

The top half of the page features a world map in a light red color against a darker red background. Below the map, there is a horizontal band with a diagonal hatched pattern. Inside this band, there is a photograph of medical equipment, including a wheelchair and a gurney, in a clinical setting.

THE PRECIS

QUALITY REFERENCE
FRAMEWORK FOR MEDICAL
EQUIPMENT SUPPORT PROJECTS
IN DEVELOPING COUNTRIES





FOREWORD

The considerable amount of dysfunctional medical devices to be found in health facilities in developing countries raises the question of the responsibility of developed countries, particularly regarding the efficacy of the aid they provide to equipment support projects. Indeed, according to figures available from the World Health Organisation (WHO) only 10% to 30% of medical devices donated to developing countries is operational in its new environment, although in some of these countries 80% of all their equipment comes from donations¹. A lot of medical devices are supplied incomplete, without manuals, have not been serviced and sometimes have already broken down. Others are sent without taking into account the real needs of the recipients' health facilities, of the advice of local authorities or the local environment. Some of these failures seem to be due to a lack of methodology by the international aid organisations in the management of medical equipment support projects, which can often be very complicated.

To improve procedures used by project holders sending medical devices to developing countries, Humatem, an organisation specialising in medical equipment support and Groupe URD, an organisation involved in research on the quality of international aid projects, decided to produce a series of methods and tools dedicated to medical equipment support projects built around a quality reference framework: PRECIS.

This series was devised in the context of an action plan² financed by the European Union (EuropeAid) as well as the following French local authorities: the Rhone-Alpes Region, the Haute-Savoie General Council and the municipality of Les Houches. It is also part of the World Initiative for Health Technologies launched by WHO following resolution WHA60.29 of May 2007 on health technologies, which aims to encourage the creation of policies and tools in this domain.

Finally, this series is in conformity with the recommendations regarding the donation of medical equipment published by WHO³.

The working group called *Medical Devices in the Actions of International Cooperation* was involved in the development of these methods and tools, which ensures that they are based on a common consensus. This working group has been managed by Humatem since 2003, and comprises international aid workers, development education organisations and health professionals.

¹ WHO (2011) « Introduction » in *Medical devices donations: considerations for solicitation and provision*, WHO medical devices technical series, Geneva: WHO, p. 10.

² Programme EuropeAid DCI-NSA/2009/205-811 "Strengthening cooperation tools and structuring the dialogue between donation stakeholders in the provision of medical equipment - To improve practices in medical equipment support projects for healthcare facilities in developing countries".

³ WHO (2000) *Guidelines for health care equipment donations*, Geneva: WHO; WHO (2011) *Medical device donations: considerations for solicitation and provision*, Geneva: WHO.

INTRODUCTION

The quality reference entitled PRECIS was specially developed for medical equipment support projects.

It was called PRECIS because each of the six letters comprised in its title correspond specifically to the required quality criterion for medical equipment support projects.

P for Pertinent

R for Rigour

E for Effective

C for Capability

I for Impact

S for Synergy

These six criteria, of equal importance and which should not be viewed chronologically, portray the values that international solidarity stakeholders represent and share, and which they are committed to ensuring throughout their projects. They also apply when supporting partner healthcare facilities and the communities benefitting from the healthcare.

>>> What need is there for a quality reference?

The first step for any plan to improve quality is to agree on a precise definition of what is expected and to commit collectively to shared values.

It is important that the various people involved in a medical equipment support project are aware of the quality criteria and apply them in order to ensure a common vision and a sense of sharing. Without them, over time, tensions can arise and harm the quality of the project.

>>> PRECIS, the quality reference : a valuable tool throughout medical equipment support project

When making an initial diagnosis, the PRECIS quality reference framework provides a tool for analyzing different situations and decision-making through systematically asking a number of questions, including: (Have the needs been clearly demonstrated? Will we be able to carry out this project? Do we know the other stakeholders so that we can work together?).

When the partnership is being confirmed and the monitoring tools put in place, this framework will act as a reminder of best practices and will help define the commitments of the project holders and the partner health facility.

When the final evaluation is being carried out, each criterion will be examined (Was the project pertinent? Did it meet the needs? Was it effective?) in order to draw lessons from the experience and improve the action or the practical management details of future projects.

>>> How to adopt and use the PRECIS quality reference?

- Organise a discussion group where the six quality reference criteria are reviewed.
- Renew this discussion when new colleagues arrive.
- Display the **PRECIS** quality reference in the organisation's offices.
- Share it with the partner health facility, or even annex it to the project partnership implementation agreement.
- Send it to the equipment donor...

THE PRECIS CRITERIA

SIX WORDS TO DEFINE THE QUALITY OF A MEDICAL EQUIPMENT SUPPORT PROJECT

THE PRECIS

PERTINENT

The medical equipment support project corresponds to clearly demonstrated needs in terms of the capacity and options on site.

RIGOUR

It is implemented in a methodical and structured manner.

EFFECTIVE

It is effective and attains the defined short and long-term aims.

CAPABILITY

The project holder has the resources, the expertise and the appropriate infrastructure to manage a project.

IMPACT

The project is seeking to have a positive impact over and above providing medical equipment support. It will avoid and limit the risk of a negative impact.

SYNERGY

It blends into its environment.

THE PRECIS QUALITY REFERENCE FRAMEWORK

P

ERTINENT

>>> The medical equipment support project corresponds to clearly demonstrated needs in terms of the capacity and options on site

It must respond to a **request for medical equipment** from the partner health facility (and not to an offer of available equipment) and its relevance to the project must be honed by discussions with the project holder.

The request must be subjected to **additional analysis** (details of the health facility and the request, prior analysis of the needs, triangulation of information, etc.) to **clarify and confirm the reality of the need for medical equipment** to which the partner wishes to respond. It is also necessary to understand the origin of the need (for example, to carry out a specific medical act, or to look after a particular community) and understand the context of the request (the current human and financial resources, the condition of the facilities, the presence of a biomedical maintenance service, etc.).

R

IGOUR

>>> The medical equipment support project is implemented in a methodical and structured manner

It is a **long-lasting** project.

The project follows a **structured process** and is flexible, so as to manage the quality of each stage (preliminary assessment of the situation, mutual commitment, planning, implementation, monitoring and evaluation).

It is conducted in a **spirit of partnership and shared responsibility** at every stage.

The project is **documented** (meeting notes, project document, partnership agreement, etc.) so that it is monitored, the process is continuous, it is traceable and can be evaluated and lessons learned from it.

E

FFECTIVE

>>> The medical equipment support project is effective and attains the defined short and long-term aims

It is **realistic** (appropriate for the resources available at the partner health facility in terms of timing, financing, equipment, medical, paramedical and biomedical personnel, etc.) and takes into account the **constraints** of the local context and the health facility.

The **aims of the medical equipment support** are clearly defined and confirmed in a partnership agreement stipulating the duties of both parties, in addition to making available the medical equipment.

The **financial viability and the sustainability** of operating the medical equipment regarding the procurement of consumables, accessories, maintenance kits and spare parts, are examined in light of the **financial stability** of the healthcare facility (running costs/income).

All of the **actions necessary** to achieve the aims have been anticipated and are then implemented (training of users and technical personnel, implementation of preventive and corrective maintenance, relationship with other programmes/players, etc.).

Monitoring and evaluation processes are in place, which implies previous creation of tools and monitoring indicators for operating the medical equipment.

CAPABILITY

>>> The project holder has the resources, the expertise and the appropriate infrastructure to manage a project

The project holder is a **legal entity** ensuring he can manage a project (registered charity, hospital, county council, etc.).

The project adheres to the principles of solidarity: non-profit, equitable, neutral, respect for human rights, etc.

The project holder has the means of calling upon and investing **the necessary resources** for the implementation of the project (human and financial resources, diversified expertise, network of partners, etc.).

The project holder operations are **appropriate** (transparent management, rigorous accounting, effective communication, capable of organising logistics, etc.).

IMPACT

>>> The project is seeking to have a **POSITIVE impact over and above providing medical equipment support**

The project is aimed at **improving healthcare** by using the medical equipment requested and thus improving the offer of healthcare and the community's overall health.

It will investigate optimal **local opportunities** (existence of a local consumer market, accessories, maintenance kits and spare parts, manufacture of hospital furniture, etc.).

Monitoring and evaluation of the impact are ensured by predefined tools and indicators.

>>> The project will avoid and limit of a **NEGATIVE impact**

The risk of a **negative impact** regarding new medical equipment are identified and anticipated (sending it to the wrong destination or failing to understand the principal use of the equipment, hijacking the equipment out of self-interest; side effects on the safety of patients and their carers, or on the environment; financial instability or unreliability of the partner health facility, etc.).

Corrective measures and/or limiting the risk of a negative impact are integral to the project (maintenance policy, mechanisms for group control of the use of the medical equipment, specific training on the risks relating to the use of the equipment, system of waste disposal, etc.).

Monitoring and evaluation of the impact are ensured by predefined tools and indicators.

SYNERGY

>>> The medical equipment support project blends into its environment

The key players in the **partner health facility** are identified: health, administrative, Customs and traditional authorities, other health centres, biomedical service providers, suppliers of consumables, accessories, maintenance kits and spare parts, etc.

The key players in the **management of the project** are identified: organisations specialising in support, procurement or logistics for medical equipment support projects, funders, Embassies, other international cooperation organisations operating in the same area or location, medical and biomedical experts, etc.

Special relationships are established with these key actors in the domains of: coordination, exchange of informations, sharing of means, partnerships, service providers, etc.

DEFINITIONS

FOR A CLEAR UNDERSTANDING OF THE PRECIS QUALITY REFERENCE FRAMEWORK

ACCESSORY: in the medical field, an object that is used in conjunction with medical equipment and is usually essential to its function: defibrillator paddles, ECG cables, handle for an electrosurgical generator, etc.

CONSUMABLE: in the medical field, this is an essential supply for an action, which is normally replaced after use. For example: bandages, compresses, gloves, masks, printing paper, X-Ray film, scan gel, sterile towels, diathermy knife blades, etc.

PARTNERSHIP AGREEMENT: formal document/agreement which dictates the relationship between several parties who have agreed to work in partnership and which defines their respective duties.

MEDICAL EQUIPMENT: medical device requiring maintenance, on which users need training, and that need to be overhauled – activities that are usually the job of biomedical engineers. It can be used alone or in conjunction with accessories, consumables and/or other medical devices.

MAINTENANCE KIT: a set of element that is required to carry out preventive maintenance on a specific piece of medical equipment. A maintenance kit could, for example, consist of filters, joints, valves, etc.

MAINTENANCE: in the biomedical field, action plan to maintain a medical device in an optimal operating mode. There are different sorts of maintenance:

PREVENTIVE MAINTENANCE: planned action to reduce the likelihood of a breakdown of an equipment and maintaining it in a state of optimal operation.

CORRECTIVE MAINTENANCE: action carrying out repairs following a breakdown or malfunction noticed on an equipment, with the aim of rendering it durably operational again.

MEDICAL DEVICES: the term medical devices as used in this document applies to all medical devices as defined by article L.5211-1 in the French public health Code as indicated below (which specifically includes medical devices) as well as the technical equipment for hospitals which is not considered to be medical devices (furniture and minor hospital instruments)

Article L.5211-1 of the French public health Code, article 1 item 2 in directive 2007/47/CE defines medical devices as: "any instrument, machine, device, software, material or other article, used alone or in conjunction with another, as well as any other accessory, including software designed by the manufacturer to be used specifically for diagnoses and/or therapy, and necessary for it to work properly, intended by the manufacturer for use on humans for the purposes of:

- Diagnosis, prevention, control, treatment or alleviation of an illness;
- Diagnosis, control, treatment, alleviation or to compensate for a wound or a disability;
- Examination, replacement or modification to the anatomy, or for a physiological process;
- Implementing a design, the desired principal action of which, in or on a human body, cannot be obtained by pharmacological or immunological means nor by metabolism, but the operation of which can be assisted by such means."

STOCK OF MEDICAL DEVICES/EQUIPMENT: all the medical devices available to a health facility.

PARTNERSHIP: in the field of international solidarity, relationship between legal entities which have decided to carry out a project in order to achieve common objectives. It is a dynamic process, usually long-lasting, based on principles of cooperation, equality, and exchange, confidence and reciprocity. It can be conveyed by a formal agreement, which often takes the form of a partnership agreement.

PROJECT HOLDER: in this document, a person or legal entity responsible for coordinating all the tasks and the stages necessary for the success of the medical equipment support project (preliminary assessment, definition of the aims, planning, recruiting partners, fund raising, management and implementation of human resources, equipment and financing, communication, logistics, monitoring, evaluation, etc.).

MEDICAL EQUIPMENT SUPPORT PROJECT: international aid project aiming to reinforce the quality and capability of care in a health facility by the provision of medical devices that is appropriate in the context and local resources.

BIOMEDICAL HUMAN RESOURCES:

BIOMEDICAL ENGINEER: healthcare professional who designs, leads and controls the investment and maintenance policy of medical equipment in conjunction with the healthcare facility's policies and the desired levels of quality and safety. They are usually in charge of a team of biomedical technicians, they keep up with technological innovation, the regulations and precautions regarding medical devices and manage all the facility's equipment throughout its life span, from procurement to withdrawal.

BIOMEDICAL TECHNICIAN: healthcare professional who ensures the maintenance of medical equipment. They are responsible for the installation of equipment and management of the stock of spare parts, accessories and maintenance kits. They train and inform the operators and participate in the detection of risks to the safety of patients and operating staff. The biomedical technician usually works under the supervision of a biomedical engineer.

BIOMEDICAL MAINTENANCE SERVICE: service responsible for the management and maintenance of medical equipment in a health facility.

THE PRECIS

The quality reference framework entitled PRECIS was specially developed for medical equipment support projects. It was called "PRECIS" because each of the six letters comprised in its title correspond specifically to the required quality criterion for medical equipment support projects:

- P** for Pertinent
- R** for Rigour
- E** for Effective
- C** for Capability
- I** for Impact
- S** for Synergy

This quality reference reflects the values to which international aid actors should commit to implementing throughout the duration of their project. From preliminary assessment to evaluation it constitutes precious guidelines for leading operations and decision-taking.

As the framework for responsible commitment, this quality reference can be shared with partners in order to set the foundations for a long-lasting relationship, guarantee a shared vision and the development of an ethical process.

This document is one of a series providing tools and a methodology dedicated to medical equipment support projects. They have all been created around the same PRECIS quality reference.

ISBN : 979-10-93082-02-84

This document has been produced with aid from the European Union. The contents of the document are the sole responsibility of Humatem and Groupe URD and can in no way be deemed to be a reflection of the view of the European Union.

Co-financed by:



Rhône-Alpes

