRDWeb/
Cochrane Library	http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME
Medline	http://medlineplus.gov/
U.S. Centers for Disease Control and Prevention	www.cdc.gov
PubMed Central	http://www.ncbi.nlm.nih.gov/pmc/
Guidelines International Network	http://www.g-i-n.net/
National Institute for Clinical Excellence	http://www.nice.org.uk/
Scottish Intercollegiate Guidelines Network	http://www.sign.ac.uk/
New Zealand Guidelines Group	http://www.nzgg.org.nz/
Open Clinical	http://www.openclinical.org/guidelines.html
International Society of Drug Bulletins	http://www.isdbweb.org/pag/summary.php

Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) tool

The GRADE tool is an internationally agreed standard for developing recommendations and can be used to determine the strength of supporting evidence. The purpose of grading is to differentiate between recommendations based on strong evidence and those based on weak evidence. Strength of evidence is determined by an objective assessment of the study design and quality as well as a judgment of the consistency, clinical relevance, and generalizability of the body of evidence.[144]

The GRADE scheme uses specific criteria to categorize the quality of the entire body of evidence according to four levels: high, moderate, low, and very low. The level of confidence in the effect estimate varies between levels. This level of confidence has implications for whether more research is needed.[145]

The baseline for rating the quality of evidence is the study design, of which there are two types—randomized controlled trials and observational studies. While randomized controlled trials are the preferred source of evidence, observational studies can be useful when randomized controlled trials are not available, ethical, relevant, or feasible. Generally, evidence from randomized controlled trials is rated as high quality, and evidence from observational studies is rated as low quality. However, these ratings can be upgraded or downgraded based on study limitations, consistency, generalizability, imprecision, and reporting bias.[146]

Recommendations should not be made when there is limited evidence on the effectiveness of an intervention. Rather than providing a recom-

GRADE working group:
http://www.gradeworkinggroup.org/

GRADE online training modules:
http://cebgrade.mcmaster.ca/

GRADE profile software:
http://ims.cochrane.org/revman/gradepro

mendation, publish the findings of the systematic review or an overview of interventions. Highlight the lack of evidence and clearly indicate that case reports, national experience, or opinion are the basis for the options presented.[147]

Committee members that have no previous experience using GRADE should consult the websites listed above, particularly the online training modules.

The Agency for Health Care Policy and Research model

The United States Agency for Health Care Policy and Research (AHCPR) developed a model for assigning levels of evidence based on the type of evidence acquired (table 5.3). This model is ranks evidence from strongest (Level Ia) to weakest (Level IV).

You can access additional critical appraisal tools on the Internet to assess the quality of medical evidence. For example, the Center for Evidence-Based Medicine website provides critical appraisal tools in several languages: http://www.cebm.net/index.aspx?o=1157.

Once evidence summaries have been completed by the methodological expert, the guideline development committee can then use the evidence to guide discussions and develop recommendations.[149]

STEP 2. Develop recommendations and arrive at a consensus

The second step to determining appropriate treatment options is to develop well-defined recommendations that are linked to the evidence gathered. These recommendations should consider cost and be arrived at through group consensus.

A. Explicitly link recommendations to evidence

Once the body of evidence has been assessed for quality, the guideline development committee must formulate clear recommendations that mirror the evidence. Since guidelines generally contain several recommendations based on varying levels of evidence, the guideline committee must apply criteria that explicitly demonstrate links between recommendations and supporting evidence.[150]

In addition to developing a model to grade levels of evidence, The United States AHCPR developed a complementary model to grade recommendations according to the levels of evidence used (table 5.4). Grade A recommendations are the strongest.

TABLE 5.3
AHCPR model on levels of evidence[148]

LEVEL	TYPE OF EVIDENCE
Ia	Evidence obtained from meta-analysis of randomized controlled trials
Ib	Evidence obtained from at least one randomized controlled trial
IIa	Evidence obtained from at least one well-designed control study without randomization
IIb	Evidence from at least one other type of well-designed quasi experimental study
III	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative, correlation, and case-control studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

TABLE 5.4
AHCPR model on grading recommendations[151]

GRADE	RECOMMENDATIONS
A (evidence levels Ia, Ib)	• Requires at least one randomized controlled trial of overall good quality and consistency that addresses the specific recommendations
B (evidence levels IIa, IIb, II)	• Requires the availability of well-conducted clinical studies on the topic of the recommendation • Does not require randomized clinical trials
C (evidence level IV)	• Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities • Indicates the absence of directly applicable studies of good quality

Strong recommendations can be differentiated from weak recommendations according to the characteristics listed in Figure 5.2.

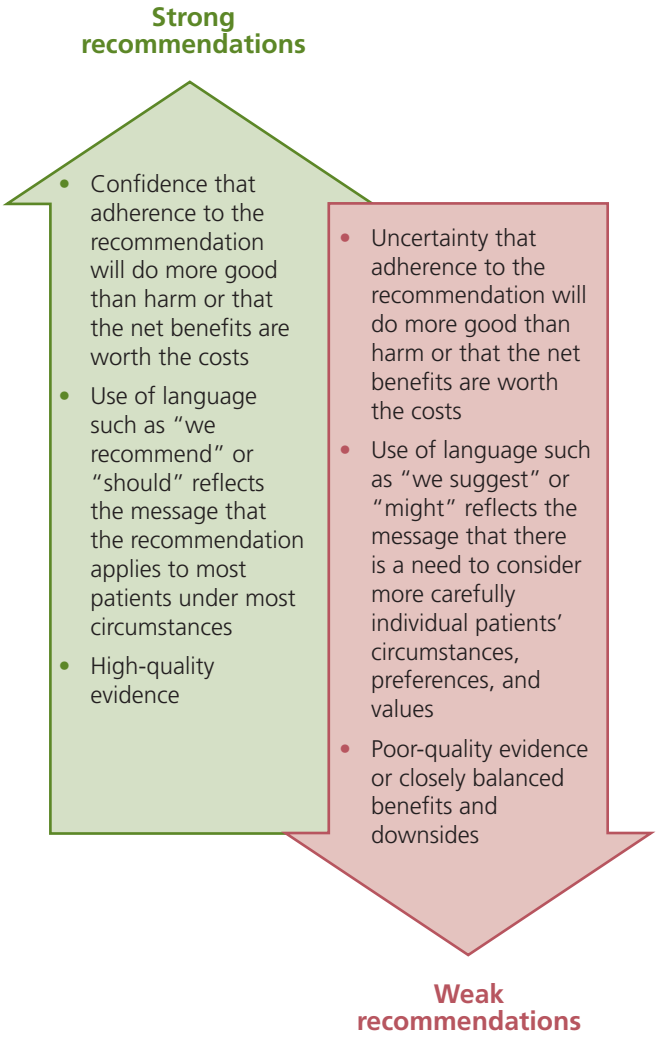
A strong recommendation is warranted—
- When backed by high quality evidence
- If the benefits of the recommendation outweigh the harms
- When there is low variability in clinicians' values and preferences
- When the intervention consumes less resources

Consider creating a decision table to record group judgments about the quality of evidence, balance of benefit versus harm and burden, values and preferences, resource use, and how each of these factors contributed to the development of the recommendation.[153]

In most situations, strong recommendations can be adopted as policy. Conditional recommendations, however, necessitate considerable debate and stakeholder involvement before they can be adopted as policy.[154]

In 2010, the Ministry of Health of Ghana published its sixth edition of STGs for use in the public and private sector at all levels of the health system. The recommendations are supported by scientific evidence and the collective opinion of national and international

FIGURE 5.2
Strong recommendations vs. weak recommendations[152]



experts. The recommendations were rated using the A, B, C grading model developed by AHCPR (table 5.4). Here, we revisit the example of amoebic liver abscess presented in the previous chapter. The guidelines recommend that adults and children suffering from this liver disorder receive oral doses of metronidazole. As indicated in the box, this pharmacological treatment has an "A" rating, indicating that the body of evidence addressing this recommendation consisted of at least one randomized controlled trial.

To develop recommendations, the guideline development committee in Ghana consulted the existing national guidelines, essential medicines list, formulary, current edition of Martindale—the Extra Pharmacopoeia, the Cochrane Collaboration Database, the Scottish Intercollegiate Guidelines Network (SIGN) database, primary literature sources (e.g., peer-review journals, reliable internet sites [MEDLINE), and secondary literature sources (e.g., textbooks)[155].

B. Be cost-conscious

Cost and affordability should be factored in when considering treatment options, particularly given the rise in health care costs. Involve health economists in the guideline development process to give fair consideration to evidence on resource use and clinical effectiveness.[156]

C. Arrive at consensus

When the methodological expert presents evidence profiles before the guideline development committee, the values, preferences, and resource implications of each intervention are discussed along with the evidence. The committee then agrees on the strength of each recommendation.[157] Where evidence is weak or insufficient, the committee may not be able to arrive at a consensus. In such cases, the committee may consider using proven consensus-building methods such as Delphi techniques, peer groups, and consensus conferences. In occasional cases, consensus may not be reached; if it happens, indicate this in the final guideline. This may occur for controversial issues.[158]

CHAPTER 5
TAKE-HOME MESSAGES

- Treatment guidelines should be based on the best available evidence. To obtain this, identify and assess national standards, international scientific evidence, recommendations by international organizations, and the views of patients and service users.
- Evidence that has been gathered must be synthesized before the information can be interpreted to arrive at recommendations. Approaches to synthesizing evidence include clinician knowledge, unsystematic literature review, systematic review, ungraded systematic review, and formal meta-analysis.
- Once the relevant evidence has been identified and synthesized, its quality and strength must be assessed. The GRADE system is an example of an internationally agreed approach to determine the strength of the supporting evidence.
- Once the body of evidence has been assessed for quality, the guideline development committee must formulate clear recommendations that are explicitly linked to the evidence. Cost and affordability should always be factored in when considering treatment options.
- The guideline development committee must reach consensus when reviewing the strength of each recommendation.

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CHAPTER 6 Drafting, Reviewing Finalizing, and Publishing the Guideline

STEP 1. Draft the guideline

You have reached the phase of drafting the guideline. To achieve this, you must first develop an overall outline, recruit authors and delegate responsibilities, and present the recommendations in a way that is clear and action-oriented. Keep in mind the importance of an attractive, user-friendly layout and use flowcharts and algorithms where appropriate to make the information easy to understand.

A. Develop an overall outline

The work completed while determining the scope of the guideline (Chapter 4) informs what needs to go into the overall outline of the document. Having a clear, well-defined template ***before*** drafting the recommendations will facilitate the development process. If this point is overlooked, then the different authors recruited to develop the guideline sections may present their information in different formats.[159]

The template should indicate what type of information is required and what format the content will take. Once the information is produced, simply insert it into the template.[160] If possible, include in the recommended template a sample write-up for an illustrative disease or condition. This will provide the recruited authors greater clarity as they complete their task.

B. Recruit chapter authors and assign tasks

Recruit a number of authors to draft different chapters of the guideline. Appropriately divide tasks among the authors and set clear timelines for completing the draft.[161] Author selection depends on several factors including knowledge, experience, writing skills, and availability. Where possible, consider including at least some authors from the level of prescribers that make up the intended user target audience.[162] In addition, consult with relevant specialists and involve well-respected opinion leaders. Ensure

In Ethiopia, SIAPS supported and strengthened the capacity of experts at the Food, Medicines and Health Care Administration and Control Authority (FMHACA) to revise standard treatment guidelines for health centers, primary hospitals, and general hospitals. The FMHACA taskforce developed a template to monitor the appropriate revision of the guidelines and advise FMHACA (see appendix D).

that the authors have the resources required to draft the guideline.[163]

C. Use clear, actionable wording and a consistent style to state recommendations

Guidelines continue to be underused because users may find them difficult to understand. When recommendations come across as vague, guideline users may encounter challenges in applying them.

Among Dutch general practitioners, vague recommendations were followed 35 percent of the time, while clear recommendations were followed 67 percent of the time.[164]

There is no standardized method of wording recommendations, which explains the current inconsistency within and across guidelines. The National Guideline Clearinghouse urges guideline authors to use the active voice when writing recommendations.[165] Writing guidelines in clear, concise, and behaviorally-specific terms is the most cost-effective way to ensure their proper implementation.[166]

Research has shown that using behaviorally-specific terms enhances confidence in the ability and intention to use recommendations.[167] Similarly, intent and actual use increase when guidelines include supplementary information that helps users understand how to apply treatment recommendations.

The following features may enhance the implementability of guidelines[168]—

- Explicit purpose statement
- Easily accessible guideline
- Managed conflicts of interest
- Authorship familiarity
- Strong supporting evidence
- Graded evidence
- Accompanying information guides for patients
- Flexible, adaptable recommendations for different patient needs and preferences
- Concise recommendations
- Feasible recommended actions
- Summaries, such as algorithms or diagrams
- Supplementary technology, tools, templates, and resources for guideline users

Key action statements are brief, precise, activity-based recommendations for specific clinical behavior. Designing a guideline around key action statements supported by text, evidence, and ratings on strength of recommendation is the best way to achieve clear, easily identifiable recommendations. Accompanying text elaborates why the recommendation is important and how it must be carried out.[169] Recommendations should clearly define "who should do what to whom, with what level of obligation."[170] For example, an easily understood recommendation would read, "Clinicians should diagnose cerumen impaction when an accumulation of cerumen is associated with symptoms, or prevents needed assessment of the ear, or both." Make sure the language is consistent across all recommendations in the guideline.[171]

Note that proprietary products should not be named. Describe technological devices and diagnostics in a general manner to avoid identifying any specific products.[162]

In Afghanistan,[173] the USAID-funded Strengthening Pharmaceutical Systems (SPS) program provided technical assistance to the STG working group to prepare and facilitate a writer's workshop. The purpose of the workshop was to orient selected writers and reviewers on the principles of writing standard treatment guidelines. Box 6.1 describes this initiative, and the pictures below show participants in action.

BOX 6.1

Learning the principles of writing standard treatment guidelines in Afghanistan[174]

The National Drug and Therapeutics Committee of the Ministry of Public Health (MoPH) appointed a standard treatment guideline working group (STGWG) to develop comprehensive treatment guidelines for primary health care facilities in Afghanistan. The STGWG sought knowledgeable physicians from the MoPH and Kabul hospitals with more than 10 years of experience and excellent writing skills to draft the guideline. With technical assistance from the USAID-funded Strengthening Pharmaceutical Systems (SPS) program, the STGWG prepared and implemented a two-day STG Writer's Workshop in May 2010 for selected writers and reviewers.

A participant presents her group's work during the STG writer's workshop in Afghanistan.
Photo credit: Terry Green

Fifty-eight participants from MoPH and Kabul hospitals, the STGWG, and SPS attended the workshop. Participants received instruction on the proposed development of STGs for primary care in Afghanistan, as well as the principles of writing. Specifically, workshop facilitators introduced writers to concepts and frameworks related to treatment guidelines, and oriented them on the specific principles of guideline writing. Participants learned how treatment guidelines are formatted and reviewed examples from Somalia and South Africa.

Participants work in groups to prepare STG monographs during the STG writer's workshop in Afghanistan.
Photo credit: Terry Green

The workshop was interactive and practical. Participants worked in groups of seven to nine people to practice writing different components of standard treatment guidelines. For example, groups prepared descriptions of conditions, diagnoses of conditions, and sections on management of conditions. Each group based their guidelines on information from MoPH guidelines, WHO guidelines and resources, and reference texts provided by the facilitators. Participants presented their guidelines to the larger group and received feedback and recommendations on their writing performance.

Following the workshop, the STGWG identified a limited number of writers to write the first group of monographs for various conditions. Additional writers were recruited and, by the end of 2010, 100 monographs were developed by the writers and were ready for review.

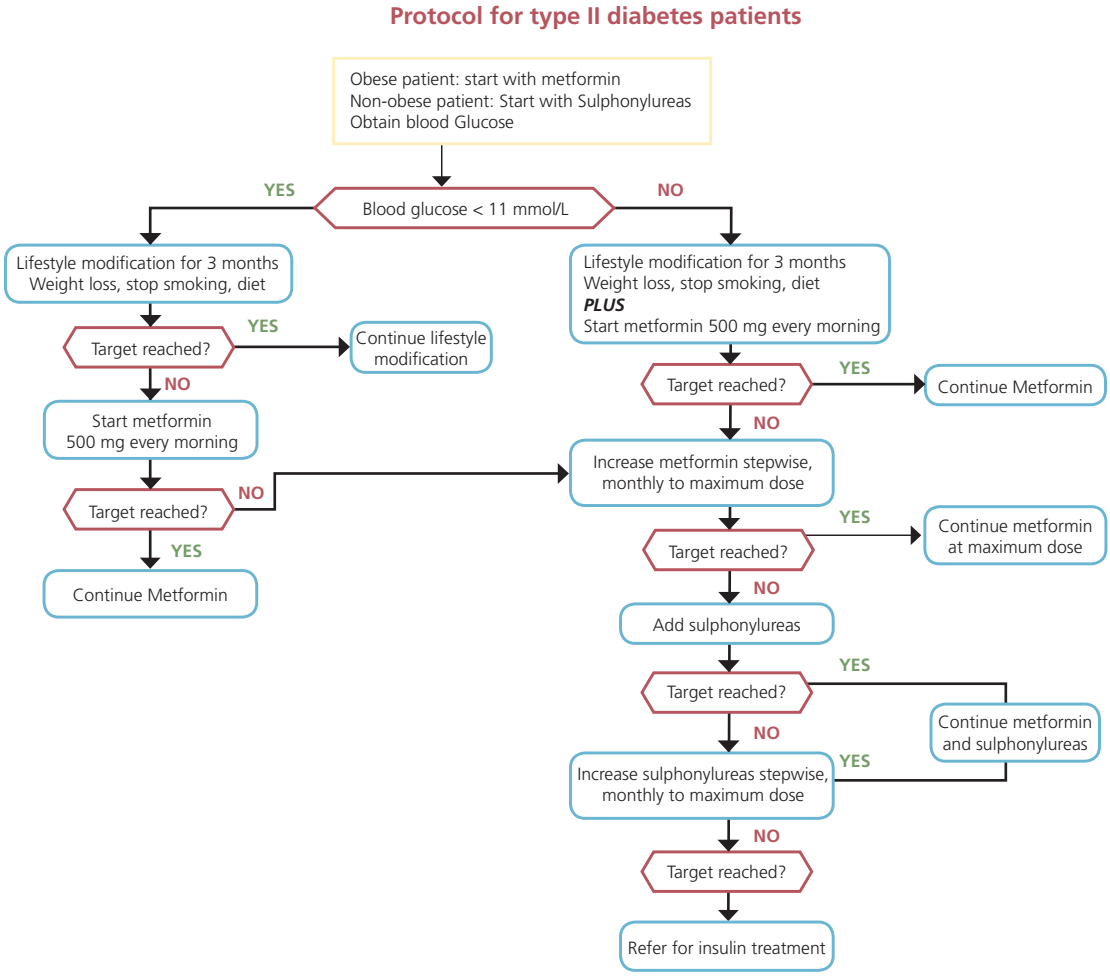
D. Use flowcharts and algorithms where appropriate

As mentioned in Chapter 4, guidelines may include flowcharts and algorithms that visually depict a course of action at each point of a decision tree. Algorithms are of greatest benefit when the decision logic of a guideline is convoluted and the sequence of activities is unclear. Figure 6.1 presents a flow diagram, or treatment algorithm, for Diabetes Mellitus Type 2. This example comes from the 2011 Namibia STG.

The flow diagram below reads from top to bottom and left to right. As you can see, it includes different types of figures and arrows. **Rectangles** describe a clinical state or diagnose a condition. **Rounded rectangles** indicate an action that is either therapeutic or diagnostic. **Hexagons** contain information to guide clinical decisions. A hexagon has an entry pathway and two exit pathways that represent alternative options. **Arrows** appear where a decision must be made.[177]

An algorithm is simple to design. It requires the use of Microsoft Publisher, PowerPoint, or Microsoft Visio.[178] In Burundi, algorithms were included in the new malaria treatment protocol (see box 6.2).

FIGURE 6.1
Treatment algorithm for Type 2 diabetes patients[175]



BOX 6.2

Guiding Clinical Decision Making through the Use of Algorithms in Burundi's Malaria Treatment Guidelines

In Burundi, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program supported the National Malaria Program and key stakeholders in reviewing, updating, and finalizing the new malaria treatment protocol. As per WHO recommendations, the new malaria treatment protocol added a new second-line treatment of quinine and clindamycin and a pre-referral treatment with injectable artesunate for severe malaria. Algorithms were developed to guide clinicians' decision making. Once the treatment guidelines were finalized, SIAPS printed all materials necessary to disseminate the new malaria STG, including 1,200 STG documents with all algorithms and annexes to support dissemination in all 650 health facilities.

STEP 2. Review and finalize the guideline

Once the guidelines have been drafted, they must undergo peer review and pilot testing before being finalized.

Algorithms quickly convey the scope and organization of the guideline; result in faster learning, higher retention, and increased compliance by health care practitioners; and specify indications for particular management strategies.[176]

A. Importance of external peer review

Through an independent external peer review, the guideline development committee can correct erroneous information and obtain input regarding the guideline's clarity, quality, and level of implementability.[179] The external review has four advantages. It[180]—

- Verifies the accuracy, comprehensiveness, and balance of the scientific evidence
- Verifies the validity of the rationale for recommendations
- Provides feedback on the clarity and feasibility of recommendations
- Engages stakeholders

Peer reviewers should be from outside the guideline development committee, and should represent the intended target audience and clinical practice settings.[181] Consider involving practicing clinicians, professional organizations, academics, consumer groups, health authorities, policy makers, and industry groups.[182] It may be helpful to organize a consultative workshop for interested parties (e.g., professional associations, academia, policy makers, and practitioners).

Box 6.3 describes how a comprehensive independent technical review was conducted with national stakeholders in Liberia to revise the standard treatment guideline.

B. Provide clear instructions and timeline for peer review

Distribute the draft guideline to peer reviewers and ask them to focus on the document's validity, reliability, and feasibility. Reviewer comments should primarily address the comprehensiveness and accuracy of the interpretation of the evidence used to support the recommendations.[184] Ask peer reviewers to consider the following questions[185]—

BOX 6.3

Revising the Essential Medicines List, Therapeutic Guidelines, and National Formulary for Liberia[183]

In 2010, the Liberia Ministry of Health and Social Welfare (MOHSW) identified an urgent national need to revise its three key policy documents: the National Therapeutic Guidelines (NTG), the National Formulary (NF), and the Essential Medicines List (EML). These documents required updates to reflect present day realities, encourage rational medicine use, improve therapeutic information, and promote the country's basic package of health services.

The USAID-funded Strengthening Pharmaceutical Systems (SPS) program provided technical assistance to the MOHSW to revise the three documents in close collaboration with national stakeholders. Stakeholder consultation served to improve the technical quality of the documents and enhance their credibility, acceptance, and subsequent use.

The MOHSW had already initiated the review and development of the three documents prior to stakeholder consultation. SPS engaged in discussions with in-country stakeholders and collaborated with MOHSW to organize and conduct a consensus workshop for 21 participants to review and revise the NTG, NF, and EML. Participants included clinicians, key specialists, opinion leaders, and other in-country stakeholders.

Through presentations and small group discussions, SPS and MOHSW worked with stakeholders to carry out a thorough technical review and obtain suggestions on:

- Additions/deletions/changes to existing contents
- Formatting, including sections and information to include
- Key additional priority diseases to be included in the NTG
- Consistency between the NTG, NF, and EML
- Harmonization between the NTG, NF, and EML and national recommendations of Liberia's public health programs

A national presentation and endorsement workshop was organized two months after the consensus workshop. Participants of this workshop included senior physicians from Liberia health services, academics from pharmacy and medical faculties, pharmacist, program managers, and donors working in the Liberian health care system. Following discussions with national stakeholders and consensus building workshops, drafts of the NTG, NF, and needs were successfully completed, endorsed, and approved for use by the MOHSW.

- Is the guideline clearly written?
- Is the guideline user friendly?
- Is the guideline suitable for everyday use in clinical settings?
- Does the guideline cite relevant literature?
- Are the recommendations clearly linked to the evidence?
- Does the guideline indicate which recommendations are based on expert opinion or group consensus?
- Are the medicines recommended in the guideline and the national essential medicines list consistent?
- Does the guideline allow for flexible decision making, e.g., in cases with co-morbid conditions?

The draft guideline is generally distributed electronically with clear instructions on how to submit comments using the line number feature of the word processor. Provide a deadline by which comments should be submitted to the guideline development committee chair.[186]

C. Establish a clear process of collating and responding to reviewer comments

The committee chair, or a delegated committee member, collects and collates comments from peer reviewers. The guideline development committee then discusses comments and revises accordingly.

The guideline committee should document how comments were addressed. Rosenfeld and Shiffman recommend creating a four-column summary table in which reviewer comments are listed by line number. In the table, the committee chair or another identified member indicates how each comment was addressed, as shown in the *disposition* column of Table 6.1. The chair or other identified members of the committee revise the guideline based on this table using "track changes" so that modifications are easy to trace.

The final guideline should take into account all comments received from peer reviewers. If no changes are made, then this should be recorded as well. The guideline committee should provide feedback to the reviewers on how each of their comments was addressed.

D. Ensure that layout and formatting of the final draft are attractive and user-friendly

As you are developing the guideline, always keep in mind that simplicity is crucial.[188] The style and presentation of a guideline affects its uptake and acceptability. The Malawi Essential Drugs Program encourages guideline developers to consider the following elements to enhance the attractiveness of a STG[189]—

- The size of the publication (i.e., pocket guide vs. desktop reference)
- The type and size of the font used for the main text, chapter, and section headings
- Features to enhance the text (e.g., bullets, boxes, shading, bold text)
- Features to summarize or illustrate information (e.g., tables, graphs, visuals)
- Features that make it easier to locate information on particular topics (e.g., a comprehensive table of contents, index, cross-referencing, headers, and footers). Note that the guidelines cannot be indexed until the pages are in place and numbered. This is nearly the last element to do before the guidelines are printed.

TABLE 6.1
Example of summary table for external reviewer comments [187]

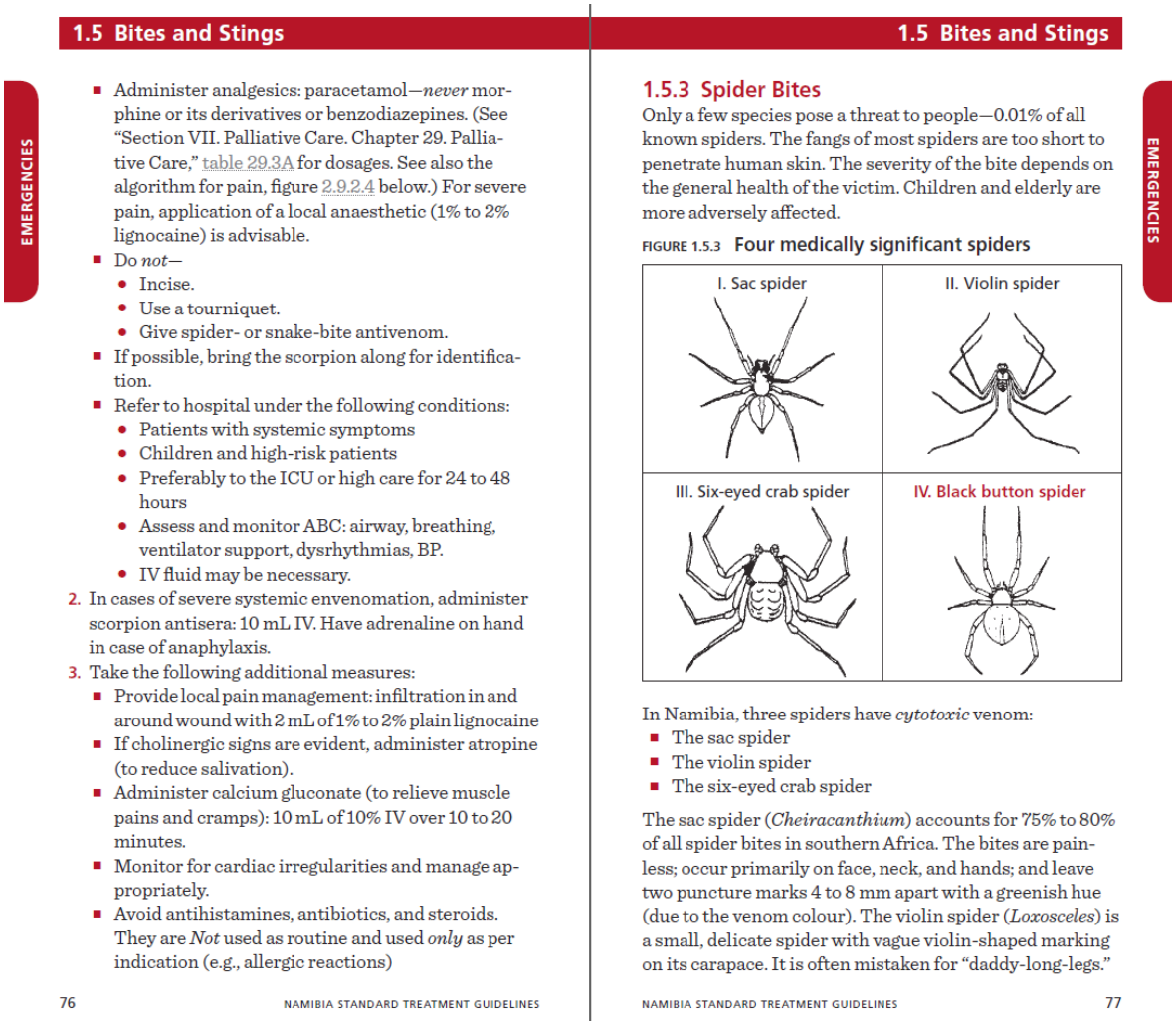
LINE	REVIEWER	COMMENT	DISPOSITION
669	Dr. D	I would be reluctant to encourage irrigations of an acutely infected ear, especially if this recommendations I going to non-specialist health care providers who may have limited experience with aural care. Gentle irrigation at most should be considered. I would favor staying with dry cleaning and suctioning.	*Your concern is appreciated, and the wording of the current statement (which includes the word "gentle") was arrived at after much discussion and consensus and specialists and primary care physicians. To soften the wording, I changed the sentence from "Aural toilet is most often done with a gentle lavage…" to "Aural toilet may be done…"*

- A carefully-designed, attractive cover. This should also be among the last steps, when the guidelines have been finalized and are ready to print or be made available online.

In Namibia, a concerted effort was made to produce an attractive layout and format for the first edition of the national standard treatment guidelines (2011). Each of the seven sections of the booklet is color-coded to facilitate searches. Sections include common emergencies and trauma (red), diseases and disorders according to body systems (dark blue), nutrition and lifestyle (light blue), infectious diseases (orange), obstetrics and gynecology (purple), diseases and disorders according to age group (green), and palliative care (yellow). Further, page numbers in the Index are hyperlinked so that, when clicked, the reader is directed to the relevant page. Figure 6.2 provides a snapshot from a page in the common emergencies and trauma section of the Namibia STG.

Similarly, the South Africa Adult Hospital Level STG-EML (2012) has a user-friendly format. One particularly useful feature is that the document contains two indexes: an index of disease conditions and an index of medicines. This feature facilitates quick information retrieval.

FIGURE 6.2
A color-coded page from the Namibia STG[190]



1.5 Bites and Stings

EMERGENCIES

- Administer analgesics: paracetamol—*never* morphine or its derivatives or benzodiazepines. (See "Section VII. Palliative Care. Chapter 29. Palliative Care," table 29.3A for dosages. See also the algorithm for pain, figure 2.9.2.4 below.) For severe pain, application of a local anaesthetic (1% to 2% lignocaine) is advisable.
- Do *not*—
  - Incise.
  - Use a tourniquet.
  - Give spider- or snake-bite antivenom.
- If possible, bring the scorpion along for identification.
- Refer to hospital under the following conditions:
  - Patients with systemic symptoms
  - Children and high-risk patients
  - Preferably to the ICU or high care for 24 to 48 hours
  - Assess and monitor ABC: airway, breathing, ventilator support, dysrhythmias, BP.
  - IV fluid may be necessary.

2. In cases of severe systemic envenomation, administer scorpion antisera: 10 mL IV. Have adrenaline on hand in case of anaphylaxis.
3. Take the following additional measures:
   - Provide local pain management: infiltration in and around wound with 2 mL of 1% to 2% plain lignocaine
   - If cholinergic signs are evident, administer atropine (to reduce salivation).
   - Administer calcium gluconate (to relieve muscle pains and cramps): 10 mL of 10% IV over 10 to 20 minutes.
   - Monitor for cardiac irregularities and manage appropriately.
   - Avoid antihistamines, antibiotics, and steroids. They are *Not* used as routine and used *only* as per indication (e.g., allergic reactions)

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1.5 Bites and Stings

EMERGENCIES

1.5.3 Spider Bites

Only a few species pose a threat to people—0.01% of all known spiders. The fangs of most spiders are too short to penetrate human skin. The severity of the bite depends on the general health of the victim. Children and elderly are more adversely affected.

FIGURE 1.5.3 Four medically significant spiders

In Namibia, three spiders have *cytotoxic* venom:
- The sac spider
- The violin spider
- The six-eyed crab spider

The sac spider (*Cheiracanthium*) accounts for 75% to 80% of all spider bites in southern Africa. The bites are painless; occur primarily on face, neck, and hands; and leave two puncture marks 4 to 8 mm apart with a greenish hue (due to the venom colour). The violin spider (*Loxosceles*) is a small, delicate spider with vague violin-shaped marking on its carapace. It is often mistaken for "daddy-long-legs."

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E. Pilot test the final draft

Pilot testing allows the guideline development committee to obtain additional input on the clarity, formatting, and usability of the guideline, and to detect any other issues with the document. Pilot testing also encourages uptake and buy-in from target groups, stakeholders, and experts.[191]

F. Edit and finalize the guideline

The final draft of the guideline and the comments are sent to the guideline development committee for review and approval along with feedback from pilot testing.[192] Together, the members of the committee ensure that each point has been addressed. Each member of the guideline committee then formally approves the final guideline for publication.[193]

G. Obtain necessary endorsements or approval of the final guideline

The appraisal and endorsement of the final treatment guideline by credible, widely respectable professional organizations and local leaders is important. This is a key step for encouraging buy-in.[194] Make sure that the proper country acknowledgments are included from such individuals as the Minister of Health, donors, etc. Also decide what logos will be needed (this should be done when the guideline cover is being designed).

H. Publish electronic and hard copy versions of the guideline

Once the necessary approval has been obtained, the guideline development committee must select a printer to publish the final document. Before obtaining quotes, carefully discuss the various requirements for the publication, including the number of copies needed, the size, the type of paper, binding, and other components.

Carefully identify the target audience and estimate the number of copies required to cover the expected life span of the publication. There should be enough copies to last until any future edition is produced. When selecting a printer, take into account the cost, quality, timeline, general reliability, and accessibility of each potential printer.[195] Note that the guideline should not be printed until an action plan for the launch, dissemination, and implementation of the guidelines has been developed, the details of which are discussed in chapter 7.

Maintain close communication with the printer throughout the printing process to ensure that the guidelines are well-produced. When hiring a printer, you will be given a timeline of how long it will take to deliver the final proof, and once that is approved by the authors, the printer can tell you how long it will take to print and bind the books. It is also helpful to have someone familiar with printing to review the final proof.

The final leg of the printing process involves packaging and delivery of the finished product. Find out when the guideline will be distributed and plan accordingly to avoid any storage fees by the printer.

Increasingly, electronic versions of the guideline are being made available online. If you choose to go this route, use a web-ready portable document format (PDF). A web-ready PDF has a smaller file size, which makes distribution, web-posting, navigation, and downloading easier. Depending on the length of the guideline and the intended audience, providing full-text hypertext mark-up language (HTML) may also be a good option.

For ease of use, treatment guidelines are best published as a pocket-sized booklet. Summary information on the guideline can also be published in professional journals, professional associations' newsletters, industry

newspapers, institutional newsletters (e.g., hospitals, consumer groups), or in the popular media, as brochures, posters, or audio or video tapes.[196] Making the document available on flash drives or CD is also a cost-effective option.

Once the print copies are delivered by the printer, you are ready to focus on distribution and implementation.

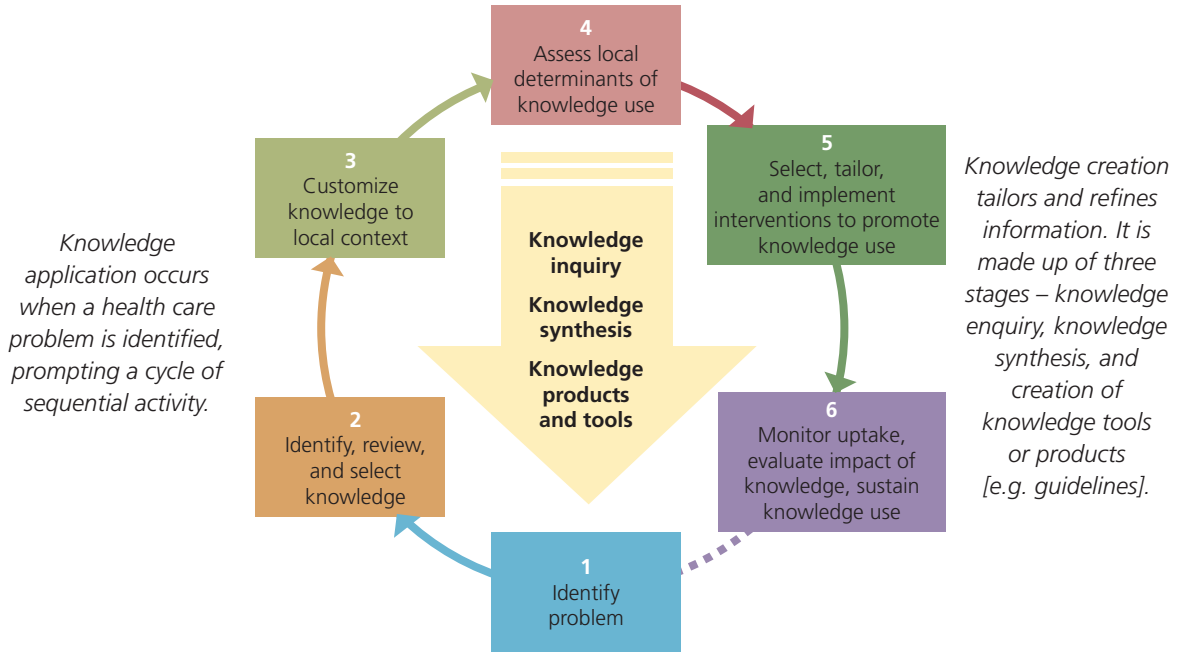
Quality assurance in guideline development

While the number of guidelines produced across the world has increased considerably in recent decades, many guidelines do not meet basic criteria for good quality. Guidelines are developed under various processes, arousing skepticism regarding credibility and quality. Agencies including the IOM, WHO, the National Institute for Health and Clinical Excellence, SIGN, the National Health and Medical Research Council, and the Guidelines International Network have proposed quality standards for guideline developers to ensure that recommendations are evidence-based and of high quality.[197] The premise of this movement is to promote trustworthy guidelines.

The knowledge-to-action (KTA) process is a dynamic, iterative framework to support improvements in health care quality. Driven by knowledge creation and action, the goal of the KTA process is to "optimize the exchange of high-quality information among key stakeholders and ensure that clinical knowledge is used to provide the highest quality and most effective health care."[198]

Figure 6.3 illustrates the KTA framework. This framework complements the model of guideline development – steps 1 to 4 correspond to the development process (chapters 2, 3, 4, 5, 6, 8), Step 5 to the implementation process (chapters 6, 7, 8), and Step 6 to monitoring and evaluation (chapters 7, 8). Following this cycle will lead to the successful development and implementation of standard treatment guidelines.[199]

FIGURE 6.3
The KTA process[200, 201]



CHAPTER 6

TAKE-HOME MESSAGES

- Recruit a number of authors to draft different chapters of the guideline. Selection should depend on knowledge, experience, writing skills, and availability. Divide tasks among the authors and set clear timelines for completing the draft.
- To provide clarity for the authors, develop a well-defined template that indicates the type of information required and the format the content will take.
- Write guidelines in clear, concise, and behaviorally-specific terms. Designing a guideline around key action statements supported by text, evidence, and ratings of the strength of recommendations is the best way to ensure successful implementation.
- The use of flowcharts and algorithms results in faster learning, higher retention, and increased compliance by health care practitioners.
- Before finalizing the guideline for publication, arrange for an independent external peer review to obtain feedback on the document's clarity, quality, and ease of implementation. Collect and document comments from peer reviewers and revise accordingly.
- Pilot test, edit, and finalize the guideline. Obtain the necessary approval of the final guideline by credible, widely respected professional organizations and local leaders.
- Ensure the layout and formatting of the guideline is simple and user-friendly. The style and presentation of a guideline affect its uptake and acceptability.
- Publish electronic and hard copies of the guideline. Carefully identify the target audience and estimate the number of copies required to cover the expected life span of the publication.
- Many guidelines do not meet basic criteria for good quality. The knowledge-to-action process is a dynamic, iterative framework to support improvements in health care quality that complements the model of guideline development. Following this cycle will lead to the successful implementation of standard treatment guidelines.

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CHAPTER 7 Implementing and Monitoring the Use of the Guideline

STEP 1. Plan for implementation

Implementation is the process of ensuring that health care providers treat patients according to evidence-based recommendations for optimal care. To do so requires planning, resources, and commitment. Guideline implementation should not happen as an after-thought; serious consideration should be given to implementation at the very outset of the guideline development process so that relevant strategies are integrated to enhance the likelihood of routine use. Be mindful that a good implementation process will provide a strong platform for future updates and continuous improvement of the document.

When introducing a guideline, first assess how current clinical practice compares to what is recommended in the guideline. Then, prepare an implementation action plan that bridges the gap between the guideline and current practice. The ultimate goal of implementation is to integrate clinical recommendations from the guideline into routine clinical practice. Successful implementation is defined by the full integration of guidelines into routine clinical practice.[202]

STGs have a bearing on both the administrative and clinical aspects of health care. For this reason, obtaining ownership/buy-in from both administrative and clinical health facility staff is critical for success. Guideline implementation should be made a high priority at each health facility and the value of guidelines in ensuring good clinical care should be well communicated.[203]

Getting policy makers and health mangers to recognize the added value of treatment guidelines is crucial for getting the necessary policy, organizational, and finance-based support to kick-start, implement, and sustain the use of treatment guidelines.

A. Identify champions and form a guideline implementation working group

The guideline development committee or the health care facility's management team should consider forming a guideline implementation working group to support all guideline implementation activities. The working group should communicate the value of the guideline and encourage local buy-in.

The working group should include prescribers, nurses, and other professionals who will be affected by the guideline. Consider including individuals that are skilled in knowledge

translation and evaluation research.[204] For the sake of historical continuity, some members should come from the guideline development committee. In fact, developers of the Namibia STGs recommend formally mandating the STG committee to manage all activities regarding guideline dissemination and implementation.[205]

The implementation team is led by the guideline champion, with assistance from the opinion leader and coordination by a qualified facilitator.

Points to consider when identifying guideline champion, opinion leader, and facilitator

The guideline champion is the leader of the implementation working group. He or she should be a respected clinician with a strong level of knowledge, experience, and influence. He or she should regard guidelines as a valuable aspect to clinical practice. The guideline champion should receive a dedicated amount of resources, support, and time to effectively lead the implementation strategy.

The opinion leader is the content expert for the guideline. He or she is a resource person for all questions regarding the content of the guideline and is responsible for validating the content of the guideline.

The facilitator coordinates and manages team operations. He or she should be experienced in managing group dynamics and should, preferably, have experience working with quantitative data. The facilitator provides technical and administrative support to the team.

Points to consider while selecting team members

Implementing guidelines requires collaboration between a variety of clinical and support staff. Include skilled representatives from different elements of the patient care process, and include team members who can influence the success of implementation. Most importantly, include team members with a healthy level of commitment.

Optimal number of guideline implementation working group members

An ideal working group consists of six to ten members representing clinical and support roles. This size allows for diversity of opinion without trumping consensus.

B. Build effective teamwork

Team leadership and membership, teamwork strategies, and communication are needed to drive the objectives of the implementation working group forward. Support this by training your team, using management tools, and encouraging efficient communications.

Before the team begins its work, all members should receive basic orientation in planning and process improvement strategies. This will build skills and increase participation. The team should adhere to timelines, carry out structured meetings, record minutes, use storyboards or flowcharts to focus their approach, and establish baseline data on existing practices.

C. Follow four basic steps

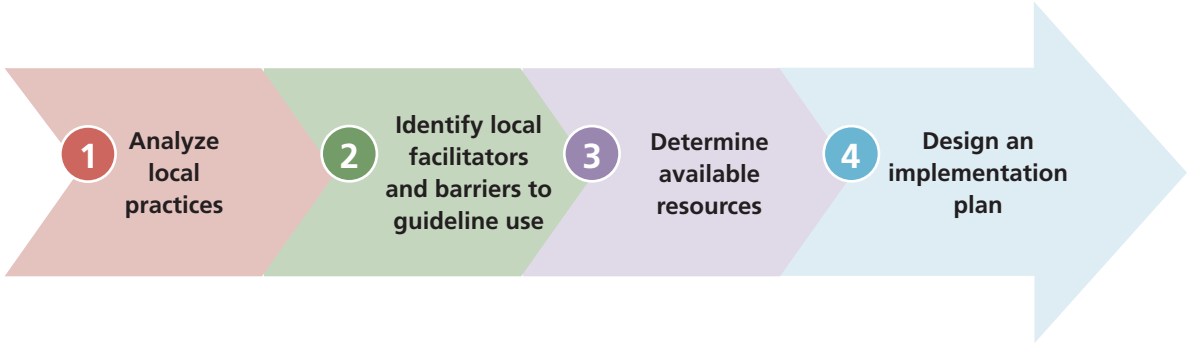
To implement a guideline, follow the four basic steps outlined in figure 7.1.

1. Analyze local practices

To better understand current practices, baseline data must be collected to identify where improvements might be made. This will allow the implementation working group to appropriately focus their efforts. The data collected will also provide a benchmark against which the effectiveness of guideline implementation can be measured.[207]

In Namibia, for example, the guideline development committee conducted a baseline survey

FIGURE 7.1
Steps to implementing a standard treatment guideline[206]



on compliance to the current guidelines in a representative sample of health facilities prior to the national launch. The committee had identified the top conditions that the Ministry of Health and Social Services was interested in improving to see how those conditions were being managed and treated.[208]

Data sources will likely have been identified during the information-gathering stage of the guideline development process. You may also find it helpful to conduct one-on-one interviews with key stakeholders to determine how best to gather baseline information.[209] In addition to gathering baseline data on treatment practices for selected key conditions, evaluate the treatment environment to determine what elements need to be in place to make the guideline work.[210] The method used to collect data prior to guideline implementation must also be used in subsequent evaluations.

Once data on current practices is gathered, create a summary for each key element. Specifically, assess the key elements for which current practice aligns with or differs from guideline recommendations.[211] Again, the key here is to highlight major gaps between clinical practice and guideline recommendations. Consider creating a map that describes how care is delivered in current practice, including the points at which decisions are normally taken. This information will be incorporated into your action plan.[212]

2. Assess facilitators and barriers to guideline use

Identifying facilitating factors and barriers to guideline use will allow you to plan your implementation strategy effectively, increasing the likelihood of successful implementation. This environmental readiness assessment will provide insight into what you can or cannot do as you move ahead with guideline implementation.[214]

Facilitator: a factor that promotes or helps implement shared decision making in clinical practice

Barrier: any real or perceived concept that interferes with a change intervention[213]

Facilitators and barriers may be related to the evidence guiding the change, the target audience for the change, the resources needed to achieve the implementation plan, and the organizational context in which implementation activities will be conducted (table 7.1).

Conduct a quick appraisal using a short survey, focused group discussion, or key informant interview to identify key facilitators and barriers.

TABLE 7.1
Facilitators and barriers for various factors[215]

FACTORS TO CONSIDER	EXAMPLES OF FACILITATORS/BARRIERS
Evidence	• Accessibility • Level of complexity • Ease of implementation
Target Audience	• Attitudes and beliefs • Knowledge and skills • Time • Buy-in • Opinions of others • Information exchange/ communication • Cohesiveness
Resources	• Human resources • Financial resources • Time as a resource • Equipment and supplies (including medicines) • Space
Organization	• Leadership • Scope of practice • Existing policy and procedures • Change agents/opinion leaders • Workload • Priorities • Organizational approval processes

Consider performing a root cause analysis (RCA) to understand the underlying cause of an identified problem. RCA is a valuable performance improvement approach designed to investigate the underlying barriers that cause variations in performance. RCA focuses primarily on systems and process, not on individual performance. Generally, the problem is a result of more than one root cause. Once the underlying causes of a problem have been uncovered, the implementation working group can classify the factors to identify effective interventions that can be put in place to make improvements. In other words, identifying underlying causes can help the implementation working group to direct a plan of action.[216]

Listen to the input of identified stakeholders. As new stakeholders are identified, as the scope of implementation expands, or as environmental issues change, pay attention to new barriers that may surface. Once you have identified facilitators and barriers, maximize the facilitators and develop a plan.

3. Design an implementation plan

The implementation working group must develop an action plan. Allow adequate time for group discussion and consensus-building so that all members of the team can contribute equally. Team members who do not speak up as much should be encouraged to provide their input.

An implementation action plan defines a set of strategies and actions to ensure use of treatment guidelines and, therefore, close gaps in clinical practice. It sets the stage for all guideline implementation activities, setting priorities and allocating resources where they are needed most. To arrive at this point, the implementation working group must participate in an organized planning process, the goal of which is to produce an action plan.

The implementation action plan should propose strategies for overcoming barriers to guideline implementation. It should summarize *who* does *what* by *when*, and what is required. Specifically, it specifies the necessary actions, tools, resources, responsible persons, and schedules. Consider using a planning matrix (table 7.2).[217] The example here was used by developers of the Namibia STG to guide the launch, distribution, and overall implementation of the national treatment guideline.

Distribution should be carefully planned so that the publication reaches the target audience promptly and efficiently. The distribution plan should be systematic, realistic, and involve key opinion leaders as partners. Key opinion leaders can be a valuable resource for discussing what approaches and tools for dissemination will work for the health system.[218] Prior to distribution, inform the target audience when they should expect to receive copies of the guideline.

The committee should also develop a dissemination strategy and materials for associated information, education, and communication for various recipient groups. These can include fact sheets, application tools, and flow charts, decision aids, and algorithms. This is a critical step because materials distributed to doctors will differ from those distributed to the general public.[219]

TABLE 7.2
Action planning matrix for the launch, dissemination, and implementation of the Namibia STGs

Recommendation	Action needed	Resource needed	Who is responsible	Deadline
Assign guideline dissemination and implementation activities to a committee	Develop recommendation to formally mandate STG committee	Staff time	National Medicine Policy Coordination	
Hold meetings to plan official launch		Staff time	STG committee	
Conduct a pre-launch baseline survey of compliance to guidelines		$$		
Assign roles for public leaders and civil societies		Staff time		
Use key opinion leaders as partners in the dissemination activities		Staff time $$		
Estimate the number of copies needed		Staff time		
Develop a distribution strategy for the guideline and its associated information, education, communication materials		Staff time $$		
Develop dissemination workshop training and presentation materials		$$	Therapeutics Information and Pharmacovigilance Center	
Hold a national launch of the guideline		$$	STG committee	
Use DTCs to oversee activities at regional and health facilities		Staff time $$		

STEP 2.
Launch and disseminate the guideline

Proper implementation of a treatment guideline requires organizing an official launch, distributing the guideline widely, and conducting initial training, reinforcement training, monitoring, and supervision to ensure its appropriate use.[220]

A. Organize an official launch

In the case of a national STG, an official public launch should be organized to give prominence and credibility to the guideline. Initiate planning meetings at least one month before the scheduled launch, and involve key stakeholders from the public and private sectors in planning to increase local ownership.[221] Use the implementation action plan to drive the planning process forward.

Develop a list of key people to invite to the launch and send out formal invitations from an appropriate office in the Ministry of Health.[222]

The launch should involve high-level officials from the Ministry of Health, professional bodies, and clinical fields, and should be covered by the press and broadcast media.[223] The picture above was captured at the high-profile official launch of the first edition of the Namibia Standard Treatment Guidelines.[224]

Alternative platforms can also be used to organize a high-profile launch at minimal or no additional cost. In Zambia, the USAID-funded RPM Plus and SPS programs provided technical assistance to develop and implement an advocacy and containment strategy for AMR. As a part of the approach, a multidisciplinary AMR working group was formed locally to advance AMR advocacy and containment

The launch of the Namibia STG with high-level officials including (from left to right) Deputy Permanent Secretary Dr. Norbert Forster, US Ambassador to Namibia Ms. Wonder Nessbit, and Minister of Health and Social Services Dr. Richard NC Kamwi.
Photo credit: SIAPS/Namibia

interventions. As part of its initiative, the working group organized an AMR call-to-action meeting in 2004, which served as a befitting opportunity to launch the national standard treatment guidelines that had just been finalized. This high-profile event, inaugurated by the Minister of Health and attended by 70 stakeholders representing various sectors, successfully boosted the original theme of the workshop while promoting the national STG as a well-recommended intervention to contain AMR.[225, 226] News of the AMR meeting and STG launch received wide coverage in Zambian newspapers.

Revisit box 4.2 to see how the AMR working group later collaborated with national stakeholders to revise the national STG, a newer version of which was published in 2008.

B. Disseminate the guideline strategically

Now you are ready to widely distribute the guideline and any associated information, education, and communication materials.

Box 7.1 describes the distribution plan for the first edition of the Malawi Standard Treatment Guidelines. Beyond the methods that were used in Malawi, distribution can also be carried out through workshops, professional associations, sales, or by including the publication with regular pharmaceutical supply deliveries. Keep in mind that free copies should be made available to health workers and students, and that the material should be officially adopted in training institutions.[227]

Consider including a cover letter for the main distribution centers, requesting them to pass the information to health personnel and institutions within their distribution area. This cover letter should indicate how to distribute the publication and how to make prescribers aware of its function. In addition, the letter should reiterate that the guideline is approved by the Ministry of Health or other approving authority, and that it should be used with any existing EML and Formulary as basic resource documents.

Malawi's National Drug Committee recommends developing a distribution database that includes the names and addresses of all the intended recipients. In this database, record the number of copies distributed, the date of distribution, and confirmation that copies have been received. Also consider having a point of contact at each

BOX 7.1

An effective distribution plan in Malawi[228]

Five thousand personal and institutional copies of the first edition of the Malawi standard treatment guidelines were successfully distributed throughout the public and private sector over a period of two months.

Personal copies, intended for use by individual prescribers, were distributed to clinicians, pharmacy personnel, senior nurses, senior policy-makers and health professionals within the Ministry of Health, and staff and students of health training institutions. Institutional copies, intended for use by health center or hospital staff that did not receive personal copies, were distributed to health institutions, relevant hospital departments, disease control programs, regional health offices and regional medical stores, health-related NGOs, a selection of international health agencies, and Anglophone African countries.

A variety of distribution methods were used. Distribution was carried out through central medical stores, regional health offices, district hospitals, or via personal delivery or direct mailing to selected institutions and individuals. In some instances, guideline copies were sent along with monthly drug supplies, while in other instances, pre-packed and pre-addressed copies were prepared for each district's hospital and its health centers.

A meticulous estimation process was used to determine the total number of copies required to cover the entire target audience (covering approximately 50 hospitals and 500 health centers) over the three-year life span of the edition. This was a challenge, however, due to unavailable or incomplete information on the numbers of health personnel and institutions.

main distribution point.[229] Actively monitor distribution to address any bottlenecks in the process and to handle requests for additional printed copies.

It is best to link training and orientation to the distribution process, rather than focusing on distribution alone. Training should closely follow distribution, as discussed later in this chapter.

Consider the benefits of disseminating electronic versions of the guideline. This strategy has wider reach, saves time and resources, and ensures continuous access to information. For example, in South Africa, a mobile version of the Adult Hospital Level STG and EML was developed to support prescriber compliance to treatment guidelines as described in box 7.2 below.

BOX 7.2

Using innovative technology to improve adherence to guidelines[230]

In South Africa, the essentials medicines list and national standard treatment guidelines are combined in books for each level of care (e.g., Hospital Level Adult STG and EML). These reference books are revised and published regularly and distributed to health care facilities.

However, these reference books are not always readily available for quick reference during patient consultations. Even when they are, some prescribers have reservations about using them in front of their patients. Such behavior has a detrimental effect on prescriber compliance to treatment guidelines, highlighting the need to strengthen guideline implementation.

In response, the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program assisted the National Department of Health (NDoH) to identify the use of a smart phone application to bring the STG and EML closer to prescribers, at the mere touch of a mobile keypad. In 2013, a web-based and smart phone application of the Hospital Level Adult STG and EML (2012) was developed. The mobile application was presented to the EML App task team at the NDoH and regular meetings were held to make the application more user-friendly. This mobile phone application enables prescribers to access the Adult Hospital EML on their smart phones, making information instantly available when a prescriber is deciding on treatment for an individual patient. Internet access is only required to download updated versions of the EML and STG to a prescriber's smart phone. Once downloaded, these documents can be accessed offline.

The STG/EML App was launched by the NDoH at an official event attended by the Minister, Deputy Minister, and Director General of Health, as well as various stakeholders.

The STG/EML Hospital Level (Adult) Mobile App is available for download at the NDoH website, http://www.health.gov.za/. The web-based STG is available at http://bwintec.com/appfront/#/ch/1.

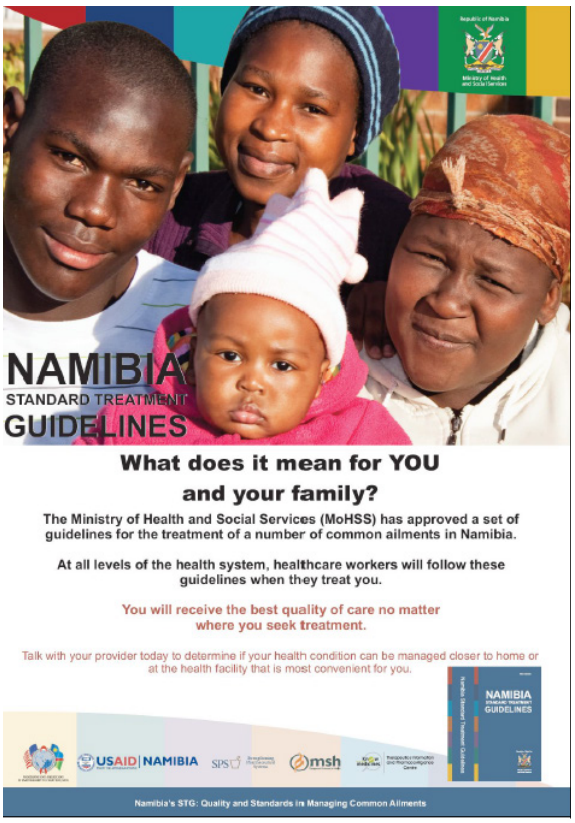
Attendees of the EML mobile phone application launch in South Africa check out the application's functionalities on their phones.
Photo credit: Stephanie Berrada

STEP 3.
Implement the guideline

To effectively change clinical practice, implementation strategies must be based on knowledge, attitude, behavior, and maintenance. A multi-faced approach that combines all four of these dimensions is most effective. Consider combining[231]—

- Education (reference materials, promotional materials, meetings)
- Social engagement (opinion leaders, educational outreach, advocacy groups)
- Embedding (clinical support systems, reminders)
- Incentive (clinical audits, academic detailing, pay-for-performance)

The message should be loud and clear—guidelines improve the quality of care and treatment at all levels of the health care system.[232] In Namibia, educational materials were developed to enhance awareness of STGs to different audiences. At right is a poster targeting patients and the community and below is a sticker targeting health care workers.[233]



Focus on behavior change

The principles of social marketing can be applied to guideline implementation to improve uptake and use. Through this lens, sustained behavior change of the health care practitioner is the main goal for designing and evaluating interventions. To understand the perspectives of the target audience, social marketing uses research to plan for, pretest, and monitor interventions. To make guideline implementation attractive and motivating, create "what's in it for me" packages that are tailored to different segments of the target audience. Minimize the burden and make the change easy and convenient. For example, use pocket-sized tools or computerized reminders. Communicate powerful messages about the value and benefits of the guideline, and pay careful attention to factors that compete for people's attention, willingness, and ability to change.[234]

Behavioral change is prompted by various structures and processes, as outlined in table 7.3.

TABLE 7.3
Structures and processes that encourage behavior change[235]

Type of support	Example	Rationale for use
Structural	• Policies and procedures • Reorganization of staffing or services • Documentation forms • Clinical pathways • Equipment	• Provides rationale for change in practice and guides practice • Ensures sufficient staffing to carry out guideline recommendations • Includes prompts to perform assessments and specific interventions • Provides a guide to recommended clinical care • Facilitates recommendations
Process-related	• Mandatory educational sessions for health care providers on guideline implementation • Key indicators of guideline implementation are included on health care providers' performance appraisals	• Supports optimal delivery of an implementation strategy • Indicates the importance the guideline recommendations for clinical performance • Provides a forum for discussion of relevant outcomes and an opportunity to make changes to implementation strategies, if required

Focus on training

Implementation is incomplete without an academic detailing training program for health care practitioners,[236] which members of the guideline development committee can help to design and plan. A guideline training program should provide instructions on how to use the document and a point of contact in case challenges are encountered when using the document.[237] In Burundi, strategic, organized, and coordinated plans were developed for nationwide training workshops on treatment guidelines, as described in box 7.3 below.

Similarly, box 7.4 describes how publication and training on both the STG and EML were treated as complementary processes in Kenya.

Treatment guidelines should be integrated into pre- and in-service education for health care personnel.[240] With support from SPS, the School of Medicine at the University of Zambia reformed the undergraduate medical curriculum to integrate topics relating to AMR and rational medicine use, including the Zambia STG and EML.[241] Box 7.5 describes how the Kingdom of Swaziland is integrating the first edition of the STG/EML into pre-service training for nurses.

Prioritize and implement the interventions identified in the action plan

The key to successful implementation is user buy-in and system-based changes. The STG must be adopted by public and private sector health professionals, and trusted by patients and the community. To effect change, implement a continuous quality improvement (CQI) methodology. CQI is an iterative process that emphasizes organizational performance, patient care processes, and outcomes. Attention is now gradually shifting from merely focusing on the practices of individual health care practitioners to changing the system in which health care practitioners operate. Through continual monitoring of outcomes, CQI encourages and supports small-scale incremental changes and is thus relevant, practical, and useful in resource-limited settings.

BOX 7.3

Strengthening malaria case management through STG training in Burundi[238]

In 2012, SIAPS supported district-level dissemination of Burundi's new STG for malaria and developed training materials to support its implementation. The distribution of the document coincided with district-level training of trainers (TOT) workshops for heads of districts, medical doctors, supervisors, and health management information system managers, which kicked off in January 2013.

The National Malaria Program (PNILP) developed a dissemination plan for the new malaria guideline, in which the provision of nationwide refresher training workshops (i.e., TOT and cascade trainings) for all health care providers was laid out. This plan was validated by all stakeholders involved, such as the PNILP, the Department of Pharmacy, Medicine, and Laboratories (DPML), the Permanent Executive Secretariat of the National Council for the Fight Against AIDS (SEP/CNLS), the Global Fund Principal Recipient, and district representatives.

SIAPS helped organize two retreats with key facilitators to review and adapt the training materials to be used during the refresher trainings. Training materials included an agenda, a facilitator's guide, a trainee's guide for health care providers, and PowerPoint presentations with case studies and practical exercises. In 2013, PNILP oriented 226 trainers and handed 1,229 packages of treatment guidelines, algorithms, and training materials over to district heads to prepare for dissemination and training of health center staff.

BOX 7.4

SCG/KEML dissemination training workshops in Kenya[239]

Kenya developed its first essential medicines list in 2003. With no system in place for monitoring, systematic review and revision, the national list soon became outdated and no longer reflected current therapeutic practice. The Department of Pharmacy (DOP), the Ministry of Medical Services, the Ministry of Public Health and Sanitation, health facility, and other stakeholders received technical assistance from Strengthening Pharmaceutical Systems (SPS) to finalize revisions of the national standard clinical guidelines (SCG) and the Kenya EML (KEML). These resources were highly regarded as companion documents, and thus were developed, published, disseminated, and implemented in a complementary manner.

A training package was developed to support planned SCG/KEML dissemination training workshops. Two hundred and thirty CDs that included the SCG/KEML training package were distributed for use at national and regional dissemination training workshops. Further, the DOP, with support from SPS and the Danish International Development Agency, conducted two TOT workshops for the dissemination of the revised SCG/KEML. The purpose of these workshops was to train adequate numbers of regional trainers to roll-out similar trainings in their respective provinces, as part of the dissemination process.

BOX 7.5

Enhancing rational medicine use by incorporating the STG/EML into preservice training of nurses in Swaziland[242]

The USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program and its predecessor, Strengthening Pharmaceutical Systems (SPS), supported the development and implementation of the STG/EML in Swaziland. This document stems from major collaborative efforts and extensive consultations with key practitioners, academics, and other stakeholders from various health fields in Swaziland, including specialists from the public and private sectors. The STG/EML has been widely disseminated and accepted as a core document in the Ministry of Health's Essential Health Care Package, a crucial compilation of the most cost-effective, affordable, and acceptable interventions for addressing the country's disease burden. The Swaziland STG/EML has also been integrated into pre-service training courses. It is currently being used by fourth and fifth year general nursing and community mental health nursing students at the undergraduate degree level. Students completing community mental health nursing training at the certificate level are also using it.

Additionally, the STG/EML will be used as one of the textbooks for the master's level family nurse practitioner program at the University of Swaziland. The family nurse practitioner is a new cadre of the health workforce that will be deployed to community-level health facilities, where there are no doctors, to manage primary health care cases that require specialists. An in-depth knowledge of the STGs gained through pre-service training will both enhance appreciation of the concept and the use of STGs.

The inclusion of the STG/EML in the family nurse practitioner curriculum illustrates the document's high level of credibility and acceptability at tertiary academic institutions in the Kingdom of Swaziland. Dr. Sifiso Sithole, Senior Lecturer at the University of Swaziland and member of the STG/EML Committee, could not contain her excitement. She remarked, "I am so thrilled that the book is finding use in the academia."

Honorable Minister of Health Benedict Xaba of Swaziland holds a copy of the first STG/EML moments before cutting the ribbon at the official launch. *Photo credit: SIAPS/Swaziland*

The reasons for implementing CQI are many, such as[243]—

- Improve quality through continual reviews and small-scale changes that do not overwhelm the staff or the health system
- Allow for the implementation of self-determined changes
- Help reduce variations in practice
- Identify opportunities for cost containment

CQI requires the use of data to analyze variations and improve processes. Clinical and population-based measures are vital to assessing the quality and impact of guidelines. By using data, health care practitioners are more likely to be convinced of the improvements that need to be made.

CQI can be successful for your team if you[244]—

- Involve an interdisciplinary group of stakeholders
- Keep each other motivated and take on a spirit of teamwork
- Allow all team members to provide input
- Focus on problem-solving rather than fault-finding
- Seek support from senior management
- Value and celebrate even small advances
- Manage the whole process based on evidence
- Identify and eliminate steps that are wasteful

Successful change requires a focus on three things: health system, system design, and work process. A systems approach looks at the health care environment as a whole, rather than focusing on individual parts. Since all parts of the health system are related, the effects on one component of the system affect the entire process of care. Improving the quality of patient care through guideline use and improving the health care practice environment is more effective than either approach separately.

The CQI approach should be used as a framework for developing, implementing, monitoring, and evaluating guidelines because it can lead to effective and sustained improvements in quality of care. In an integrated CQI and systems approach, the guideline implementation working group would use CQI to concentrate on a specific improvement need and would look at the systems to then examine the multiple factors in the health care setting that may affect that need.[245] It is critical that the treatment environment be evaluated to determine what elements of the system need to be enhanced or improved.[246]

Box 7.6 illustrates how the USAID-supported SPS and SIAPS programs provided technical support to the Ministry of Health to improve the use of antibiotic prophylaxis in cesarean section in Jordanian hospitals. A multidisciplinary team of hospital stakeholders

TABLE 7.4

Strengthening health system building blocks to improve antibiotic prophylaxis for cesarean section in Jordan[251]

HEALTH SYSTEMS STRENGTHENING BUILDING BLOCKS	ACCOMPLISHMENTS
Leadership and governance	• Interdisciplinary effort coordinated between health providers, departments, and units • Roles and responsibilities delineated through protocol/procedures • Engagement of drug and therapeutics committees and infection control committees • Aligned with hospital accreditation process
Human resources	• Training of stakeholders on current evidence, best practices, and recommendations • Skills development on continuous quality improvement principles
Information	• Use of worksheet, Excel cesarean section log, and other monitoring tools to track key indicators over time
Medical products	• Ensuring availability of the preferred antibiotic (cefazolin) in hospitals (not available when the program started)
Finance	• Evidence-based, cost-effective interventions • Analysis and tracking of financial costs
Service delivery	• Development of evidence-based standard protocol and procedures: selecting the right antibiotic, specifying appropriate timing of use, specifying number of doses

BOX 7.6

Monitoring key indicators to improve the use of antibiotic prophylaxis in cesarean section in Jordanian hospitals[247]

The use of antibiotics to prevent surgical infections accounts for up to half of all antibiotic use in hospitals, yet many times, antibiotic prophylaxis is used incorrectly or inappropriately.[249] The Jordan Food and Drug Administration recently conducted a study which demonstrated that antimicrobials were used inappropriately before and during common surgical procedures, like cesarean section.[250] To help address this issue, the USAID-funded SIAPS program and its predecessor, SPS, provided technical assistance to three hospitals in Jordan to strengthen practices in administering antibiotic prophylaxis for cesarean sections.

SPS worked with a multidisciplinary team of stakeholders in each hospital to collect baseline data and make evidence-based recommendations. The hospital stakeholders carried full ownership of this initiative, spearheading the development of customized protocols and procedures for the prophylactic use of antibiotics in cesarean section. A cesarean section log, Excel monitoring tool, and indicators were developed, which standardized tracking of antibiotic prophylaxis practices in each facility.

Applying the principles of continuous quality improvement to help implement the new protocols in their respective facilities, stakeholders from each facility worked together to identify gaps and improve processes on a continual basis. The program was successful in all three hospitals; results indicate good compliance to the protocols and procedures as measured by the use of the preferred prophylactic antibiotic (cefazolin), the timing of administration, and the number of doses administered.

Combined results	2010	2012
Correct antibiotic use	0%	86%
Correct timing of first dose (less than one hour before skin incision)	0%	92%
Correct number of doses (single dose except for pre-identified exceptions)	0%	88%

The use of the new protocols resulted in substantial cost savings for the hospitals. When compared to baseline costs, the hospitals saved roughly 10,905 Jordanian dinars, or USD 15,397 in 2012. Furthermore, all of these results were achieved with a low surgical site infection rate of 1.59%.To institutionalize appropriate prophylactic use of antibiotics in cesarean section, the Ministry of Health developed and mandated an antibiotic prophylaxis protocol for cesarean section in February 2013 for all public ministry-run hospitals providing obstetrics and gynecology services.

applied a CQI-like approach to help implement new protocols in their respective facilities. Performance monitoring was integral to this activity; see the protocol and procedures developed by Prince Hussein Hospital[247] in appendix E of this manual.

Table 7.4 goes on to illustrate how the team also addressed and strengthened the various health system building blocks to enhance performance.

Proactively seek user feedback on the guideline

Following implementation, obtain feedback on the acceptability and usefulness of the treatment guideline.[252] To obtain feedback, send questionnaires out to a representative sample of people in the target audience and interview health care practitioners directly. Consider asking senior health staff to obtain comments and feedback during health staff meetings.

In Malawi, feedback on the availability and usefulness of the second edition of the standard treatment guidelines was received through letters, verbal comments from individuals, informal comments received during field visits by staff of the Essential Drugs Program to health units, and health center support visit checklists. Such checklists document the availability of reference documents, prescriber adherence to recommended treatments, and comments on the usefulness of the guideline. In obtaining feedback, the Malawi Essential Drugs Program learned that the guideline had reached nearly all of its intended audience, was in regular use at all levels, and was considered user-friendly and valuable.[253]

STEP 4. Monitor and evaluate implementation progress

A. Importance of planning monitoring and evaluation from the start

One of the key components of guideline implementation is to monitor and evaluate the document's use. Monitoring and evaluation provides feedback on the effectiveness of implementation, creates accountability for implementation, and assesses the effects of the guideline on quality of care. Closely monitor launch, dissemination, and implementation activities, evaluate the impact of STGs on prescribing practices, and monitor and evaluate cost-effectiveness.[254]

Take the case of Namibia, which published, disseminated, and implemented comprehensive treatment guidelines in 2011. An STG implementation plan was developed, which indicated a need for several tools to properly monitor and evaluate the effectiveness and impact of the treatment guideline. To evaluate effectiveness, the guideline development committee led an assessment of the impact of the new standard treatment guidelines on outpatient prescribing practices in public health facilities in Namibia. Data for the baseline assessment and subsequent evaluations were collected and maintained using a survey protocol, a survey tool, and an Access database electronic tool (figure 7.2). The survey protocol and survey tool are presented in appendix F. The guideline implementation working group should develop a plan to monitor progress as soon as possible. Appropriate measures to do so should be identified, and a data collection and reporting system that regularly generates data on those measures should be established.[256] Initially, focus on process measures to see whether activities indicated in the implementation action plan are actually taking place. Then, identify measures that demonstrate adherence to the guideline. All measures should be quantifiable and focus on the desired changes in the implementation plan. As you identify measures, consider the type and importance of the outcome, as well as the feasibility and interpretability of the measure.[257] Over time, the working group will use that data to modify or initiate new implementation activities.

B. Collect necessary data

An accurate assessment of progress requires appropriate data and careful interpretation.[258]

FIGURE 7.2
Access database for monitoring and evaluating compliance to STGs[255]

Namibia Standard Treatment Guidelines(STG)
Survey tool

101.Serial ID (5 digits)	1	109)Prescriber's position:		116.Other diagnosis	arthritis
102.Date of data collection	13-Apr-11	110.Gender	Female		
103.Date of Rx	19-Apr-11	111.Date of Birth	14-Apr-38	117.Severity	Moderate
104.Data collector initials	EMC	112.Age	73	118 .List presenting complaints.[Using coma(,) e.g: cough,fever,pain..]	body itching, coughing
105.Health facility type	Health center	Unit of age	Years		
106.Facility Name		113.Group of age	Adult		
		114.Diagnosis	Oral candidiasis	***119.For official use only. Diagnosis complies with STG recommendations.***	YES
107.Ownership	Government	115.Diagnosis recorded on RX	YES		
108.Region	Khomas			120.Referred for specialized care	YES

COMMENTS on the regarding treatment

Management of the condition

1.Treatment prescribed	2.Generic Name used	3.Dose	Unit dose	Frequency	4.Treatment duration	Unit	Antibiotic	Injection	*FOR OFFICIAL USE ONLY. Treatment complies with STG.*	*FOR OFFICIAL USE ONLY. Aspect not compliant.*

Ideally, there should be baseline measures against which performance is assessed. It is important to have complete counts of relevant patient populations. Having identifiable and measurable denominators will allow you to produce accurate reports of select measures. When deciding which evaluation method to use, consider the scientific merit and practicality of the method.[259] Use evaluation methods that are the least burdensome in terms of time and financial resources. A given method may generate reliable, valid, and clinically sensitive results, but if the resource capacity is not there, then it will be of no benefit.

Use appropriate data collection techniques

First, identify information that is routinely available and information that needs to be created. In resource-limited settings, it is more practical to identify and work with what already exists. There are two basic methods of data collection: routine monitoring of existing data and special studies. When choosing a data collection technique, always consider whether the measures will produce the desired information.[260]

Various study designs can be used to collect data, including randomized controlled trials, observational study designs, and surveys. Randomized controlled trials, while scientifically rigorous, necessitate a considerable amount of skill and resources. Where a randomized trial is not feasible, an observational study design (e.g., interrupted time series analysis, controlled before-after study) is a more practical option. Box 7.7 briefly describes an observational study conducted in Switzerland to investigate the effect of a flow chart on use of blood transfusions in patients with joint replacements.

Similarly, an observational descriptive study was carried out by SIAPS, in collaboration with the Gauteng Department of Health in South Africa, to assess non-compliance to the ART guideline (box 7.8).

BOX 7.7

A hospital-based observational guideline evaluation[261]

Müller et al. carried out a prospective before-and-after study to examine the effect of a flow chart on use of blood transfusions in primary total hip and knee replacement in Switzerland. A one-page flow chart was developed by hospital physicians and nurses to reduce the use of blood transfusion in patients undergoing hip and knee replacement surgery. Once this tool was endorsed, an intervention was carried out to widely distribute the flow chart among hospital physicians and nurses, present it during small-group teaching sessions, and include with patient charts. Following the intervention, the proportion of patients receiving a blood transfusion after total hip and knee replacement dropped by greater than 40 percent, simultaneously reducing costs. From this observational study, the researchers concluded that the flow chart was so effective because it was simple, widely distributed, endorsed by local leaders, and because hospital physicians felt a sense of local ownership and responsibility.

Pre- and post-implementation surveys are another category of special studies that measure the impact of the introduction of treatment guidelines. Such surveys must capture aspects of drug use and clinical practice that routine guideline use intends to improve.[263] Revisit Step 4, section A for reference to a sample survey tool used in Namibia to evaluate the impact of treatment guidelines on outpatient prescribing practices in public health facilities.

With a simple pre- and post-monitoring design and an intervening supportive intervention, facility-based Medicine and Therapeutics Committees in resource-constrained settings can help achieve quantitative improvements in prescribing compliance to treatment guidelines. Box 7.9 describes how two Ecumenical Pharmaceutical Network (EPN) member organizations—Mission for Essential Medical Supplies (MEMS) in Tanzania and Joint Medical Stores (JMS) in Uganda—carried out simple interventions to assess and improve prescribing adherence to STGs with technical support from the SPS Program.

Administrative data should be monitored on a monthly basis, whereas special studies should be conducted strategically. Special studies are not carried out frequently because of associated costs. Design these appropriately to obtain as much data as possible on several priority measures.

Using data from existing automated information systems is recommended in resource-limited settings because it poses the least burden on resources. Consider adding new data elements to computerized systems to fully capture the necessary information. Since routine monitoring and special studies are complementary monitoring techniques, a combination of both will result in a well-rounded effort to monitor data.

C. Interpret and report findings of monitoring

When analyzing data, you must bear in mind causal direction, subjectivity, and missing data.

- Causal direction: An increase or decrease in a measure should not be considered good or bad until all other interpretations have been considered thoroughly.
- Subjectivity: Raw numbers do not determine whether the courses of action were appropriate. Solicit the judgment of experienced clinicians.

BOX 7.8

The reasons for switching ART patients to second-line regimen in public health care settings in Gauteng[262]

South Africa has the largest ART program in the world. By the end of 2010, more than 1.4 million patients were on ART. With such a high number of patients on treatment, inappropriate use of ARVs has important implications for the HIV and AIDS program.

According to ARV consumption data, statistics showed that the Gauteng province had wide variations in the proportion of patients on second-line regimens across public health care facilities. This raised a red flag regarding compliance with the 2010 South African Clinical Guidelines for the Management of HIV and AIDS in Adults and Adolescents. SIAPS, in collaboration with the Gauteng Department of Health, carried out an observational descriptive study to identify the reasons for switching patients from first- to second-line regimens in public health care facilities across five districts in the Gauteng Province. Specifically, the researchers set out to—

- Assess adherence to guidelines for switching ART patients to a second-line regimen
- Document the reasons for switching from first- to second-line regimens
- Identify clinical and other factors that contribute to the switch
- Calculate the cost implications of nonadherence to ART guidelines

To achieve these objectives, the researchers reviewed medical records for patients at least 15 years of age on a second-line ART regimen. The findings revealed the following:

- **Adherence to standard treatment guidelines.** Only 49.4 percent of patients were switched to the second-line regimen in compliance with guidelines, revealing low compliance. In many cases, this switch was made without supporting laboratory evidence.
- **Reasons for switching.** The most frequently cited reasons for switching from first- to second-line regimens were adverse drug reactions and pregnancy, which are not in line with guideline recommendations. In some instances, regimen failure was stated as a reason for switching, but there was no supporting evidence.
- **Factors contributing to the switch.** The district in which the patients were seen was a factor that contributed to switching regimens, with the highest risk of non-compliance in Ekurhuleni facilities. In addition, patients initiated on tenofovir-based regimens stayed on first-line regimens for a shorter period before being switched.
- **Cost implications of nonadherence.** Based on 2013 government contract prices, 50.6 percent non-compliance to guidelines costs an extra 8.79 million SA rand (USD 800,000+) per year per 10,000 patients.

As the HIV and AIDS program grows and the percentage of the population on treatment increases, it is critical to ensure that only patients experiencing true virological failure are switched to second-line regimens. Since the findings of this study were published in 2013, the Ministry of Health has worked with relevant stakeholders to review the treatment guidelines and clarify the definition of a "good record of adherence." Only patients with confirmed virological failure and a good record of adherence should be switched to second-line regimens. The updated national HIV guidelines, published in 2014, are expected to standardize approaches for adherence assessment and counseling. The Ministry of Health, with SIAPS support, is engaging provincial and institutional Pharmaceuticals and Therapeutics Committees to support the implementation of the guidelines and improve ARV use.

BOX 7.9

Assessing and improving prescribing adherence to STGs[264]

The goal of the Mission for Essential Medical Supplies (MEMS) project was to improve the functions of two Hospital Therapeutic Committees in Tanzania. To achieve this, the project set out to enhance the use of and adherence to the Tanzania STG and to ensure that outpatient department treatments comply with the Tanzania EML. Following a thorough review and analysis of outpatient department files, baseline data demonstrated that less than half (45.5 percent) of treatments complied with the STG. Commonly identified adherence problems included (1) incorrect prescription of antibiotics for the diagnosis, (2) wrong combination of antibiotics, (3) incorrect dose of antibiotics, and (4) over-prescription. In response, MEMS developed a multi-pronged intervention to improve STG adherence. MEMS staff presented the baseline data at clinical and DTC meetings, provided reference books, and conducted a training workshop for DTC members and hospital staff. Following the six-month project, findings from the post-intervention survey revealed that adherence to STG significantly increased to 94 percent.

Similarly, Joint Medical Stores (JMS) implemented the Medicines and Therapeutics Committee (MTC) project at St. Joseph's Hospital in Uganda to improve medicines use. Specifically, JMS set out to build the capacity of the MTC to identify medicine use problems and select interventions to address them, including adopting STGs. Prior to the intervention, JMS staff oriented MTC members to the project; conducted a baseline survey to measure prescription habits, awareness, and acceptability of the Uganda STGs; and audited 100 prescriptions. Findings from the baseline data revealed that 31.8 percent of hospital staff had never seen a copy of the latest STGs, and only 40.9 percent of staff reported regularly using them in patient care. In response, JMS implemented an intervention in which the Uganda STGs were disseminated, and staff were trained on how to use STGs and how to treat specific infections. The staff also received regular reinforcement trainings. Following the six-month project, a post-intervention survey and audit demonstrated a decrease in the percentage of staff that had never seen a copy of the latest STG (2.1 percent) and an increase in the percentage of staff that reported regularly using the STG in patient care (89.6 percent). Together, the MEMS and JMS studies illustrate improved prescribing adherence to STGs following concerted efforts to monitor availability and compliance to STGs.

- Missing data: Incomplete data can lead to erroneous conclusions.

Use simple graphics, brief summaries, and specific recommendations to report your findings.[265] Only include the most important information.

D. Develop and track selected indicators

To measure availability and compliance to treatment guidelines, consider using the following generic indicators:

- Percentage of facilities with available copies of STGs
- Percentage of prescriptions in compliance with STGs

In addition, the following indicators have been used to measure the quality, availability, and use of standard treatment guidelines[266]—

- Is the national EML consistent with STG recommendations?
- Is there a national drug policy statement to encourage use of the STG?

- Is the STG used for basic and in-service training of health personnel?

Supportive supervision should be integrated into monitoring how treatment guidelines and medicines are used. Providing supportive supervision will enhance prescribing compliance and promote rational medicine use.

STEP 5.
Sustain guideline use

To ensure that treatment guidelines are used long after their initial implementation, it is critical to develop a plan for sustainability early in the implementation process. Planning for the long term will ensure that treatment guidelines are fully integrated into the health system. Leadership, organizational culture, training, facilitation, and resources are some of the most necessary elements required to sustain evidence-based care.[267]

Institutionalization and routine guideline use

Institutionalization can be defined as "the relative endurance of change within an organization, as it becomes part of everyday activities or normal practices."[268] Similarly, when an innovation becomes embedded into regular activities and loses its distinct identity, it has undergone a process of become routine.[269] Changing clinical practice is not an easy task. It requires systematic planning and action, along with policies, procedures, and documentation systems to support an institutional shift in care.

There are several factors that facilitate change in practice and long-term sustainability in implementing treatment guidelines in health care settings. Table 7.5 summarizes some key factors.

Sustained guideline implementation depends on supportive leadership, motivated human resources, and professional development

TABLE 7.5
Factors that facilitate practice change and long-term sustainability of guideline use[270]

FACTOR	ISSUES TO CONSIDER
Topic relevance	• Is the need and priority for the topic of the guideline well-defined? Is there consensus toward what knowledge needs to be sustained and how to sustain it? How does the new knowledge fit with current priorities?
Benefits	• What are the anticipated benefits of knowledge implementation?
Attitudes	• What are the attitudes of the patient, their family, the community, health care providers, and decision-makers toward the guideline?
Networks	• What groups can be engaged to facilitate sustainable knowledge use?
Leadership	• What actions can leaders and managers at all levels of the health system take to support sustainable knowledge use? Are there champions of change? Who is responsible for continuous implementation? Who is responsible for making modifications as new knowledge emerges? Who is responsible for ensuring that relevant outcomes are met?
Policy articulation and integration	• How will the fit between new knowledge and existing policies be assessed? How will the knowledge be integrated into relevant policies, procedures, regulatory, and documentation systems?
Financial	• What funding is required to implement and sustain knowledge? Are there any cost-effective strategies that can be used?
Political	• Who are the stakeholders? What power or support can be leveraged? Who will initiate the scaling up process?

programs in health facilities. In a study published in 2006, organizations that sustained guideline implementation for at least two years had different patterns of leadership activities when compared to organizations that did not sustain guideline implementation.[271] The following leadership strategies were identified as crucial to successfully implementing and sustaining guidelines—

- Facilitating individual staff to use guidelines
- Creating a positive environment of best practices
- Influencing organizational structures and processes

Providing support and role models, and reinforcing organizational policies that are consistent with evidence-based care are just a few examples of strong leadership. Ongoing staff education plays a particularly important role in reinforcing the value of standard treatment guidelines in daily clinical practice.[272]

Sustained guideline implementation also requires the continual integration of new knowledge into daily practice. Medical knowledge is ever-evolving and clinical practices change with the advent of new medicines and medical technology.

The following sections outline additional factors that sustain guideline use.

A. Reinforcement for guideline maintenance

The capacity of a health system's organizational memory and knowledge reservoirs[273] has important implications for the ability to sustain changes in practice. Organizational memory comprises the storage of information in various reservoirs within an organization.[274] This can include formal staff orientation and education, policies and procedures manuals, computerized reminder systems, audits, feedback, and follow-up programs.[275]

B. Maintaining and expanding stakeholder collaboration

Multiple stakeholders play an important role in sustainability, including administrators, clinical leaders, patients, and family. Administrators are interested in whether the resources used to implement the treatment guidelines were necessary, while clinical leaders are interested in promoting the best care for patients. When they receive good quality care, patients and their families uphold the trust and satisfaction that the community has in evidence-based care.[276]

C. Ongoing monitoring of guideline use

Monitoring progress toward sustainability is the best way to ensure whether guideline use will be fully integrated into the health system in the long term. To assess and monitor the sustainability of treatment guidelines, choose indicators that examine structure, process, and outcome. In other words, focus on what you need to sustain guidelines, how to meet those needs, and what the results will be.

Progress toward sustainability can be assessed at the facility, provider, patient/family, or financial levels. For example, if you are monitoring the organizational unit, assess whether structures are in place to support use of treatment guidelines. Are health care professionals involved? Are the necessary materials available? Does the organization uphold a mission to support the necessary changes? You should also look at the process in place to use treatment guidelines. Are leaders engaged and accountable in their clinical practice? Has the facility developed or modified policies and procedures to promote the use of guidelines? Are there computer

systems in place to support to the use of guidelines? Finally, think about the desired outcome. Is there an increased awareness of in-house resources? Has the health facility improved staff and patient satisfaction with management?

DTCs as a key body to oversee STG maintenance

A DTC is a highly relevant entity that can be used to oversee the STG implementation process. DTCs represent a valuable resource for regional, district, and facility-level dissemination, training, and evaluation activities. Prepare DTCs well in advance on their roles and responsibilities for disseminating, implementing, and monitoring the use of treatment guidelines. Schedule dissemination workshops and meetings and build in time for DTCs to plan for the event. The DTCs should receive the necessary resources and materials to manage these functions efficiently and effectively.[277]

CHAPTER 7

TAKE-HOME MESSAGES

- Implementation of STGs requires ample planning, resources, and commitment. The ultimate goal of implementation is to integrate clinical recommendations from the guideline into routine clinical practice. Guideline implementation should be made a high organizational priority at each health facility, and the value of guidelines in ensuring good clinical care should be well communicated.
- The guideline development committee or the health care facility's management team should form a guideline implementation working group to support all guideline implementation activities. Team leadership and membership, teamwork strategies, and communication will ensure the working group's viability.
- Implementing an STG requires four preparatory steps: analyzing local practices, identifying local facilitators and barriers to guideline use, determining available resources, and designing an implementation plan.
- To properly implement a treatment guideline, organize an official launch, distribute the guideline widely, and conduct training, monitoring and evaluation, and supervision to ensure its appropriate use.
- Continuous quality improvement is an iterative approach that emphasizes organizational performance, patient care processes, and outcomes. This approach should be used as a framework for developing, implementing, monitoring, and evaluating guidelines because it can lead to effective and sustained improvements in quality of care.
- Planning for the long term will ensure that treatment guidelines are fully integrated into the health system. Changing clinical practice requires systematic planning and action along with policies, procedures, and documentation systems to support an institutional shift in care. Leadership, organizational culture, training, facilitation, and resources are necessary elements for sustain evidence-based care.

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CHAPTER 8

Updating Guidelines

Standard treatment guidelines should be updated regularly to keep up with changing health trends and evidence-based best practices, and to maintain credibility.[278] When published, the guideline should document the publication date and, if possible, a proposed date for a future review.[279] Debate continues to circle and vary as to how often and by what process guidelines should be updated[280].

A. Consider situations that might necessitate guideline updates

There following situations may warrant an update to standard treatment guidelines[281]—

- Changes in evidence on the existing benefits and harms of interventions
- Changes in outcomes considered important
- Changes in available interventions
- Changes in evidence that current practice is optimal
- Changes in values placed on outcomes
- Changes in resources available for health care
- Changes in international recommendations

B. Determine a reasonable frequency for updates

The guideline should include a statement describing how and when the need for a revision will be assessed.[282] There are different approaches for deciding when a guideline should be updated. For example, you may implement a policy declaring that guidelines undergo revision at a specific time interval (e.g., every two years) or you may include a date for a scheduled review in the current guideline.[283] These approaches, however, may not make the most efficient use of time and resources.

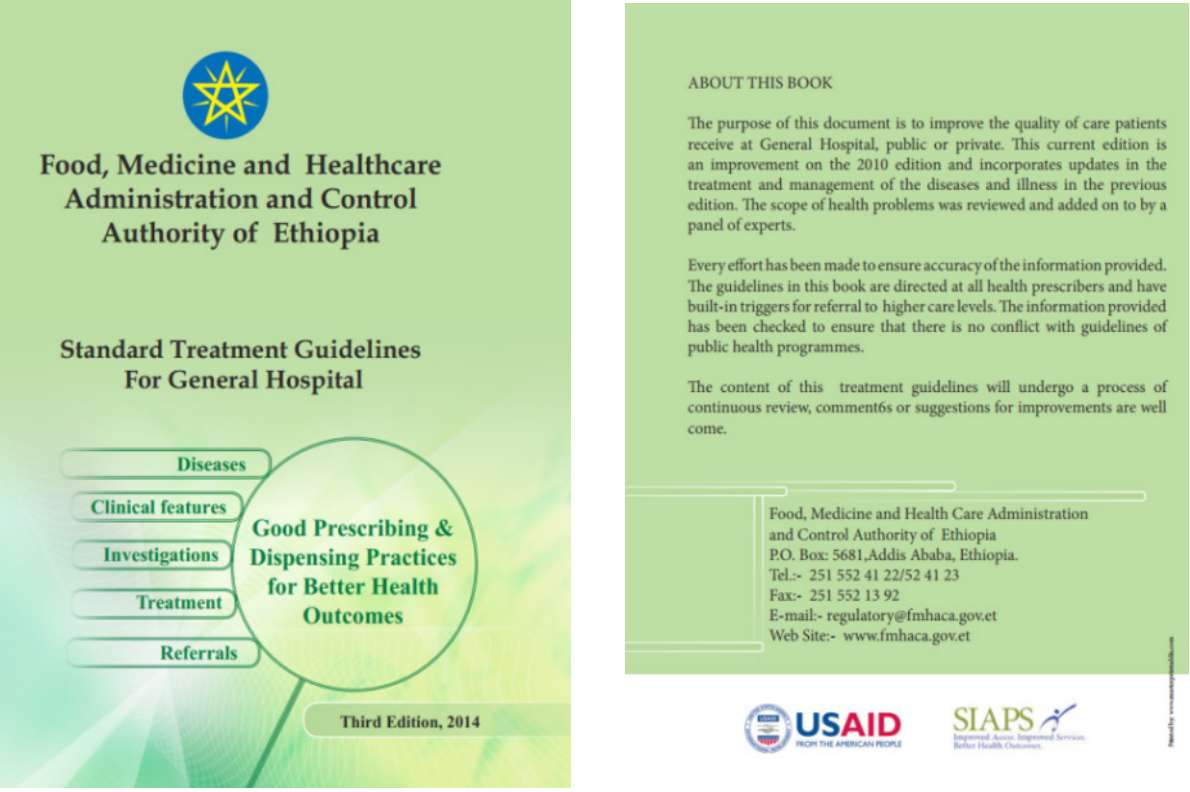
There is no standard for how long guidelines remain valid. When deciding when to review guidelines, consider any changes in evidence.[284] Define when new evidence on interventions, outcomes, and performance justifies an update by identifying significant new evidence and assessing whether this new evidence necessitates updating.

Following the publication of the guideline, monitor the literature regularly to identify any new, relevant evidence and important scientific breakthroughs. When new evidence suggests the need for revisions to recommendations, then an update is necessary. This is particularly crucial for clinically important recommendations that can cause substantial harm if left unchanged.[285]

In Malawi, the National Drug Committee recognized the need to update the first edition of the standard treatment guidelines just months after it was distributed in 1991, as there had been several developments in the treatment of clinical presentations in HIV and AIDS, malaria, sexually transmitted diseases, and acute respiratory infections in children during this time. The second edition of the guideline was published two years after the first edition was released.[286]

Three editions of STGs (2004, 2010, 2014) have been published in Ethiopia. After the second edition was published in 2010, changes were made to the national list of drugs and new developments in diagnosis and treatment were introduced into the health system. To accommodate these changes, a third edition was updated and published with support from the SIAPS program and a panel of experts at Bethel Teaching General Hospital. This 2014 edition addresses common health problems and includes new diseases.

The Lesotho's Ministry of Health has recently completed revision of the country's STGs and EML with technical assistance from SIAPS. The 2015 version of the guidelines include some medicines relating to HIV and AIDS, pediatrics, nutrition, and obstetrics and gynecology, which were not in the previous version of the STGs and EML. These medicines, which contribute



The third edition of the Ethiopia STGs, published in 2014, incorporates updates in the treatment and management of diseases and conditions.

to USAID's AIDS Free Generation (AFG) and Ending Preventable Child and Maternal Deaths (EPCMD) goals, include:

- HIV and AIDS: The inclusion of option B+ for the treatment of all HIV-positive pregnant women to bring the STGs in line with the new Lesotho HIV treatment guidelines
- Pediatrics: Zinc sulfate for childhood diarrhea; chlorhexidine for umbilical cord care
- Nutritional: F75 and F100 for the treatment of malnutrition
- Obstetrics and gynecology: Addition of misoprostol for postpartum hemorrhage

Shekelle and colleagues (2001) conclude that guidelines should be re-evaluated no less than every three years.[287] Similarly, WHO recommends guideline revisions should occur at a minimum of two years and a maximum of five years.[288]

After initial implementation of the guideline, an ongoing process should be established to regularly review new evidence and outcomes.[289] The process of updating the guideline should follow the same systematic, organized approach as the original development process. In the first edition of the Swaziland STG/EML (2012), users will find a Motion to Amend the STG/EML. This form (appendix G) standardizes the approach for updating guidelines in Swaziland. It asks for, among other things, what changes are being proposed, the reasons for the request, and the evidence backing the suggested change. Additionally, the form confirms whether the request has already been presented to and reviewed and approved by the facility or regional Pharmacy and Therapeutics Committee.

CHAPTER 8

TAKE-HOME MESSAGES

- STGs should be updated regularly to keep up with changing health trends and evidence-based practices and to maintain credibility. WHO recommends guideline revisions at a minimum of two years and a maximum of five years.
- An ongoing process should be established to regularly review new evidence and outcomes. The process of updating STGs should follow the same systematic, organized approach as the original development process.

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CHAPTER 9 Conclusion

This how-to-manual provides practical information to walk you through the process of developing, implementing, and monitoring the use of STGs. The information provided here is based on international evidence, recommendations, and experience. With guidance from this manual, health professionals and other stakeholders will be better equipped to produce high quality STGs.

High quality standard treatment guidelines are developed based on a systematic, transparent process that minimizes bias and conflict of interest. Table 9.1 summarizes the characteristics of high quality guidelines, all of which have been covered in different sections of this manual.

Ensuring that guidelines become an integrated and useful part of health care remains a challenge. A survey of organizations in Africa, Asia, Europe, Latin America, the United States, and the United Kingdom revealed that few entities actively implemented their guidelines.[291]

A review of the literature shows that the following characteristics can have a negative impact on guideline implementation[292]—

- The focus is almost entirely on behavior change by individual clinicians
- There is no specific plan or focus for systems change
- There is no attention to the change process needed for implementation
- There is too little emphasis on evaluating the influence of the context of the practice setting and environment on the effects of the guideline intervention
- The influence of patient needs and preferences is often overlooked

High quality standard treatment guidelines are developed based on a systematic, transparent process that minimizes bias and conflict of interest.

Ongoing studies have shown that guideline developers should develop professional relationships with members of the health care system that are responsible for distributing and implementing guidelines.[293] Then, the following strategies should be used to support guideline uptake[294]—

- Identify potential barriers to recommendations and generate solutions to address them
- Use behaviorally specific language in the guideline
- Use multiple channels for guideline dissemination based on preferences of health care practitioners

TABLE 9.1
Characteristics of high quality guidelines[290]

CHARACTERISTIC	DESCRIPTION
Composition of guideline development committee	• Committee should be made up of multiple stakeholders from multiple disciplines • Committee should be balanced, including members with relevant backgrounds and expertise • Committee should include effective participation from patient and consumer representatives
Decision making process	• Guideline committee should establish a process to reach consensus before guideline development begins • Guideline should describe the process used to reach consensus
Conflicts of interest	• Guideline should document any conflicts of interest among guideline development committee members • Guideline should describe how conflicts of interest were recorded and managed
Guideline scope	• Guideline should specify objectives and scope
Methods	• Guideline development process should be rigorous • Guideline should provide a detailed description of methodology used to develop the document
Evidence reviews	• Guideline should be based on a systematic review of the evidence
Guideline recommendations	• Guideline recommendations should be clearly articulated and based on evidence of benefits, harms, and costs • Guideline recommendations should include a summary of relevant available evidence, and a description of the quality, quantity, and consistency of the available evidence
Rating of evidence and recommendations	• Guideline should use a transparent, systematic rating system to communicate the quality and reliability of evidence and the strength of recommendations
External peer review and stakeholder consultations	• Guideline committee should solicit a full spectrum of relevant stakeholders (e.g. scientific and clinical experts, patients, representatives from health care organizations, government) to review guideline draft • Guideline committee should document and consider all comments
Guideline update	• Guideline should be revised, as appropriate, when new, potentially relevant information warrants modifications
Financial support	• Guideline should disclose financial support for the development of the evidence review and recommendations

- Develop educational resources adapted in content
- Identify the resource implications of recommendations and ensure their availability before starting
- Use data collection tools

A study in the United States found that organized systems in the clinic, commitment to change by leadership, clinician champions for the guideline, priorities for quality of care, continuous quality improvement skills in the organization, and a collaborative working environment can have a major effect on how and whether changes are made successfully.

The following box provides practical tips for implementing guidelines successfully.[295, 296, 297]

PRACTICAL TIPS FOR IMPLEMENTING GUIDELINES SUCCESSFULLY

- To achieve change, adopt a multi-faceted approach to guideline implementation
- Identify potential barriers at various levels of the health system ahead of time, and apply solutions to enhance your chances of success
- Identify and collaborate with local stakeholders and identify the necessary financial, material, and human resources to support implementation
- Guideline implementers and supply managers must ensure that the medicines recommended in the STG are consistently available at service delivery points where health providers are expected to follow the guidelines while prescribing

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APPENDIX A.
Zambia national formulary committee[298]

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298 *Reproduced from:* Ministry of Health and Zambia National Formulary Committee. 2008. *Standard Treatment Guidelines, Essential Medicines List, Essential Laboratory Supplies for Zambia* (2nd ed.). Lusaka, Zambia: Zambia Ministry of Health.

APPENDIX B.
The AGREE II instrument[299]

DOMAIN 1. SCOPE AND PURPOSE

1. The overall objective(s) of the guideline is (are) specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

2. The health question(s) covered by the guideline is (are) specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

299 *Source:* Appendix to: Brouwers MC, Kho ME, Browman GP, et al.; the AGREE Next Steps Consortium. AGREE II: Advancing guideline development, reporting and evaluation in health care. CMAJ 2010. DOI:10.1503/cmaj.090449. http://www.cmaj.ca/content/suppl/2010/07/05/cmaj.090449.DC1/advance-brouwers-appendix.pdf

APPENDIX B (continued)

DOMAIN 2. STAKEHOLDER INVOLVEMENT

4. The guideline development group includes individuals from all relevant professional groups.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

5. The views and preferences of the target population (patients, public, etc.) have been sought.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

6. The target users of the guideline are clearly defined.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

APPENDIX B (continued)

DOMAIN 3. RIGOUR OF DEVELOPMENT

7. Systematic methods were used to search for evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

8. The criteria for selecting the evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

9. The strengths and limitations of the body of evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

APPENDIX B (continued)

DOMAIN 3. RIGOUR OF DEVELOPMENT continued

10. The methods for formulating the recommendations are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

12. There is an explicit link between the recommendations and the supporting evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

APPENDIX B (continued)

DOMAIN 3. RIGOUR OF DEVELOPMENT continued

13. The guideline has been externally reviewed by experts prior to its publication.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

14. A procedure for updating the guideline is provided.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

APPENDIX B (continued)

DOMAIN 4. CLARITY OF PRESENTATION

15. The recommendations are specific and unambiguous.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

16. The different options for management of the condition or health issue are clearly presented.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

17. Key recommendations are easily identifiable.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

APPENDIX B (continued)

DOMAIN 5. APPLICABILITY

18. The guideline describes facilitators and barriers to its application.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

20. The potential resource implications of applying the recommendations have been considered.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

APPENDIX B (continued)

DOMAIN 5. APPLICABILITY continued

21. The guideline presents monitoring and/or auditing criteria.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

APPENDIX B (continued)

DOMAIN 6. EDITORIAL INDEPENDENCE

22. The views of the funding body have not influenced the content of the guideline.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

23. Competing interests of guideline development group members have been recorded and addressed.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

APPENDIX B (continued)

OVERALL GUIDELINE ASSESSMENT

For each question, please choose the response which best characterizes the guideline assessed:

1. Rate the overall quality of this guideline.

1 Lowest possible quality	2	3	4	5	6	7 Highest possible quality

2. I would recommend this guideline for use.

Yes	
Yes, with modifications	
No	

NOTES

APPENDIX C.
Guidelines for adverse drug reaction reporting[300]

GUIDELINES FOR ADVERSE DRUG REACTION REPORTING

National Pharmacovigilance Programme
The Medicines Control Council (MCC) has a responsibility to ensure the safety, efficacy and quality of all medicines used by the South African public. The National Pharmacovigilance Programme is coordinated by the MCC and has a dedicated Unit, The National Adverse Drug Event Monitoring Centre (NADEMC), in Cape Town, which monitors the safety of all registered medicines in South Africa.

What is Pharmacovigilance?
Pharmacovigilance is defined as the science and activities concerned with the detection, assessment, understanding and prevention of adverse reactions to medicines (i.e. adverse drug reactions or ADRs). The ultimate goal of this activity is to improve the safe and rational use of medicines, thereby improving patient care and public health.

What is an Adverse Drug Reaction (ADR)?
The Medicines Control Council (MCC) defines an Adverse Drug Reaction (ADR) reaction as a response to a medicine which is noxious and unintended, including lack of efficacy, and which occurs at any dosage and can also result from overdose, misuse or abuse of a medicine.

Who should report Adverse Drug Reactions?
All health care workers, including doctors, dentists, pharmacists, nurses and other health professionals are encouraged to report all suspected adverse reactions to medicines (including vaccines, X-ray contrast media, traditional and herbal remedies), especially when the reaction is not in the package insert, potentially serious or clinically significant.

What happens to a report?
All ADR reports are entered into a national ADR database. Each report is evaluated to assess the causal relationship between the event and the medicine. A well-completed adverse drug reaction/product quality form submitted could result in any of the following:

- Additional investigations into the use of the medicine in South Africa
- Educational initiatives to improve the safe use of the medicine
- Appropriate package insert changes to include the potential for the reaction
- Changes in the scheduling or manufacture of the medicine to make it safer

The purpose of ADR reporting is to reduce the risks associated with the use of medicines and to ultimately improve patient care.

300 *Reproduced from:* South Africa NDoH. 2012. *Standard Treatment Guidelines and Essential Medicines List for South Africa: Hospital Level Adults.*

APPENDIX C (continued)

Will reporting have any negative consequences on the health worker or the patient?
An adverse drug reaction report does not constitute an admission of liability or that the health professional contributed to the event in any way. The outcome of a report, together with any important or relevant information relating to the reaction, will be sent back to the reporter as appropriate. The details of a report are stored in a confidential database. The names of the reporter or any other health professionals named on a report and that of the patient will be removed before any details about a specific adverse drug reaction are used or communicated to others. The information is only meant to improve the understanding of the medicines used in the country.

Is the event possibly an ADR?
The following factors should be considered when an adverse drug reaction is suspected:

1. What exactly is the nature of the reaction? (*Describe the reaction as clearly as possible and where possible provide an accurate diagnosis*.)

2. Did the reaction occur within a reasonable time relationship to starting treatment with the suspected medicine? *(Some reactions occur immediately after administration of a medicine while others take time to develop.)*

3. Is the reaction known to occur with the particular medicine as stated in the package insert or other reference? *(If the reaction is not documented in the package insert, it does not mean that the reaction cannot occur with that particular medicine.)*

4. Did the patient recover when the suspected medicine was stopped? *(Some reactions can cause permanent damage, but most reactions are reversible if the medication is stopped.)*

5. Did the patient take the medicine again after the reaction abated (i.e. rechallenge). If so, did the same reaction occur again? *(In most situations it is not possible or ethical to rechallenge the patient with the same medicine. If such information is available or if such a rechallenge is necessary, recurrence of the event is a strong indicator that the medicine may be responsible.)*

6. Can this reaction be explained by other causes (e.g. underlying disease/s; other medicine/s; toxins or foods)? *(It is essential that the patient is thoroughly investigated to decide what the actual cause of any new medical problem is. A medicine-related cause should be considered, when other causes do not explain the patient's condition.)*

APPENDIX C (continued)

What types of reactions should be reported?
The following adverse drug reactions should be reported:
- All ADRs to newly marketed drugs or new drugs added to the EDL
- All serious reactions and interactions
- ADRs that are not clearly stated in the package insert.
- All adverse reactions or poisonings to traditional or herbal remedies

Report even if you are not certain that the medicine caused the event.

What Product Quality Problems should be reported?
The following product quality problems should be reported:
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures

How can ADRs be prevented from occurring?
Some ADRs are unavoidable and cannot be prevented. However, most ADRs can be prevented by following the basic principles of rational use of medicines.

How are adverse drug reactions reported?
An Adverse Drug Reaction/Product Quality Report Form is enclosed in this book and should be completed in as much detail as possible before returning it by fax or post to any of the addresses provided below. Additional forms can be obtained by contacting the MCC at these addresses. Report forms may also be accessed via the following website: *http://www.mccza.com*

1. **The Registrar of Medicines**
   Medicines Control Council, Department of Health, Private Bag X828
   Pretoria, 0001
   Tel: (021) 395 8003/8176; Fax: (012) 395 8468

2. **The National Adverse Drug Event Monitoring Centre (NADEMC)**
   C/o Division of Pharmacology, University of Cape Town,
   Observatory, 7925
   (021) 447 1618; Fax: (021) 448 6181

APPENDIX C (continued)

Adverse drug reaction ARF 1

ADVERSE DRUG REACTION AND PRODUCT QUALITY PROBLEM REPORT FORM

(*Identities of reporter and patient will remain strictly confidential)*

health Department: Health REPUBLIC OF SOUTH AFRICA	**NATIONAL ADVERSE DRUG EVENT MONITORING CENTRE NADEMC** The Registrar of Medicines Private Bag X 828 Pretoria 0001 In collaboration with the WHO International Drug Monitoring Programme

PATIENT INFORMATION

Name (or initials): .....

Patient Reference Number: ……..

Sex:	**M**	**F**	**Age:**	**DOB:**	**Weight (kg)**	**Height (cm)**
			.....	..... / ...../	.....	.....

ADVERSE REACTION/PRODUCT QUALITY PROBLEM (tick appropriate box)

Adverse reaction ☐ **and/or Product Quality problem** ☐

Date of onset of reaction:
...../...../.....
Time of onset of reaction:
….....hour.....min

Description of reaction or problem (Include relevant tests/lab data, including dates):

APPENDIX C (continued)

1. MEDICINES / VACCINES / DEVICES (include all concomitant medicines)					
Trade Name & Batch No. (Asterisk Suspected Product)	Daily Dosage	Route	Date Started	Date Stopped	Reasons for use

ADVERSE REACTION OUTCOME (Check all that apply)			
	death		life-threatening
	disability		hospitalisation
	congenital anomaly		Other.....
	required intervention to prevent permanent impairment/damage		

Reaction abated after stopping medicine:

	Y		N

Event reappeared on rechallenge:

	Y		N		Rechallenge not done

Recovered:

	Y		N

Sequelae:

	Y		N

Describe Sequelae:.....

COMMENTS: (e.g. Relevant history, Allergies, Previous exposure, Baseline test results/lab data)

APPENDIX C (continued)

Adverse drug reaction ARF 1

2. PRODUCT QUALITY PROBLEM:

Trade Name	Batch No	Registration No	Dosage form & strength	Expiry Date	Size/Type of container

Product available for evaluation?: **Y** **N**

REPORTING HEALTHCARE PROFESSIONAL:

NAME: .....

QUALIFICATIONS:.....

ADDRESS: .....

.....Postal Code: ……

TEL: (.....).....

…….. ……..
Signature Date

This report does not constitute an admission that medical personnel or the product caused or contributed to the event.

APPENDIX C (continued)

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:
- medications (drugs, vaccines and biologicals)
- medical devices (including in-vitro diagnostics)
- complementary / alternative medicines (including traditional, herbal remedies, etc)

Please report especially:
- adverse drug reactions to newly marketed products
- serious reactions and interactions with all products
- adverse drug reactions which are not clearly reflected in the package insert.

Report Product Quality Problems such as:
- suspected contamination
- questionable stability
- defective components
- poor packaging or labelling
- therapeutic failures

Report even if:
- you're not certain the product caused the event
- you don't have all the details

Important numbers:

Investigational Products and Product Quality Problems:
- fax: (012) 395-9201
- phone: (012) 395-9341

Adverse Events Following Immunisation:
- fax: (012) 395 8905
- phone: (012) 395 8914/5

Confidentiality: Identities of the reporter and patient will remain strictly confidential.

Your support of the Medicine Control Council's adverse drug reaction monitoring programme is much appreciated. Information supplied by you will contribute to the improvement of medicine safety and therapy in South Africa.

PLEASE USE ADDRESS PROVIDED BELOW - JUST FOLD, TAPE and MAIL

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0001

APPENDIX D.

Ethiopia template for the revision of standard treatment guidelines for health center, and primary and general hospital

FOOD, MEDICINE AND HEALTHCARE ADMINISTRATION AND CONTROL AUTHORITY OF ETHIOPIA

STANDARD TREATMENT GUIDELINES FOR GENERAL HOSPITAL

THIRD EDITION

January 2013

FMHACA, January 2013

APPENDIX D (continued)

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Website: fmhaca.gov.et

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APPENDIX D (continued)

Part I: General Guidance

A. Purpose

Treatment of diseases may have many different approaches. Applying the most effective treatment benefits both the patient and the health care system. Include a statement to clearly indicate that the guideline should always be used with regard to clinical judgment to determine the appropriate treatment or care for each patient or client.

Reassure users that reasonable steps have been taken to ensure that the guidelines were properly prepared and are based on the best information available at the time of publication and have the following advantages as examples.

- It will make the health care system standard.
- Provides standardized guidance to practitioners.
- Promotes high quality of care by directing practitioners to the most appropriate drugs for specific conditions.
- Provides best quality of care since patients are receiving optimal therapy.
- Facilitate to use essential drugs from the drug list.
- Provides assistance to all practitioners.
- Enables providers to concentrate on making the correct diagnosis.
- Provides effective therapy in terms of quality.
- Serves to integrate special programs (LEP, TB & HIV) with a single set of guidelines.
- STG/formulary drugs becomes well known and can be easily listed;
- Provides information for forecasting and ordering according to the morbidity
- Provides information for purchase of pre-packed drugs; fixed dose combinations, and of various relevant formulations.
- Patients receive optimal drug therapy.
- Enables consistent and predictable treatment from all levels of providers and at all locations.
- Allows for improved availability of drugs because of consistent and known usage patterns.
- Avails best treatment regimens: good outcomes with the lowest possible cost.

The information provided in “the Standard treatment guideline” is intended for information purposes. Standard treatment guidelines are designed to improve the quality of health care and decrease the use of unnecessary or harmful interventions. Variations, which take into account individual circumstances, clinical judgment and patient choice, may also be appropriate.

APPENDIX D (continued)

B. How to use the STG
Please refer the existing STGs

C. Patient History Taking
The basics of patient history taking should be presented here

D. Physical Assessment
The basics of physical assessment should be presented here

E. Laboratory Investigation
The basics of such investigations should be presented here

F. Investigation using Imaging Techniques
The basics of such investigations should be presented here

G. Differential Diagnosis
The basics of taking differential diagnosis should be presented here

H. Interpretation of Findings
The basics of interpreting diagnostic findings should be presented here

For the following general guidance sections, please refer the existing STGs and describe accordingly.

I. Good Prescribing Practices

J. Good Dispensing Practices

K. Patient Medication Use, Counseling and Adherence

L. ADE and its Management

M. Drug Interactions and Solutions

N. Medication Management for Special Groups
- Pregnant women
- Nursing women
- Infants/Children
- Elderly patients
- Renal Failure
- Liver Disease

O. Palliative Care

P. Topical Steroids

Q. Narcotic Drugs and Psychotropic Substances Use

R. Antimicrobial Resistance

APPENDIX D (continued)

While a normal physical assessment of the patient is presumed, on many occasions specific assessments will be required (e.g. digital rectal examinations in cases where enlargement of the prostate is implicated in lower urinary tract symptoms). Include the need for any physical assessment that may be age, gender or past medical history dependent.

- **Compliant Specific Interpretation of Findings**
  If there are several possible diagnoses, consider including a decision tree (algorithm) that illustrates the pathway used to arrive at the diagnosis. Identify any clinical differences for specific populations e.g. geriatric or pediatric that may apply. Listing "pearls of practice" (e.g. rebound tenderness is less likely in geriatric patients with appendicitis) may also be useful.
  Summarize the options for treatment that arise from the presentation, history, physical assessment and results of investigations. Support the inclusion of each alternative in the list of options with a reference to the relevant evidence.

G. Treatment Objectives

For example, elimination of ***Plasmodium*** parasites from a blood smear; sputum negativity in a previously sputum-positive TB patient.

H. Management of Disease:

- **Pharmacological Treatment**

The drug of choice for the specific disease or condition, identify first line treatment drugs, when appropriate 2nd, and if necessary 3rd line treatment options drugs and shall be sequential. Include the generic name, dose, route, frequency, duration, therapeutic class, schedule, indications, contraindications, cautions, side effects, warnings, toxicity and/or inter-actions as applicable.Where medication is necessary, the individual dose regimes are stated in a standard format as follows:

Generic name: This is the officially recommended name of the medication as listed in Ethiopian medicine list which should be used in all prescribing, dispensing, medicines administration and medication record procedures.

Dose size: This is the size of each individual dose of the medicine and is usually expressed as a quantity of the particular medicine, either as a weight (e.g. 100mg, 250mg, 500 micrograms) or, for certain medicines whose strength is expressed in terms of international units (IU) as a number of units (e.g. 20,000 IU, 2MU). In some cases, the dose may be expressed as a particular volume of a liquid of particular strength (e.g. IV infusions)

Pediatric doses: (For patients of 12 yrs or less) where applicable, these are specifically indicated. Whenever possible and where relevant, the dose size is stated in terms of body weight (e.g. 5mg/kg) so that a precise dose may be accurately determined to suit individual patients. In other cases, a fixed dose may be related to a particular age range (e.g. <5yrs: 125mg; 5-12 yrs: 250mg). Where weighing is not possible but the age is known, age/weight charts may be used to estimate the weight of the child. Where weighing is not possible, and specific pediatric doses are not indicated, suitable pediatric doses may be approximated in terms of the normal adult dose as follows:

APPENDIX D (continued)

Part II: Presentation of Information

This part of the template tries to explain about the content of the treatment approaches for every disease/health problem category.

A. Title/Health Problem

Each condition is given a title and where relevant an alternate familiar name (in parentheses) by which it may be also be known, e.g. Human trypanosomiasis (Sleeping sickness), Hemorrhoids (Piles). Unless diagnosis is confirmed title should reflect the presentation – rather than a condition (e.g. chest pain – not myocardial infarction, ankle trauma, and not sprained ankle).

B. Description of the Disease

C. Disease Cause

Listed here are the pathological organisms, circumstances or reasons which are involved in the transmission of the disease or occurrence of the condition. Where relevant any pre-disposing factors will also be given in this part of the monograph.

D. Clinical Features

Listed here are the main signs and symptoms which characterize the disease or condition together with an indication of any particular groups of patients which may be more susceptible, e.g. children, pregnant women, the elderly where relevant, complications which may result from having the condition (usually in a serious or chronic form) should also be given.

E. Differential Diagnosis

This part gives any other conditions which may produce similar signs and symptoms, and which should therefore be considered and excluded in making an initial diagnosis.

F. Investigations (Patient History Taking, Physical Assessment, Laboratory or Imaging)

The most important diagnostic tests and investigations which would be needed to help reach a possible definitive diagnosis should be indicated. Specify the relevant diagnostic investigations such as pathology and medical imaging, which will assist in making a definitive diagnosis. For investigations used infrequently or which are controversial or expensive, include a reference to the evidence supporting the practice. Include any required pathology tests – including biochemistry, hematology and microbiology normal levels or ranges and test results, which will indicate a need for further consultation. Available tests may be limited at lower levels of the health system.

- **Complaint Specific Patient History Taking**

  If there is any special patient history taking for a particular disease or health problem, it has to be stated here.
- **Complaint Specific Physical Assessment**

APPENDIX D (continued)

<5yrs: ¼ of adult dose
5-8yrs: ½ of adult dose
9-12yrs: ¾ of adult dose

Route of administration: The oral route is to be used unless otherwise indicated. Approved abbreviations are used for parenteral routes.

Dose frequency: in most cases, this is expressed in terms of the number of hours (interval) between doses (e.g. 8-hourly, every 4-6 hours). For many medicines this is more appropriate than expressing as a stated number of times per day. In the latter case, the dose interval may vary and this may have adverse effects on blood levels of the medicine and consequent therapeutic effectiveness of the medicine.

Duration of treatment: Where applicable the recommended period for which treatment should be continued is indicated as a number of days, weeks, etc. Where the duration is not stated treatment should be continued for as long as necessary to obtain the desired therapeutic outcome, e.g. until the patient is cured or the condition resolves.

Special instructions:

1) These give further information on the correct administration of the medication and, where relevant, should be written on any related prescription, e.g. taken after food, applied sparingly, given slowly over a 4 hour period, etc
2) Use approved formulary list drugs only (although the formulary list may need to be changed according to a review of the evidence).
3) Use the fewest medicines necessary —by making sure the drug given is efficacious—do not prescribe two drugs when one can do the same.
4) Suggest therapeutic dosages for medications for specific populations (children, neonates, aged and or renal or hepatic impaired patients).
5) Choose the most cost-effective treatments.

➢ Non - Pharmacological Treatment

Non drug treatment as optional or supportive treatment shall be indicated as requires.

➢ Referral

The appropriate level of health service facility at which a particular condition or a step in the sequence of treatment of a condition shall be indicated. In some treatments, although the actual medicine recommended may be available at a lower level than indicated, the management of the condition requires the capacity, available skills, etc. of the higher level shown.

➢ Prevention Related Interventions:

Practical measures which can be taken to avoid the particular condition occurring or prevent it developing are given. These should be clearly communicated to the patient as part of the counseling which should be a vital and routine part of patient management.

APPENDIX D (continued)

I. Expected Outcomes

Expected outcomes should be specified for all recommended interventions. This will facilitate the evaluation of the services provided by Practitioners, and enable audits to be conducted on specific elements of the service they provide and Actions that will be taken if outcome(s) not achieved.

Describe the expected response with regard to timeframe. Failure to achieve the expected response in the given time may be an indication of the need to refer the patient to other health professionals.

APPENDIX D (continued)

Part III: Additional Notes to the Consulting Firm

1. Authorship/Endorsement/Review

- The names of the guideline developers, the name of the organization sponsoring the standard treatment guidelines and a list of names, signatures, dates and roles of those endorsing it should appear at the end of the document.
- The date of endorsement and the date when the standard treatment guidelines should be reviewed must also be included.
- Previous editions should be indicated with the critical information described above.

2. Clinical Protocols or guidelines

- Any clinical protocols or procedures to which the standard treatment guidelines refer will also require approval by food medicine and health care administration and controlling authority who endorsing the Standard treatment guideline. Attach these documents as an Appendix to the Guideline.

3. Language

- The guidelines should be of a written standard expected for professional papers. The language should be scientific, specific, clear and unambiguous and where possible write in “plain” English.
- Where abbreviations are used, the full description should be included for the first time with its abbreviation or acronym. For subsequent use the shortened form can be used. Where many specialty-specific abbreviations need to be used, consider attaching a list of abbreviations to the guideline.

4. Clarity of Expression

- While there is always room for the use of clinical judgment when using guidelines; the recommendations made in the guideline should be specific in regard to the patient population, care priorities, assessment and management.

5. Draft Guidelines

- “Watermarks” are useful to identify draft documents.
- “Footers” may be useful to identify which version of draft document is being submitted and the date of writing.
- Use of the “Track Changes” tool easily identifies changes to a draft version.

APPENDIX D (continued)

6. Proof Reading

- Guideline developers often find it difficult to detect errors or ambiguities. It is therefore recommended that standard treatment guidelines are carefully proof read by an experienced health care professional.

7. Reference materials

- The consulting firm should include all reference materials used for the revision of this STG.

APPENDIX E.

Protocols and procedures for antibiotic prophylaxis in cesarean section – developed by the participating MOH hospitals[301]

Ministry of Health: Prince Hussein Hospital

Protocol and Procedures for Antibiotic Prophylaxis in Cesarean Section (CS)

Protocol

Prophylactic Antibiotic: Cefazolin

Dose: **Single dose**: 1 gram if woman's weight < 80 Kg; 2 grams if > 80 Kg

Route: Intravenous: direct injection into vein or via running intravenous fluids (over 3-5 minutes)

Time Administration: Within 60 minutes prior to skin incision

Criteria for Additional Doses:

I. Give a **second** dose cefazolin 8 hours after the first dose in the following cases:
   1. Presence of full adhesions
   2. Failure to progress in labor **with no** ruptured membrane and decision for CS is made
   3. Pendular (obese) abdomen
   4. Woman is diabetic
   5. History of infection post previous CS
   6. Prolonged surgery (>3 hours) or if blood loss > 1500 mL (**2nd dose 3-4 hours after 1st dose**)

II. Give total of **3** doses of cefazolin at 8 hour intervals in the following cases:
   1. Woman presents with ruptured membrane > 24 hours
   2. Failure to progress in labor **with** ruptured membrane and decision for CS is made

If Beta Lactam Allergy: Clindamycin 600 mg intravenous single dose **AND**, gentamicin 1.5 mg/Kg intravenous single dose **BOTH immediately after cord clamping**

……

Procedures

- OBGY physician orders prophylactic antibiotic (PAB) on red *Doctor Order Sheet* on admission (Pre-Op).
- Nurse/mid-wife transcribes order onto *Pharmacy Order Sheet*.
- Nurse/mid-wife performs skin sensitivity (allergy) test (SST) in ward prior to transport to Operation Reception Room (ORR):
  - OBGY physician evaluates test site for allergy result.
  - OBGY Nurse/mid-wife or physician records results of skin test (negative or positive) on red *Doctor Order Sheet* and in Nursing Notes. If positive allergy, also records on front cover of patient chart.
  - Nurse/mid-wife administers PAB in the ORR once a signal is given from anesthetist to bring woman into the Operating Room (OR), and records time of administration and dose in *Medication Administration Record*.
- Anesthetist records time of induction in *Anesthesia Notes*, and surgeon records time of incision in the *Operation Notes*.
- Physician records presence of any infection during hospitalization in the *Progress Notes*.
- During discharge, physician performs dressing, records in notes, and councils the woman to return after one week for follow-up visit.
- Physician or nurse records outpatient follow-up visit including any treatment and presence of infection in *patient chart*.
- Physician or nurse/mid-wife reports presence of any surgical site infection to Infection Control Committee and to Laboratory for cultures.

301 *Reproduced from:* Gammouh S, and M. Joshi. 2013. *Improving Antibiotic Prophylaxis in Cesarean Section in Jordanian Hospitals: SIAPS Technical Report.* Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health. http://pdf.usaid.gov/pdf_docs/PA00JRMS.pdf

APPENDIX E (continued)

- If an emergency occurs in Labor Room where a decision to perform CS is made, PAB dose is obtained from OBGY ward and administered as described above if possible. In top emergency, the anesthetist may administer PAB on induction of anesthesia and records in Anesthesia Notes time and dose.
- All entries of the *CS Log* must be filled in at each step accordingly by the responsible personnel.

Ministry of Health: Prince Faisal Hospital

Protocol and Procedures for Antibiotic Prophylaxis in Cesarean Section (CS)

Protocol

Prophylactic Antibiotic: Cefazolin

Dose: **Single dose**: 1 gram if woman's weight < 80 Kg; 2 grams if > 80 Kg

Route: Intravenous: direct injection into vein or via running intravenous fluids (over 3-5 minutes)

Time Administration: Within 60 minutes prior to skin incision; preferably 30 min before

Criteria for Additional Doses: Give additional doses of cefazolin in the following cases as described:

1. Emergency CS surgery in diabetic woman with no time to control blood sugar, give 2nd dose 8 hours after the first dose.
2. Excessive blood loss (>1500 mL) or long procedure (greater than 3 hours), give 2nd dose 4 to 5 hours after the first dose.
3. If woman presents with ruptured membrane, give an additional dose 8 hours after first dose (if first dose is given pre-incision) for a total of 2 doses.
4. If woman presents with ruptured membrane, with no time to administer 1st dose pre-incision, then give 1st dose as soon as possible followed by 2 additional doses at 8-hour intervals for a total of 3 doses.

If Beta Lactam Allergy: Clindamycin 600 mg intravenous single dose prior to skin incision AND, gentamicin 1.5 mg/Kg intravenous single dose immediately after cord clamping

……

Procedures

- OBGY physician orders prophylactic antibiotic on red *Doctor Order* sheet on admission.
- Nurse or mid-wife transcribes order onto *Pharmacy Order* sheet.
- Nurse or mid-wife performs skin sensitivity (allergy) test (SST) in ward prior to antibiotic administration and prior to transport to Operating Room:
  - OBGY physician evaluates test site for allergy result
  - Nurse/mid-wife or physician records results of SST (negative or positive) on red Doctor Order Sheet. If positive allergy, also records on front cover of patient chart
- Ward nurse administers prophylactic antibiotic upon call to transfer to Operating Room, and records in *Nursing Medication Administration Record*. **Antibiotic must be administered within 60 minutes prior to skin incision.** Nurse communicates antibiotic administration time with surgeon.
- For non-elective (emergency) cases, the physician may give a verbal order to administer prophylaxis cefazolin; the verbal order must be written down as soon as possible after the procedure is over.

APPENDIX E (continued)

Annex G: Protocols and Procedures for Antibiotic Prophylaxis in Cesarean Section – Developed by the Participating MOH Hospitals

- For non-elective (emergency) surgeries, nurse/mid-wife obtains cefazolin from stock supply and performs SST, communicates results to surgeon, then administers the antibiotic prior to skin incision as time permits and records both the results of SST and the administration time and dose as appropriate.
- Physician or nurse/mid-wife records presence of **any infection** during hospitalization on *Progress Notes*.
- At the follow-up (CPP) visit, physician records in *CPP Clinic File* the visit date, presence or absence of infection, and course of treatment if any. If woman is new to the clinic, nurse/mid-wife creates a new file.
- OBGY ward nurses and CPP nurse/mid-wife to inform Infection Control Committee of any cases of infection.
- Physician must record ALL antibiotics ordered during hospitalization on *Doctor Order* sheet, on *Discharge Summary*, and in outpatient record as appropriate.

Ministry of Health: Dr. Jamil Al Totanji Hospital
Protocol and Procedures for Antibiotic Prophylaxis in Cesarean Section (CS)

Protocol

Prophylactic Antibiotic: Cefazolin

Dose: **Single dose**: 1 gram if woman's weight < 80 Kg; 2 grams if > 80 Kg

Route: Injected direct intravenous over 3-5 minutes after skin sensitivity (allergy) test

Time Administration: 15 to 60 minutes prior to skin incision

Criteria for Additional Doses:

1. Blood loss >1500mL and/or presence of full adhesions; give 2nd dose 3 to 5 hours after first dose
2. Ruptured membrane (>12 hours) with no signs/symptoms of infection, then give 3 doses of cefazolin in total at 8-hour intervals.
3. If surgical complications (surgical injury to adjacent organs) consider the protocols and practices currently followed for such complications, and **document in the chart**.

If Beta Lactam Allergy: Clindamycin 600 mg single IV dose, AND gentamicin 1.5 mg/Kg single IV dose BOTH immediately after cord clamping

……

Procedures

- OBGY physician orders prophylactic antibiotic on red *Doctor Order* sheet on admission, pre-operatively.
- Nurse transcribes order onto *Pharmacy Order* sheet.
- Nurse performs skin sensitivity (allergy) test (SST) in ward prior to antibiotic administration and prior to transport to Operating Room (OR):
  - OBGY physician evaluates test site for allergy result.
  - Nurse/physician records results of skin test (negative or positive) on red *Doctor Order* sheet. If positive allergy, also records on front cover of patient chart.
- Ward nurse administers prophylactic antibiotic upon transfer to OR, and records in nursing *Medication Administration Record*. **Antibiotic must be administered 15 to 60 minutes prior to skin incision.** Nurse communicates antibiotic administration time with surgeon.

APPENDIX E (continued)

- Surgeon records time operation begins (incision) and ends on *Operation Sheet.*
- **For emergency surgeries**, surgeon obtains the antibiotic from OR stock supply. Surgeon/nurse performs SST, and then administers the antibiotic prior to skin incision.
  - Surgeon records antibiotic administration and time in *Operation Notes*.
  - Surgeon records use of stock antibiotic with patient name on the OR stock-supply register.
- Physician or nurse records presence of any infection during hospitalization in the *Progress Notes* or at outpatient clinic follow-up in the patient chart.
- Physician must record ALL antibiotics ordered during hospitalization on *Doctor Order* Sheet, on *Discharge Summary*, and in outpatient record as appropriate.
- Physician or nurse reports presence of any infection to Infection Control Committee.
- All entries of the *CS Log* must be filled in at each step accordingly by the responsible personnel.

APPENDIX F.
Namibia STG evaluation protocol and survey tool[302]

Dissemination and Implementation of the Namibia STG: Translating Evidence into Practice

ANNEX 2. SUMMARY OF THE EVALUATION PROTOCOL

Assessment of the Impact of the New Standard Treatment Guidelines on Outpatient Prescribing Practices in Public Health Facilities of Namibia: A Medicine Use Evaluation

Background

The aim of this assessment is to determine the impact of the new comprehensive STGs on the quality of outpatient prescribing practices in Namibia. Though STGs have been shown to improve the quality of health care and improve health system outcomes, inappropriate prescribing of medicines such as over prescribing of antibiotics, polypharmacy, and noncompliance to STGs are still major medicine use problems in Namibia.

Methodology

The assessment will consist of a retrospective review of 1200 outpatient prescriptions for consistency with the STGs and prescriber interviews both at pre- and post-implementation. Information for ten selected conditions including oral candidiasis, acute diarrhoea without blood, diabetes, hypertension, vaginal discharge, urethral discharge, common cold, community-acquired pneumonia, and asthma will be reviewed per facility; 14 public health facilities from 6 geographical regions of Namibia were purposively selected for assessment. Prescribing indicators and treatment according to STGs were measured before and after the interventions. Data will be collected by a team coordinated by a regional pharmacist and pharmacy staff.

Interventions

Following the pre-intervention assessment, an interactive training on the new STGs and use of aids or posters will be launched.

Outcome measures

The impact of the intervention will be assessed over a one-year period. The main outcome measurements will be improved medicine prescribing indicators, compliance to treatment guidelines, and factors associated with the use of STGs.

302 ***Reproduced from:*** SPS Program. 2011. *Dissemination and Implementation of the Namibia Standard Treatment Guidelines: Translating Evidence into Practice.* Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

APPENDIX F (continued)

ANNEX 3. SURVEY TOOL

Assessment of the Impact of the Standard Treatment Guidelines on Outpatient Prescribing Practices in Public Health Facilities of Namibia: A Medicine Use Evaluation

Instructions: Please Tick or fill the spaces below

101) Serial #: ----------	**102) Date of Data Collection:**	**103) Date of Rx:**	**104) Data Collector Initials**

Health Facility details **105) Type:** (1) ☐Hospital (2) ☐Health Center (3) ☐Clinic	**106) Facility name:** **108) Region:** (1) ☐Erongo (3) ☐Khomas (5) ☐ Ohangwena (2) ☐Karas (4) ☐Kunene (6) ☐Omaheke	**107) Ownership:** (1) ☐Government (2) ☐ FBO

109) Prescriber's Rank/Position	(1) ☐Intern doctor (2) ☐Medical Officer (3) ☐Specialist (specify)	(4) ☐ Nurse (specify if indicated) a. ☐Registered Nurse/midwife b. ☐Enrolled Nurse (5) ☐Other_____

Patient's Details **110) Gender:** (1) ☐Male (2) ☐Female	**111) Date of birth** *(dd-mm-yyyy)*: _____/_____/_____	**112) Age:** *(years or months)* **113)** ☐**Adult** ☐**Child**

114) Diagnosis: *(Tick where applicable, choose records with one of the below mentioned indications from 1 to 10. Indicate any other concurrent diagnosis under 116)*	**115) Diagnosis recorded on RX:** (1) ☐ YES (2) ☐ NO	**117) Severity**	(1) ☐mild (2) ☐Moderate (3) ☐Severe (4) ☐can't be evaluated

(1) ☐Asthma	**(6) ☐Hypertension**	**118) List Presenting Complaints**
(2) ☐Comm. Acquired Pneumonia	**(7) ☐ Intestinal helminthiasis**	
(3) ☐Common Cold	**(8) ☐Oral Candidiasis**	
(4) ☐Diabetes Mellitus II	**(9) ☐Urethral Discharge**	
(5) ☐ Diarrhoea without Blood	**(10) ☐Vaginal Discharge**	
116) Other diagnosis *(list below)*		**119) Diagnosis complies with STG recommendations (for official use only)** (1) ☐ YES (2) ☐ NO

120) Management of the Condition							**121) Treatment complies with STG** *(if NO, indicate aspect that is not compliant with STG)* – For official use only.					
	(1) Treatment Prescribed *(write exactly as the prescriber has written, including abbreviations)- please include non-pharmacological interventions at the end also*	**(2) Generic Name used Y/N**	**(3) Dose & frequency**	**(4) Duration of treatment**	**Antibiotic Y/N**	**Injection Y/N**	☐**Yes**	☐ **No**				
								1	**2**	**3**	**4**	**All**
a												
b												

APPENDIX F (continued)

Dissemination and Implementation of the Namibia STG: Translating Evidence into Practice

c												
d												
e												
f												
g												
h												
i												
j												
k												
l												

120) Patient Referred for Specialized Care: (1) □ YES (2) □ NO

Any other comments or observations regarding treatment of the condition on this prescription

_____

_____

_____

_____

_____

APPENDIX G.

Motion to amend the STG/EML[303]

Return to: Ministry of Health
Department: Pharmaceutical Services, PO Box 5, Mbabane

Motion To Amend The STG/EML

SECTION 1: TO BE COMPLETED BY APPLICANT (The applicant can be prescriber, dispenser, Pharmacy Therapeutic Committee, secretariat)	
Name:	Designation:
Name of facility:	Region:
Date of submission:	Signature:
Request for changes to (tick appropriate) ☐ Standard Treatment Guideline ☐ Essential Medicines List	
Has the motion been presented, reviewed, and approved by one of the following (kindly attach minutes of meeting)? ☐ Hospital/Institution Pharmacy Therapeutic Committee ☐ Regional Pharmacy Therapeutic Committee	

PART A: AMENDMENTS TO THE STG Note: If the proposed change involves medicines used for the management of the condition, please also complete PART B
Indicate the condition to be changed Condition:
Request for the following changes to be made on the STG:
Reasons for the request:
Evidence:

303 *Reproduced from:* The Government of the Kingdom of Swaziland Ministry of Health, US PEPFAR, USAID, and SPS. 2012. *Standard Treatment Guidelines and Essential Medicines List of Common Medical Conditions in the Kingdom of Swaziland:* 1st edition.

APPENDIX G (continued)

PART B: AMENDMENTS TO THE EML
Type of Request (tick appropriate): ☐ Deletion of listed medicine ☐ Addition of a new medicine ☐ Replacement of a listed medicine ☐ Reclassification of a listed medicine
For replacements, please complete below: Replacement of *(generic name, strength, and dosage form)*: Replacement with *(generic name, strength, and dosage form):*
F**or reclassifications,** please complete below: Reclassification of *(generic name, strength, and dosage form)*: From this class: To this class:
For additions please complete below: Addition of *(generic name, strength, and dosage form)*:
For deletions please complete below: Deletion of *(generic name, strength, and dosage form)*:
Reasons for request:
Evidence:

APPENDIX G (continued)

SECTION 2: TO BE COMPLETED BY CMS
Estimated cost of proposed medicine: E _____ per _____ Current cost of similar acting medicine(s) on the EML 1. Name, strength, dosage form: E _____ per _____

SECTION 3: TO BE COMPLETED BY STANDARD TREATMENT GUIDELINES & ESSENTIAL MEDICINES LIST COMMITTEE	
For requested changes to STGs ☐ Accept proposed changes to the STG ☐ Deny/Reject proposed changes to the STG Reasons for decision:	
For requested changes to EML ☐ Accept proposed changes to the EML ☐ Deny/Reject proposed changes to the EML Reasons for decision:	
Signature of STG/EML Secretariat:	Date:
Signature of STG/EML Chairperson:	Date:

Systems for Improved Access to Pharmaceuticals and Services
Management Sciences for Health
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