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Health care technology management



Health care technology policy formulation and implementation

*World Health Organization
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PREFACE

Technological changes in all areas including medical technologies have proceeded, and will continue to proceed, at a rapid pace. Medical technologies usually are associated with diagnostic or therapeutic devices or procedures. With the continuing technology advances, there is a continuously growing gap between developing countries and the rich countries with “established market economies” in appropriate technology use. It is surprising that most developing countries have neither established an efficient national system for appropriate health technology transfer nor established a mechanism for systematic evaluation of new health technologies and their suitability to local circumstances and conditions in the light of available national resources, infrastructure, knowledge and skills. Such a system and a mechanism represent an essential ingredient for establishing and maintaining up-to-date, cost effective and high quality appropriate health care services. Because of a lack of such a system and mechanism, many developing countries waste precious resources by introducing technologies and purchasing medical devices that are not appropriate to local conditions, substandard, obsolete, improperly reconditioned or have reduced life expectancies.

Many developing countries do not have a comprehensive national health care technology policy that maps out national vision and strategy for rational introduction and application of technology. What is appropriate for one country may not be appropriate for another owing to different needs, policies, priorities and capabilities in health care. In order to make the transferred technology viable, cost-effective and sustainable, there is an urgent need for each country to formulate and implement policies consistent with that country’s needs, priorities, resources and capabilities. This document proposes a policy to serve as a stem policy and to provide a framework for the operational and technical policies still to be developed by individual countries.

This is the third in a series of four books. The first and second volumes introduce the idea of health technology management and what a health technology management policy might look like, and the development of a regional strategy for health technology management. The volume following this outlines guidelines for conducting a country situation analysis for health technology management purposes. This volume looks at national policy formulation and implementation. It identifies the important players in the process and outlines the procedures to be followed and

bodies to be set up as the policy is developed and implemented. The importance of public participation in the process is emphasized. Finally, convenient checklists are provided, breaking down the policy formulation and implementation process.

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The authors are grateful to the WHO Regional Office for the Eastern Mediterranean for taking the lead by inviting them to write this publication and the three other associated publications, which hopefully will form a part of an interregional approach aimed at producing a complementary set of guidelines and documents to assist countries in health care technology policy formulation and implementation.

1. INTRODUCTION

1.1 Rationale

The word “policy” has several connotations. Throughout this document, it is taken to mean an orientation, a guide for action based on a set of guiding principles or values, aimed at influencing and determining long-term decisions and actions.

A health care technology policy facilitates and supports integrated and rational needs assessment, acquisition, distribution, use and management of technological and associated infrastructure resources. It also provides a vision and clear guidance for all health workers.

The intentions of all international collaborating agencies are to help a host country on development of capacity or facilities. Successful development projects depend to an extent on critical factors such as political will and financial support. However, if the host country does not have a clear national policy, the collaborating agencies can only do what they think best for the country. Since different agencies may think in different ways, this may lead to scattered, uncoordinated efforts. On the other hand, a host country with a clear national policy can take charge to guide all national and international development efforts toward achieving national goals.

The situation in these countries can be likened to a ship: given a captain and crew (political will, operating support) and fuel (financial support), the ship can move along. If the captain has no clear direction in which to steer the ship, however, the ship could be moving around in circles in the middle of the ocean. A national strategy is like giving the captain a direction to steer the ship toward a productive destination.

It should be recognized that because circumstances change, policies are living documents requiring periodic review and update. Finally, health care technology policy does not occur in a vacuum, but is situated within a context provided by broader policies, such as health policy and development policy.

This document logically follows the *Country situation analysis* (part 4 of this series) and the *Health care technology policy framework* (part 1). The formulation and implementation phases of the policy process are separated, since they address different issues within the process.

1.2 Background

Health care technology is an important component of health care delivery and its impact on health outcomes. Technological advances have had a profound impact

and will continue to greatly influence health care delivery. For technology interventions to be cost-effective, however, appropriate management of all available resources, including human resources, is required.

The 1978 Alma-Ata Declaration included clear support for appropriate technology that was accessible and affordable. National promotion of primary health care with the assistance of nongovernmental organizations, both international and national, has caused the need for appropriate infrastructure as well as medical devices and associated managerial elements to increase dramatically.

The need to ensure the smooth running of these managerial elements, has led to health care technology-related issues being neglected, partly because of donor activities focusing on health care services without addressing the limitation of absorbing capacities and resources available in most developing countries.

Health care technology management capacities—including skilled and adequate human resources—are crucial for the achievement of adequate health care delivery within the referral system.

1.3 Objectives

These guidelines are intended to strengthen the capacity of countries of the Region entering the process of setting up a health care technology policy. They should also promote appreciation of the benefit of implementation of such an instrument and its incorporation in a national health policy framework. However it should be noted that the basis of any policy is a body of values, norms, standards and principles which guide decisions, strategies and actions.

The objectives of these guidelines focus on the following elements.

- Target audience: health ministers, health care planners, managers and administrators, other health professionals.
- Aim: to guide formulation and implementation of policies on health care technology.
- Scope: health care technology as defined in volume 1 of this series, excluding drugs/pharmaceuticals since these are covered by parallel policy initiatives. A different approach for the physical infrastructure component could be used in some countries because of administrative preferences and regulations. However, a consistent and coordinated approach for all technology elements is essential for the success of the formulation and implementation phases of the policy process.

1.4 Content

This brief guide outlines the policy process from policy formulation to policy implementation. The entire process is based on the principles of continuous quality improvements, a participatory approach and shared responsibility among all stakeholders

In policy formulation, a document is drafted and then presented to all stakeholders for comment, input and problem identification. The draft document is then revised and, if necessary, redistributed for discussion. This process may be repeated until a mutually acceptable proposed policy is reached among the majority of the stakeholders.

In policy implementation, the process is systematically planned, executed and monitored to ensure that actions are on track according to the master plan. Periodic evaluation is conducted to see if policy objectives have been achieved. Evaluation includes the experience of and comments from stakeholders. Any new problems created by the policy implementation will be noted and used as input for later amendment of policy elements.

The consultation and participation of all stakeholders in the policy process is essential to a good policy document and subsequent successful implementation. Stakeholders are individuals, groups or organizations directly or indirectly involved with or affected in some way by health care technology. This includes staff at all levels of the health care system, within the government as well as within private companies and nongovernmental organizations.

Transparency of the policy process is an important contributing factor for successful formulation and implementation. The participation of all stakeholders ensures transparency of the policy process; it also provides opportunities for invaluable input. The perspective and input of all stakeholders must be sought in order to make the policy practical and to promote shared responsibility.

It should be emphasized that with rapid progress in the health care technology arena, policies should remain dynamic. Periodic review with possible amendments should be made to meet changing needs.

2. POLICY FORMULATION PROCESS

Formulation or drafting of a policy should commence only after a country situation analysis has been conducted and its results analysed and disseminated. Recommendations for change should be grafted on the first book in this series, *Health care technology policy framework*. What follows is a description of the common steps in the policy formulation process, assuming that country situation analysis and recommendations are available.

Obtaining a mandate

The essential first step in the process is the receipt of a mandate from the highest possible government authority. Then the task of policy drafting should be assigned to a steering committee and task forces.

Steering committee and task forces

The steering committee is set up and decides on tasks to be performed; it oversees the process. The number of committee members can vary, depending on local situation. Membership should include all senior administrators whose departments are affected by health care technology management issues. The steering committee should appoint task forces with responsibility for different health care technology elements. Terms of reference should be established for each task force since these will assist in identifying activities necessary for the achievement of overall objectives. The coordination and facilitation of the work of the task forces is an important responsibility of the steering committee.

The task force(s) will undertake the bulk of the work. Task force members are mostly experts or knowledgeable people on the task to be performed. The number should be between five and seven members. The chairman should be a senior person in the ministry of health with authority to take quick action to facilitate the work of the task force.

Drafting of the policy document

Before drafting a policy, it is essential to identify what problems exist and the proposed solutions. This information should be available in the country situation analysis and policy framework. The task force and stakeholders consultation sessions during the country analysis stage should obtain the proposed solution from

observations. A draft policy integrates and summarizes all information, and proposes solutions in a clear and logical manner.

The steering committee should decide whether it is desirable to involve other stakeholders at this stage to draft the policy. In general, it would be more rapid to have the task force make the first draft and then revise it with the stakeholders.

A policy document should have the following content:

- purpose or objective
- background (history—what leads to the need for this policy)
- scope (what the policy covers or does not cover)
- definitions (if necessary)
- policy statement(s)
- policy requirements/responsibilities/procedures.

Identification of stakeholders

Stakeholders are individuals, groups or organizations directly or indirectly involved with or affected in some way by health technology. For example, stakeholders can be directly or indirectly involved with health care technology provision, assessment, acquisition and use. Moreover, the beneficiary of health care, the patient, is an important stakeholder. In many countries, hospitals have patient representatives. National representatives of patients or the public can be drawn from nongovernmental organizations.

Core stakeholders include health planners, decision-makers, managers and administrators, health care and technical professionals, facility planners and architects, technology vendors/suppliers, “third-party” service providers such as public sector health care organizations, other government ministries (finance, public works, education, and so on), donor and technical aid agencies, other nongovernmental organizations, professional associations and standards organizations.

It is advisable to have an extensive and transparent stakeholder identification process to ensure the participation of all stakeholders:

Sensitization of stakeholders

It is important to inform the stakeholders about the intent of the government to establish policy and invite them to the consultation session.

This step is of great importance since the exclusion of key stakeholders could result in a flawed process with suboptimal output and outcomes, as well as rejection of the document at a later stage. Additionally, valuable experience and knowledge could be omitted from the policy drafting and refinement process.

Before conducting consultation sessions with the stakeholders, the draft policy (with comprehensive objectives and background explanation) should be sent to all stakeholders well in advance. This allows the stakeholders sufficient time to read and understand the issues and think of possible problems created by the proposed policy.

Public consultations

The purposes of consultation sessions are:

- to ensure transparency in the policy establishment process
- to allow stakeholders to identify issues or problems that may arise as a result of the proposed policy
- to seek input from stakeholders
- to promote common understanding and shared responsibility among the stakeholders.

These increase the likelihood of success in implementing the policy.

During the consultation session, the draft policy document will be presented to the stakeholders for comments and suggestions. Issues and problems will be identified. Some suggestion for holding consultation sessions are given below.

- To be effective, consultation must be based on openness, trust, integrity, mutual respect for the legitimacy and point of view of all participants, and transparency of purpose and process.
- The outcome of consultation should not be predetermined. Consultation should not be used to communicate decisions already taken.
- The initiative to consult may come from inside government or outside—each should respond as constructively as it can.
- Whenever possible, consultation should involve all parties who can contribute to or are affected by the outcome of consultation.
- Participants in a consultation should have clear mandates. Participants should have influence over the outcome and a stake in implementing any agreed action.
- Some participants may not have the resources or expertise required for participation. Thus, financial assistance or other support may be needed to ensure their representation.

- Effective consultation is about partnership and implies shared responsibility, commitment and a clear mutual understanding of the issues and objectives. Additionally, the purpose and expectations of all parties should be considered; the agenda and process should be negotiable, and any constraints should be established from the outset.
- Participants should have a realistic idea of how much time a consultation is likely to take and plan for this in designing the process.
- All participants must have timely access to relevant and easily understandable information and commit themselves to sharing information.
- Effective consultation will not always lead to agreement; however, it should lead to a better understanding of each other's positions.
- Where consultation does lead to agreement, participants should hold themselves accountable for implementing the resulting recommendations whenever possible.
- Effective consultation requires follow-through. Participants are entitled to know what use is made of the views and information they provide. Participants should also be made aware of the impact their ideas and involvement has on government decision-making.

Resolution of problems

The identification of issues by stakeholders will point to problem areas that must be addressed, and further investigation and exploration may be needed to discover the underlying causes. This may again require the active participation of most or all of the stakeholders. Activities related to each problem should be defined and the assignment of responsibilities for various activities should be discussed at this point. Appropriate facilitation within this step is of crucial importance. It should include relevant demographic, socioeconomic, epidemiological and geographical considerations.

Revision of policy document

Any issue and problem arising during the consultation session should be addressed and resolved in order to arrive at a mutually acceptable solution by all stakeholders. These resolutions should then be used to amend the draft policy.

Countrywide dissemination and gathering of input and feedback

Often only a limited number of participants can attend the formal consultation meetings. To ensure transparency and subsequent stakeholder acceptance, the

inclusion of all referral levels within the public health care system is essential. District health workers and administrators (peripheral stakeholders) should also be given the opportunity to comment, in order to ensure compliance with their general “environmental” situations or conditions prevalent on site. The steering committee and task forces should ensure that this step is carefully considered and executed if necessary.

A low-cost way for a countrywide dissemination of the draft policy would be to circulate the proposed policy together with a questionnaire for consultation.

This activity requires a defined timetable and allocation of resources since feedback might not be available from all involved without support from the relevant task forces. Intensive discussions (in person, or via fax or telephone) with countrywide stakeholders will have to take place to ensure the quality of feedback.

Collection and integration of feedback

Appropriate logistics need to be in place for the successful completion of this step. The value of the comments received at this stage cannot be emphasized enough. The quality of the final document as well as the successful implementation of the policy depend highly on the outcome of this step.

A proper analysis should be made of the feedback received, which should ideally represent a cross-section of experiences and skills available in a country, and decisions taken on how these will be incorporated into the final policy document. Again it needs to be stressed that sociocultural, economic and topographic issues must be considered.

Finalization of draft policy

The final policy document should harmonize recommendations from across the country and therefore represents a consensus of a majority of the stakeholders.

Depending on the amount of amendments made to the draft as a result of the countrywide feedback, it may be necessary to repeat the previous two steps relating to feedback to assess the potential impact on the various parts of the country. Stakeholder consultation should be repeated as often as is necessary until a satisfactory final policy document is produced.

Ministerial approval of policy

It is essential that the final document be approved at ministry of health level. The ministry will ensure that the proposed policy does not cause problems for other government organizations. The incorporation of the proposed policy into overall health policy may be necessary. However, lengthy administrative processes (which could include amendment of existing health policy) may be an obstacle to implementation and the identification of alternative implementation steps should be encouraged; for example, the approval of the proposed policy on a temporary basis could be considered.

At this stage it is assumed that existing task forces will be dissolved, while the steering committee would remain as an important consultative board embracing experiences and knowledge of health care technology within the public and private health systems.

Legal approval of policy

This step is optional. In many countries, the introduction of policy requires the approval of parliamentary or other legislative bodies. A policy provides a direction or course of action. Policy elements may or may not require legislation depending on a country's social and governing systems. If legislation is desired, the policy element is transformed into a regulation. An advantage of a regulation is that it has legal power. On the other hand, when an amendment is needed, it may require a lengthy and involved procedure.

3. IMPLEMENTATION PROCESS

3.1 Identification of implementation requirements

After the appropriate national authority has approved the final policy document, and policy implementation has been given the go-ahead, the health care technology steering committee and implementation task force(s) should be activated. Members of the task forces for the policy formulation process can be reappointed for implementation if their usefulness and competence have been demonstrated. These people have the added advantage that they are already familiar with the policy issues and the environment.

The initial task of the steering committee and task force(s) will be to ensure that all resources and support required for successful policy implementation are available

when needed, in accordance with established project-management principles and practices.

3.2 Establishment of a master plan

Since the implementation process may take a number of years, the steering committee and task force(s) should establish a master plan using an outline similar to the following:

Action	Task manager	Team or resource	Time frame								Remark
Facilities											
Equipment											
Human resources											
Training											
Budget											
Etc.											

3.3 Development of project management and procedure manuals

The next task of the task force will be to develop project management and detailed procedure manuals. These manuals will define the organizational structure and specify responsibility for execution of specified tasks and will be distributed to

all personnel involved in the policy implementation process. Details of each task to be completed at top level will also be described in the procedure manuals.

3.4 Formalization of performance indicators and measures

At the same time, indicators and measures for successful policy implementation (or completion of key tasks) should be identified. These are essential prerequisites for the monitoring and evaluation steps described below.

Training of staff

To ensure smooth operation of the implementation process, training of staff is essential. Based on the project management and procedure manuals, training workshops or seminars must be conducted to familiarize relevant personnel with the new operational systems and procedures. Due attention should be given to selection of candidates for training in order to ensure quality of outputs and outcomes. Given the length of the implementation process, training may have to be repeated, particularly if key personnel leave the health system or are redeployed to positions which prevent them from fulfilling their project responsibilities

Implementation

Once training has been completed the actual implementation phase can commence. Again it is important that all relevant personnel, at every level of the health system, are included in the implementation process. Assignment of responsibilities and transparent personnel resource management by the authorities will facilitate the achievement of objectives.

Monitoring

It will be necessary to monitor the implementation process in order to ensure that actions are on track according to the master plan. Decentralized monitoring at each level using "internal" resources on a regular basis at fairly short intervals should be sufficient to allow for continuous support of the process and, if necessary, corrective measures in good time to ensure success of process. However, where appropriate and necessary, "external" assistance can be used.

Evaluation

At an appropriate stage after the implementation of the policy, its effectiveness in terms of achieving policy objectives will have to be evaluated. This will be based on formalized outcome indicators and measures. An evaluation plan should identify:

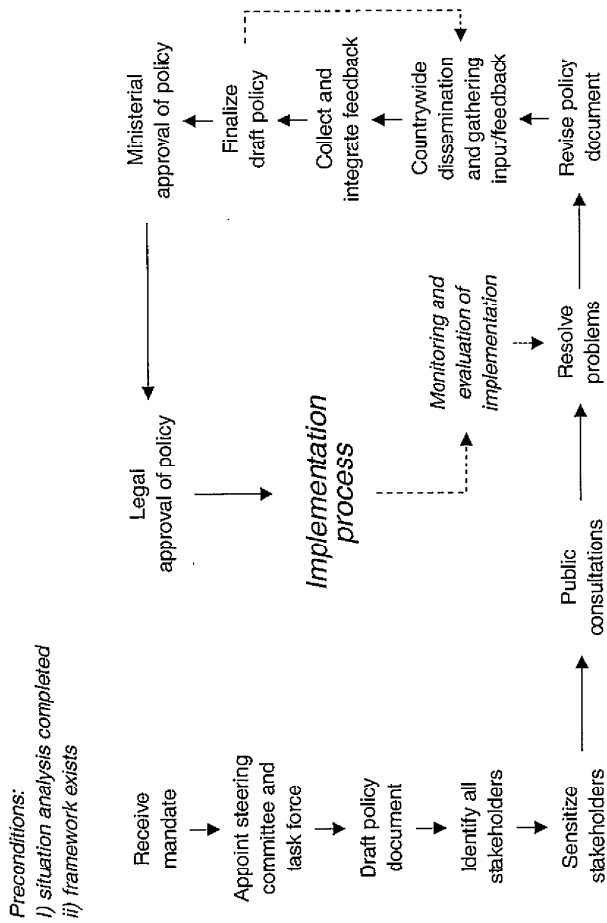
- the outcomes expected from the implementation process on both short-term and long-term bases
- how the relevant data relative will be collected
- when the data will be evaluated.

The evaluation task force will identify new problems created by the implementation process and recycle those through the problem solving process if necessary (step 7 of the policy formulation process). This reflects the dynamic nature of policy establishment.

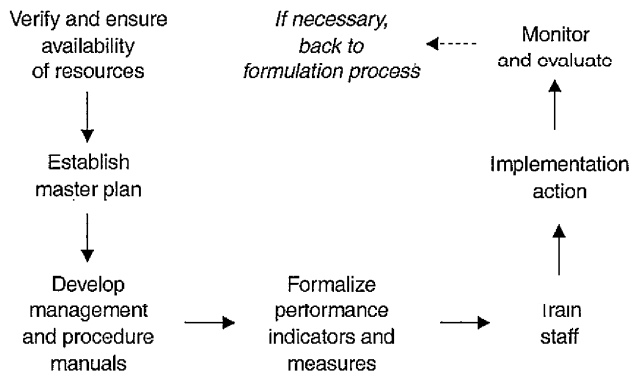
4. RECOMMENDATIONS

- Countries should establish national policies in order to have integrated and systematic approaches for the optimum use and management of health care technology.
- Countries should ensure that the national policies are clearly understood by all health workers and other relevant people, including those in the private sector, in order to guide their work.
- Countries should use national policies to steer the efforts from different international collaborating agencies towards achieving the national goals.
- Countries must use their policies as instruments to comply not only with today's challenges but also for future demands and developments in health care technology for the benefit of health systems.

Annex 1 Policy formulation process



Annex 2 Policy implementation process



Annex 3 Policy formulation checklist

Phase	Step	Question/action	Responsible party
Prerequisites	Situation study	Has the situation analysis been done?	Ministry of health
		Are health care issues prioritized? Does a health care technology management infrastructure exist? Has a technology package been identified?	
Preparation	Obtaining a mandate	Has a <i>mandate</i> been granted by the relevant ministry to develop the policy?	Ministry of health Steering committee
		Has the scope of the policy been defined?	
First draft	Steering committee and task forces	Are personnel available for the policy development process?	Task force(s)
		Have leaders of groups sufficient power to effect action?	
		Are operational procedures developed?	
First draft	Drafting the policy	Should other stakeholders be involved?	Task force(s)
		Are plain words used for easy understanding?	

Annex 3

Policy formulation checklist *continued*

Phase	Step	Question/action	Responsible party
Stakeholder participation	Identification of stakeholders	<p>What will the level of cooperation be?</p> <p>What are the responsibilities of the public and private sector?</p> <p>What is the methodology of cooperation?</p>	Steering committee Task force(s) Stakeholders
	Sensitization of stakeholders	<p>Has the intent of the government been clearly communicated to stakeholders?</p> <p>Has sufficient background information been given to stakeholders?</p> <p>Do stakeholders understand clearly the policy process?</p>	
	Public consultation	<p>Has sufficient time been given to stakeholders for preparation for consultation?</p> <p>Has sufficient self-interest been aroused among the stakeholders in order to encourage their participation and shared responsibility?</p> <p>Is the agenda clear to all stakeholders? The sessions well organized?</p> <p>What will the level of cooperation be?</p> <p>What are the responsibilities of the public and private sector?</p> <p>Are the principles of good public consultation (see text) applied?</p>	

Annex 3 Policy formulation checklist *concluded*

Phase	Step	Question/action	Responsible party
Stakeholder participation	Problem resolution	What are the contributing factors to problems? Has the government listened with an open mind? What are the constraints and potential methods of cooperation? Explore innovative ideas. Make creative thinking deliberate.	
		Are all problems raised by stakeholders addressed?	
Revised draft	Revising policy document		
Countrywide dissemination	Countrywide dissemination	What is the best affordable way to reach all stakeholders country-wide? Has a mechanism been provided for feedback?	
		Are sufficient resources allowed for collection of feedback? Is a practical system in place to integrate the feedback and draw useful conclusion?	
Finalized draft	Finalizing the draft policy	Are all issues raised by country-wide feedback addressed? Should the revised draft be re-distributed for further feedback?	Steering committee task force(s)
		Should other agencies be consulted?	Minister
Approval of policy	Ministerial approval		
		Legal approval (optional)	Minister Legislative authority
		What are the advantages and disadvantages of legislating the policy? How feasible is it when the policy needs amendments?	

Annex 4

Policy implementation checklist

Phase	Step	Question/action	Responsible party
Prerequisite Preparation	Approval of policy	Has policy been approved?	Ministry of health
	Activate steering committee and task forces	Should the same committee for country situation analysis be reactivated? Have leaders of task forces good managers? Are operational procedures developed?	
	Identify implementation requirements	Is personnel available for the implementation process? Are financial and material resources available?	Steering committee/task forces
Master plan	Intragovernmental cooperation	Has possible policy impact to other government agencies been considered? Have potentials for cooperation with other agencies been explored? Have alliances with other agencies been developed?	
	Establish master plan	Is the master plan realistic? Has the plan been reviewed by other agencies that are implicated?	Task forces

Annex 4 Policy implementation checklist *concluded*

Phase	Step	Question/action	Responsible party
Document development	Develop project management and procedural manuals	Do the manuals cover all project elements? Have plain words been used for easy understanding?	Task forces
	Formalize performance indicators and measures	Do the indicators really reflect the quality of the performance? How reliable are the measures?	
Execution	Training of staff	How should the trainer be trained? Should training be conducted in classrooms or in the shop? Should external trainers be used?	Steering committee/ task forces/ stakeholders
		Has training been sufficient? What is the staff morale? Are there facilitators?	
Monitoring	Monitoring	Are programmes on time according to the master plan? Are actions on track according to the management manuals? Are workers familiar with the correct operating procedures?	
		Should external evaluators be engaged? Are comments sought from all stakeholders? Should policy elements be reviewed and modified?	
Evaluation	Evaluation		Ministry of health Steering committee/ stakeholders

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