POLITECNICO DI MILANO

II School of Engineering

Master of Sciences Degree, Biomedical Engineering

Topic:

SETTING UP OF A CLINICAL ENGINEERING SERVICE IN A HIGH-TECH HOSPITAL IN A REMOTE AREA THE CASE OF SHISONG CARDIAC CENTRE IN CAMEROON

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Sommario

La problematica dell'assistenza sanitaria nei paesi in via di sviluppo è un tema importante perché è un dato di fatto che non c'è sviluppo duraturo senza un efficiente sistema di assistenza sanitaria. Le tecnologie sanitarie è un fattore strategico importante nel determinare le prestazioni di un sistema sanitario e la percezione della comunità di esso. Le parole "tecnologia sanitaria" si riferisce ai prodotti farmaceutici, dispositivi, procedure mediche e chirurgiche utilizzate nella prevenzione, diagnosi e cura delle malattie, e per la riabilitazione, comprese le tradizionali tecnologie mediche, la conoscenza associati a questi, la struttura organizzativa e sistemi di supporto in cui è avvenuta la prestazione comprese le strutture che ospitano pazienti, i prodotti alimentari, tecnologie dell'informazione e le tecnologie utilizzate nella promozione della salute, tutto questo con lo scopo di risolvere i problemi di salute e migliorare la qualità della vita [1].

Le decisioni di investimento relative a tecnologie sanitarie sono fondamentali in quanto sono generalmente irreversibili, impegnando grandi quantità di denaro per operazioni che sono difficili, se non impossibile, di annullare, chiudere o ridimensionare.

Ciò implica la necessità di investimenti precisi in stanziati dispositivi biomedici. Questa tesi ha lo scopo di presentare ciò che è Servizio di Ingegneria Clinica, una visione generale del sistema sanitario in Camerun. In particolare si concentrerà sul servizio di ingegneria clinica in un ospedale con attività clinica specializzata: in questo caso il Shisong Cardiac Centre. Il Servizio di Ingegneria Clinica deve fondamentalmente sostenere l'uso della tecnologia biomedica dai professionali della sanità e dalle organizzazioni ospedaliere con competenze e informazioni adeguate in modo da raggiungere il miglior compromesso tra efficacia clinica / efficienza; la sicurezza dei pazienti / degli operatori; la qualità della cura / l’innovazione; costi di gestione delle attrezzature/ costi delle attrezzature.

Ci sarà quindi da discutere sulla necessità di equilibrio tra costi finanziari e l’adeguatezza delle tecnologie sanitarie: processo di valutazione delle tecnologie, a causa dell’elevato numero di potenziali pazienti e le problematiche dei vari paesi in via di sviluppo.

Infine si presenterà come un servizio di ingegneria clinica in un ambiente con problemi specifici, quali i problemi di gestione delle apparecchiature mediche nei paesi in via di sviluppo possono essere gestiti dando la giusta priorità a diversi fattori come lo stato di apparecchiature mediche, le competenze degli operatori sanitari, l'assenza di supporto tecnico esterno, il tipo di attività cliniche, la dimensione di ospedale, organigramma già esistente, numero e valore dei dispositivi medici ...

Nel corso degli anni molti modelli sono stati utilizzati per dimensionare i servizi di ingegneria clinica, in questo documento una breve presentazione di questi modelli viene fatta. Vi presentiamo inoltre come il servizio di ingegneria clinica del Shisong Cardiac Centre può essere dimensionato usando il modello di *Claudio Lamberti et Al*; modello molto più adatto e realistico nelle nostre condizioni rispetto agli altri.

Abstract

The problematic of health care in developing countries is an important topic for it's already a fact that there is not durable development without an efficient health care system.

Healthcare technology is a major strategic factor in determining a health care system's performance and community perception of it. The words "health care technology" refers to pharmaceuticals, devices, medical and surgical procedures used in the prevention, diagnosis, and treatment of diseases, and for their rehabilitation, including traditional medical technologies; the knowledge associated with these; and the organizational and supportive systems within which the care is provided including facilities that house both patients and products; as well as environmental, food and information technologies; and technologies used in health promotion, all this with the scope of solve health problem and improve quality of lives.[1]

Investment decisions related to healthcare technology are critical as they are generally irreversible, committing large amounts of money to interventions which are difficult, if not impossible, to cancel, close or scale down. This implies the necessity of accurate investments in appropriated biomedical devices.

This thesis is aimed to present what is Clinical Engineering Service, a general view of healthcare system in Cameroon and specifically will focus on a clinical engineering service in a hospital with specialized clinical activities, in this case Shisong Cardiac Centre.

Clinical Engineering Service basically has to support the use of biomedical technology by health professionals and hospital organizations with appropriate skills in order to reach the best compromise between clinical efficacy/efficiency, patient and operators safety, care quality and innovation, and management and equipment costs. We will then argue about the necessity of equilibrium between financial cost-clinical activities-appropriateness of health technologies because of a high number of potentials patients and the various problematic of developing countries: The Health technology assessment process.

Finally we will present how a clinical engineering service in an environment with specific problems like medical equipment management issues in developing countries can be managed giving the right priority to various factors like the state of medical equipment, skills of healthcare professionals, absence of out sourced technical support, type of clinical activities, size of hospital , already existing organization chart, number and value of medical devices…

Over the years many models have been use to staff clinical engineering service, in this document a brief presentation of these models is made. We present also how Shisong Cardiac Centre can be staffed using *Claudio Lamberti et Al* model which is the most adapted and realistic in this specific case.

I - Presentation of the Clinical Engineering service

I.1- History

Hospitals began engaging (employing or contracting) clinical or biomedical engineering in the 1960s as a consequence of [2]:

- Proliferation of and reliance on increasing complex medical equipment
- Popular reporting of safety issues related to medical equipment ("electrical safety")
- Advent of standards regarding need for routine medical equipment testing, prospect of country's regulations

Primarily clinical engineering was seen as a "maintenance" function. The 90% of clinical engineering service activities were:

- General inspection
- Function and safety checks
- Repairs

Consequently, clinical engineering was typically associated with maintenance department or facilities and plant engineering.

Throughout its history, clinical engineering has focused on medical devices as they are used in healthcare delivery settings: dealing with acquisition of appropriate equipment; inspection, maintenance, and repair; regulatory compliance; and related technical issues. Over time, clinical engineering has assumed a leading role in management of medical equipment during its entire life span of use. As a result, clinical engineers have become deeply involved also in quality improvement and risk management activities. An understanding of equipment operation
and maintenance can draw attention to likely failure modes and the effect of support systems of device performance. An understanding of systems theory and human factors engineering can shed light on the interaction between machines and humans

I.2- Role of Clinical Engineering service

The health service's most valuable assets which must be managed are its human resources, physical assets, and other resources such as supplies. Physical assets such as facilities and healthcare technology are great capital investment in any health sector. It makes financial sense to manage these valuable resources, and to ensure that healthcare technology [3]:

- is selected appropriately
- is used correctly and to maximum capacity
- last as long as possible.

Such effective and appropriate management of healthcare technology will contribute to improved efficiency within the health sector. This will result in improved and increased health outcomes, and a more sustainable health service.

Thus the role of clinical engineers[1] in hospitals is related to the functioning of biomedical technologies: to that complex of devices of varying size and complexity, which contribute, often in a very decisive manner in the exercise of effective diagnostic and therapeutic activities of a hospital. The concept and model of clinical engineering has evolved in time from “equipment management” to “technologies management”. Areas of clinical engineering expertise identified by International Federation of Medical and Biological Engineering (IFMBE) are the following ones [4]:

- Advice on technologies available on the market, both in response to defined clinical problems, both by promoting the introduction of new products or methods deemed appropriate.
- Assessment, planning and acquisition of biomedical equipment to replace those outdated, based on the cost-effectiveness, operating costs, costs of consumables and other incidental expenses, based on the adequacy of the equipment to perform his or task requested in compliance with safety standards, evaluating the reliability and the assistance services offered.
- Installation, testing, preventive maintenance and repair of equipment, through a policy of planned maintenance is essential for the safety and efficiency and also to ensure continuity of service
- Safety and functional checks to prevent incidents or errors.
- Training of medical and paramedical staff about the safe and appropriate use of equipment
- Technical support and general services: The clinical engineer can help improve the quality of health services, such as modifications to equipment to improve performance or development of specific software products for managing health data;
- Research and development of new equipment and devices, both in the identification of problems and search for appropriate solutions (verification of the characteristics and performance).

[1] *American College of Clinical Engineering defines Clinical Engineer as professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology*

- Biomedical risk management

  Kavaler and Spiegel define risk management as "…an organized effort to identify, assess, and reduce where appropriate, risks to patients, visitors, staff and organizational assets" (Kavaler and Spiegel, 2003). As the American Society of Health care Risk Management explains, risk management in healthcare is the process of making and carrying out decisions that will assist in prevention of adverse consequences and minimize adverse effects of incidents upon patients, operators or organization.[5]

  Risk can be define as "a combination of the probability of occurrence of harm and severity of that harm"[6]

  The five mains steps of risk management in Clinical Engineering Service are:

  - Risk identification and analysis of exposure to risk
  - Assessment of possible risk treatments techniques
  - Selection of the best technique to manage and treat the risk
  - Implementation of the selected technique
  - Monitoring and improvement of risk management program

To summarize, the main aim of Clinical Engineering is to support the use of biomedical technology by health professionals and hospital organizations with appropriate skills in order to reach the best compromise between clinical efficacy/efficiency, patient and operators safety, care quality and innovation, and management and equipment costs.[7]

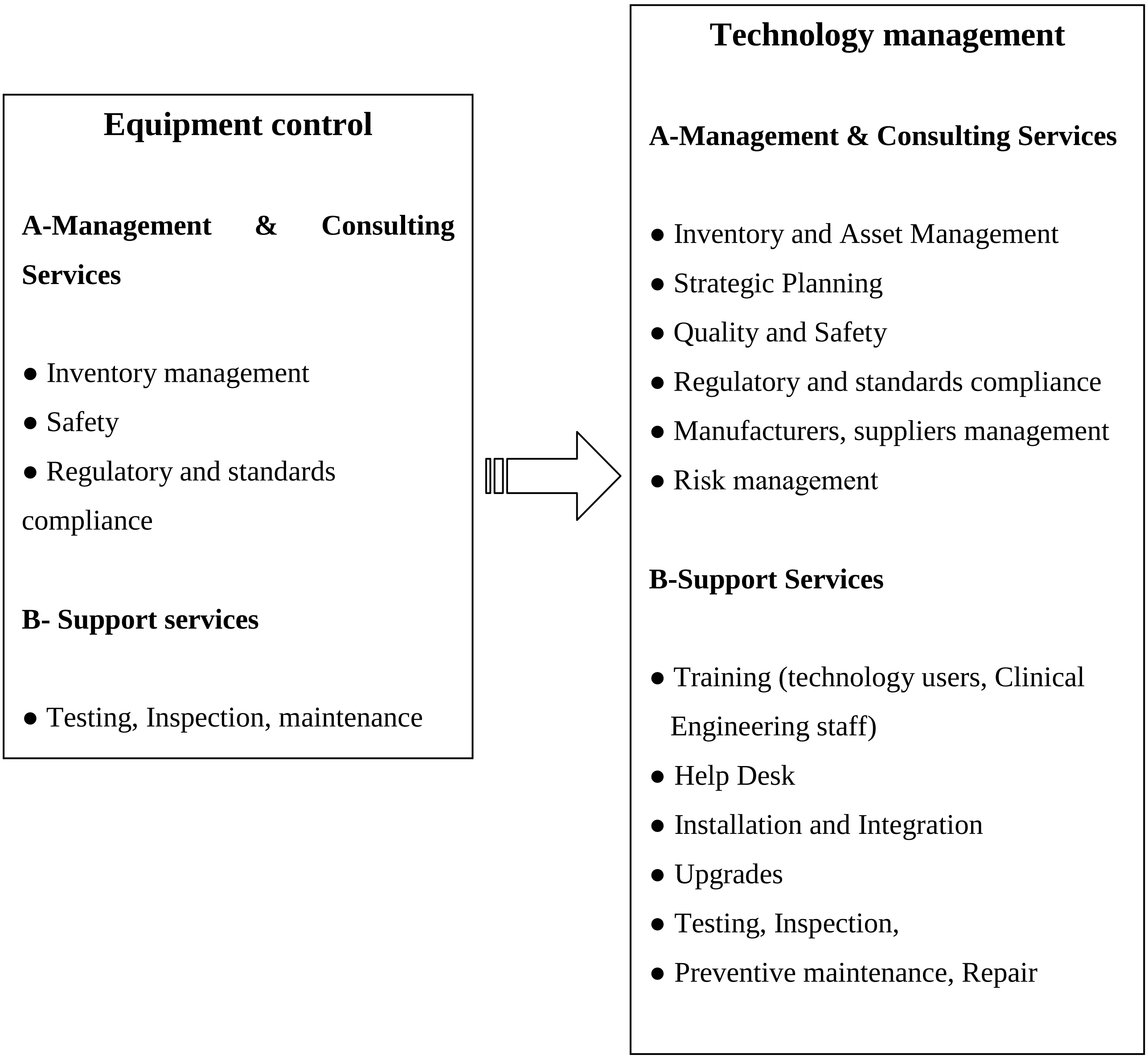


Fig. 1: From Equipment maintenance control to Technology management

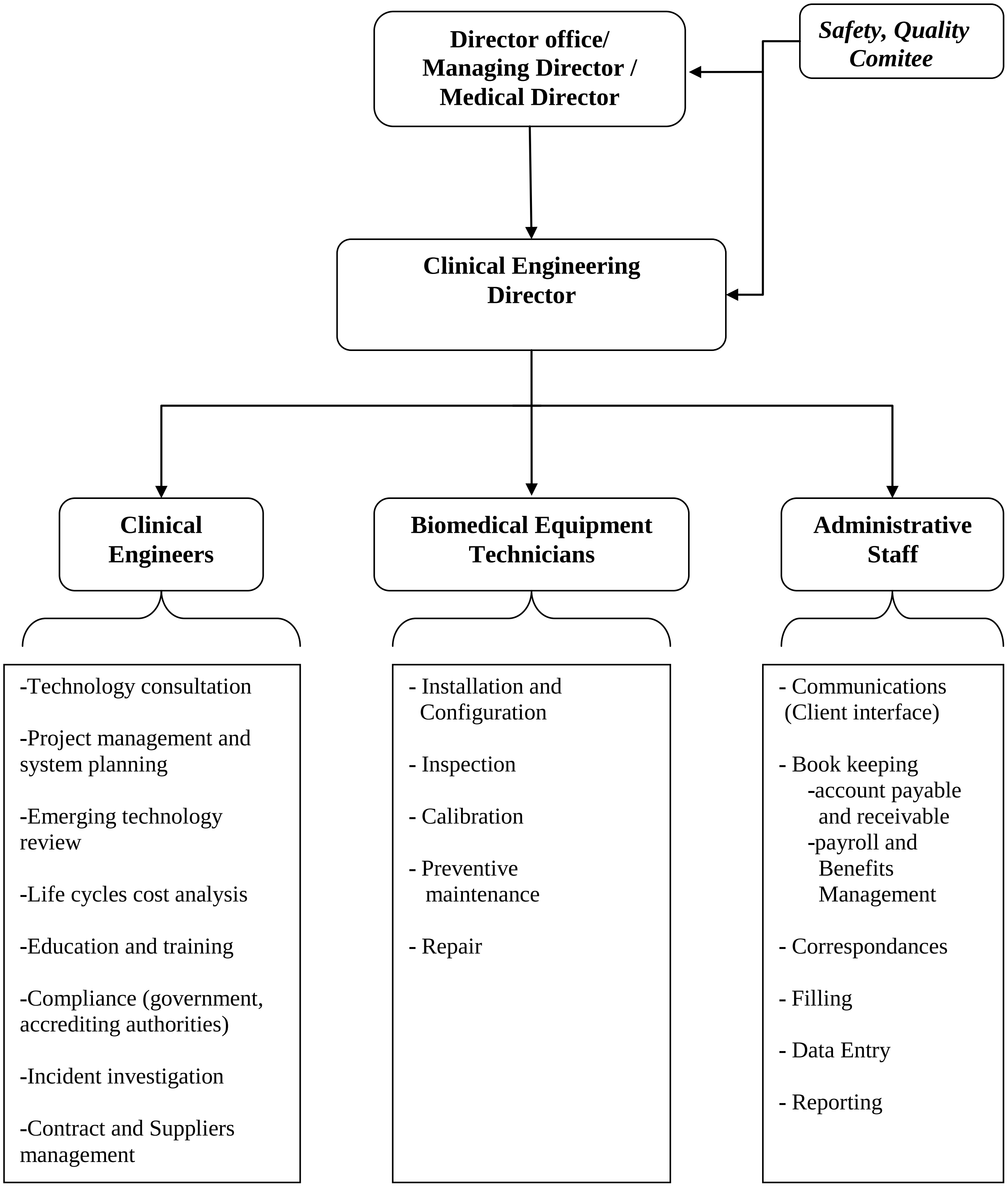


Fig. 2: <u>Typical Clinical Engineering Service: Organization Chart</u>

II- Presentation of the Shisong Cardiac Centre

II.1- Overview

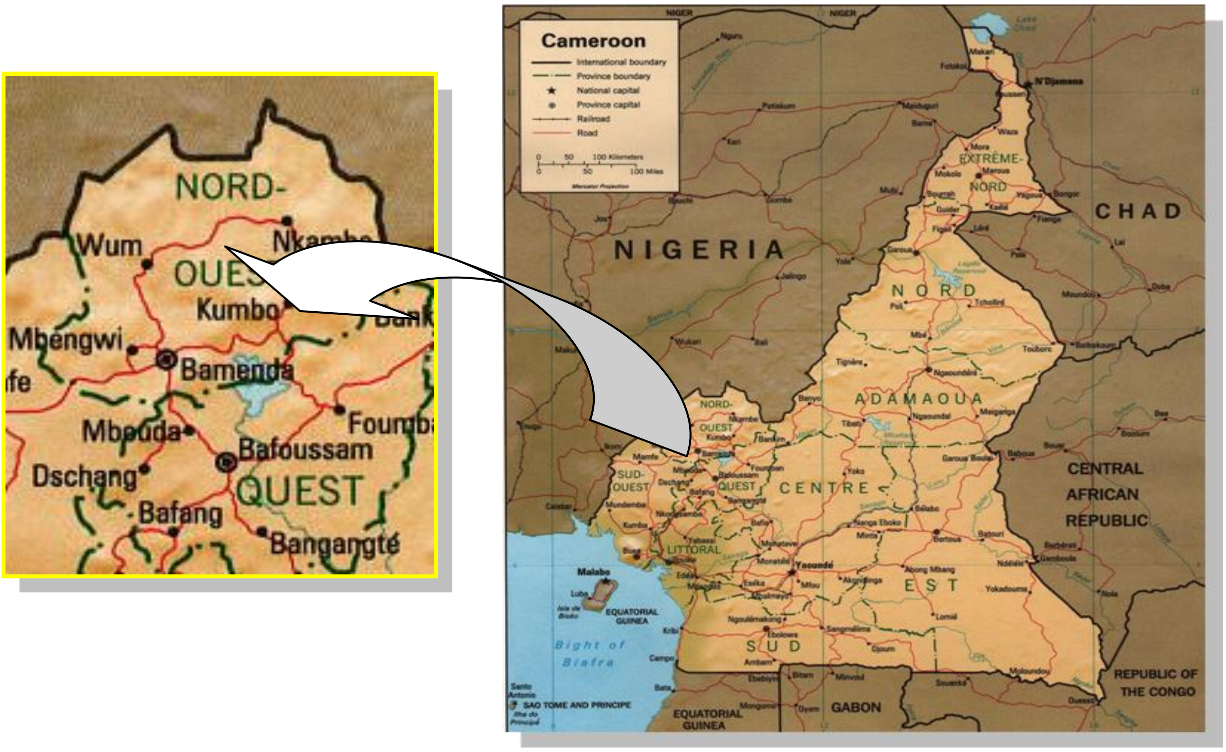


Fig.3: <u>Kumbo in the west region of Cameroon, Central Africa</u>

Cameroon is located in Central Africa, overlooking the Gulf of Guinea, and has an area of 475,442 Km^2. It is bordered on the north by Chad, east by Central African Republic, Congo and south by Equatorial Guinea and to the west by Nigeria. The climate is tropical, wet in south and dry to north, with temperatures averaging from 25 ° C to 32 ° C, with a dry season and a rainy season. In mountain areas of the West as Shisong (1700m above the sea level), the climate is temperate. For its geographical variability and climate, Cameroon is called "little Africa". All the possible variables can be found in this African nation: from the desert to the sea, the mountains to the bush, temperate, equatorial and tropical climate.

The population counts about 19 million (divided into almost 150 ethnic groups). It's a "young country" as 43% of its population is less than 15 years old [8].

The official languages are French and English. Cameroon is a laic state, the main religions that are animist, Christian and Muslim in the north.

The main cities are Douala (1,200,000 pop.), Yaoundé (the capital, 1,000,000 pop.), Bafoussam (200,000 pop.), and Garoua (120,000 pop.).

II.2-Why a Cardiac Centre

Meeting the healthcare needs of African countries is an enormous challenge. The World Health Organization (WHO) lists sub-Saharan Africa as one of the geographic areas least served by healthcare providers (doctors, nurses…), for instance in Cameroon the rate was 0.2 physicians and 0.8 total healthcare professionals per 1000 inhabitants in 2009[9]. Socio economic barriers to cardiovascular care in Africa included inadequate financing, lack of training of health workers, and poor laboratory support. Besides, poverty, political instability, and corruption exist in many parts of Africa today.

In 2002 it was estimated that 29% of deaths worldwide (16.7 million deaths) were due to cardiovascular diseases and that 43% of global morbidity and mortality, measured in disability-adjusted life years (DALYs), was caused by cardiovascular diseases [10]. Furthermore 86 % of mortality and morbidity from cardiovascular diseases occurs in developing countries. By 2020 it is estimated that cardiovascular diseases will become the leading cause of the global health burden, accounting for 73 % of total global mortality and 56% of total morbidity [11,12]. In many African countries cardiovascular diseases (CVD) are the second most common cause of death after infectious diseases, accounting for 11% of total deaths. CVD is a major cause of chronic illness and disability. Projections from the Global Burden of Disease project suggest that from 1990 to 2020, the burden of CVD faced by African countries will increase to 25%. A large proportion of the victims of CVD will be middle-aged people. The poor will suffer disproportionately as a consequence of their higher disease risk and limited access to health care.

The burden of CVDs is increasing rapidly, and it is now a public health problem throughout the African Region. CVDs have a major socioeconomic impact on individuals, families and societies in terms of health-care costs and lost productivity due to absenteeism and premature deaths. The epidemiology of CVDs in the African Region, reported mainly on hospitalized patients, may not represent the true pattern of heart disease but suggests a high burden of neglected conditions such as rheumatic valve disease, cardiomyopathies, and tuberculosis pericarditis.

The WHO has reported that the disability adjusted life years (DALYs) lost to CVDs in

Sub-Saharan Africa rose from 5.3 million for men and 6.3 million for women in 1990 to 6.5 million and 6.9 million in 2000 respectively, and could have risen to 8.1 million and 7.9 million in 2010. They cause higher mortality in Africa than in developed countries, and affects younger people and women disproportionately [13].

In other words for a country like Cameroon:

Total population 19.5 million

General Mortality: 12.2‰

Total death by CVD: 12.2‰ x 20% x 19500 000 = 46 000 persons per year.

Life expectancy: 53 years

DALYs related to CVDs= 2025 per 100 000 persons which means 394875 for all the country which is the equivalent of having no economic productivity in the third and the fourth means cities of the country (Bafoussam 200.000 pop. and Garoua 120.000 pop.) for a whole year.

Table1: Comparatives parameters with Italy

Parameters 2009	**Cameroon**	**Italy**
Area	475.442	301.341
Population	19,580.005	58,462375
Population < 15 years	45%	15%
Birth rate	36/1000	9.5/1000
Infant mortality	154/1000	5.5/1000
Congenital heart disease/ yr	5000	4000
Cardio surgery centre (paediatric, adult)	1	110 +18

The Cardiac Centre of Shisong is aimed to deserve the area of Cameroon and all neighbouring countries (Tchad, Congo, Gabon, Equatorial guinea, Central African Republic...)

The Cardiac Centre of Shisong, in Cameroon, is a joint project of tree organizations:

- The Tertiary Sisters of Saint Francis, set in Brixen, South-Tyrol, Italy, in Cameroon since early 1930's, working in the field of healthcare and education
- The “Associazione Bambini Cardiopatici nel Mondo ONLUS”, a charity set in Milan, formed mainly by Doctors of the San Donato Hospital Group (cardiac-surgeons, cardiologists and anaesthetists) who conduct several projects of cooperation in the field of cardiology for children in developing countries
- The “Associazione Cuore Fratello ONLUS”, a charity set in Milan, which contributes in organizing the transfer and care of children from developing countries in need of cardiac surgery at the “Policlinico San Donato” Hospital.

The Cardiac Centre will operate as an independent Unit of the existing Saint Elizabeth General Hospital of Shisong, conducted by the Tertiary Sisters. This center will have a joint management among the 3 organizations involved, for the first years of activities.

The construction, equipment, start-up of the Cardiac Centre is a 5million euros project, mainly fund by private donors.

The project includes the training of clinical personnel from Cameroon at the Policlinico San Donato (Milan) in Italy.

In 2002 the project started with the setting up of a cardiac Unit at the existing hospital.

The construction of the Centre started in late 2004. The new facility includes an outpatient department, paediatrics wards, adult wards, neonatology, catheter lab, sterilization, 2 operating theatres, 2 intensive care units, and blood unit.

The main steps:

November 2000	**Idea of the project**
Febuary 2001	Agreements between Hospitals
July 2001	Italian doctors first mission in Shisong
September 2001	Start of 1 year stage for: - 1 cardiologist - 2 nurses (sisters)
May 2002	Start of construction of the Cardiac diagnostic Unit
November 2002	Donation of an adjacent area for the construction of the new Cardiac Center
18 November 2002	Inauguration of Cardiac Unit
June 2003	Progressive arrive in Italy of other doctors and nurses from Cameroon for training.
December 2004	Start of the new Cardiac Center construction
16 March 2005	Surgical mission and first cardio surgical intervent in Shisong
27 November 2006	First open heart surgery in Shisong

In July 2009 as expected, the transfer of activities of the Cardiac Unit (outpatients and wards) from the existing Saint Elizabeth Hospital to the new facility took place.
In September 2009 started the installation of devices in the critical area (catheter lab, operating theatre and intensive care. On November 17th 2009 the official inauguration took place.

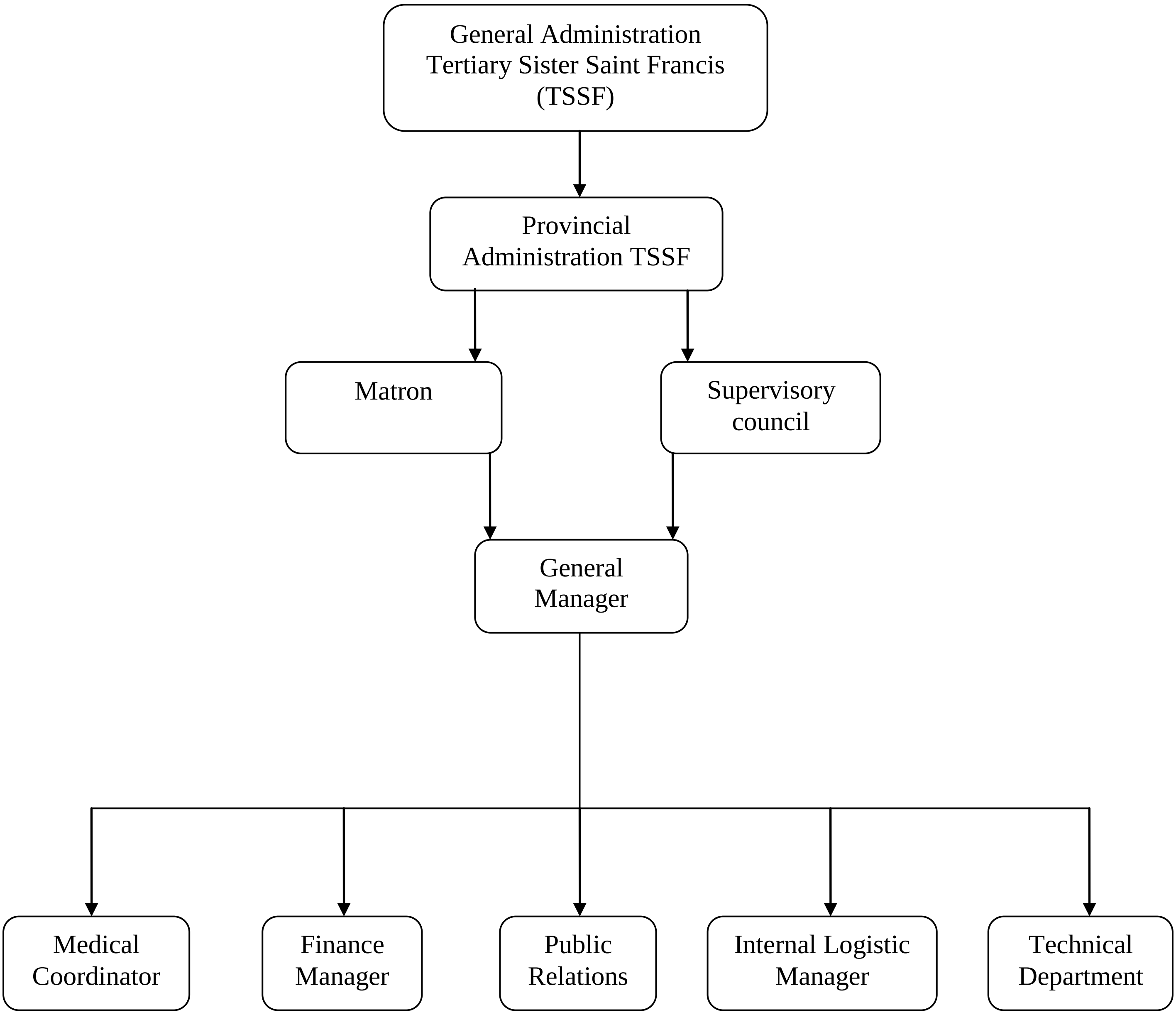
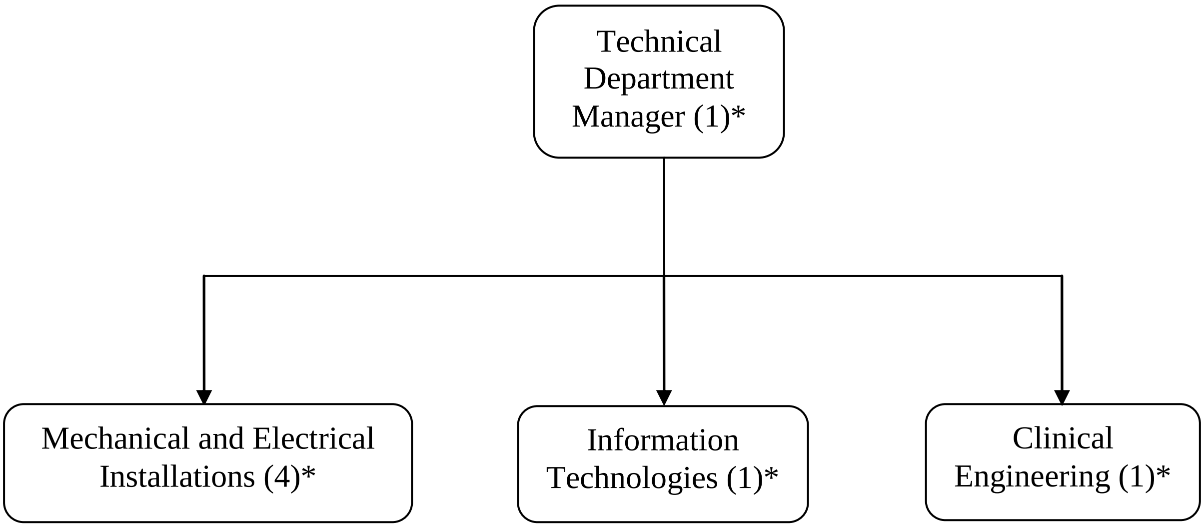


Fig. 4: Shisong Cardiac Centre's Organization Chart



*Number of operators working on the specific field actually

Fig.5: Technical Department Organization Chart

II.3-Mission, Vision, Values statements

The following Vision Statement, mission statement and values statement was proposed during an official meeting in Shisong and it is taken from an approved document produced in that occasion:

Vision Statement:

"To be recognized and respected in Cameroon and Africa as a centre of clinical and academic excellence, where patients receive the highest standards of care, and people want to come to work and learn"

Mission Statement:

"Our mission is to offer affordable, quality medical attention to cardiac patients of all status and works of life in Cameroon and neighbouring countries by providing sustainable services from our facilities in St. Elisabeth's Catholic General Hospital, in Shisong, Cameroon"

Values Statements:

"To see and serve Christ in simplicity, joy, respect for human person and nature, humility and hospitality"

Goals and Objectives

The following Goals and Objectives were proposed during an official meeting in Shisong and are taken from an approved document produced in that occasion.

II.3.1-Goals

-*Goal 1: Eradicate in the cardiac centre by 2012 practices in medicine that are not based on international, reputable evidence*

-*Goal 2: Provide by 2015 health services without being dependent on international support*

-*Goal 3: Become by 2015 a national and international referral hospital for children and adults with cardiac problems who cannot be treated in their local hospitals*

-*Goal 4: become by 2020 a teaching hospital for specialist doctors in cardiology with full recognition from the Ministry of Public Health of Cameroon.*

II.3.2-Objectives

- *Obj 1.1: Develop and implement by 2010 a system to facilitate the continuous professional development of the personnel*
- *Obj 1.2: Develop and implement by 2010 a system to appraise and evaluate the performance of the personnel on an annual basis*
- *Obj 2.1: Provide by 2015 full staff of the Centre on long-term contracts*
- *Obj 2.2: Achieve financial sustainability by 2015*
- *Obj 3.1: Form by 2012 partnership with other hospitals in Cameroon and neighbouring Countries that share our concern for cardiac patients*
- *Obj 3.2: Work together with the Ministry of Public Health to develop and implement a national health plan for cardiac services by 2012, in which our hospital is recognized as a referral centre*
- *Obj 4.1: Form by 2015 partnerships with the faculty of medicine in Cameroon that aim to include our hospital as a teaching centre for specialist doctors in cardiology*
- *Obj 4.2: Apply by 2018 to the Ministry of Public health for the recognition as a referral hospital for cardiac diagnosis and treatment*

II.4-Brief description of infrastructure

II.4.1-Infrastructure and security system

The Shisong Cardiac Centre is composed by:

-2 Intensive Care Units with 12 beds equipped and 4 babytherms

-2 Operating Theaters completed

-1 Blood Bank Unit

-1 Adult ward (men, women)

-1 Paediatric ward

-1 Catheterization Laboratory

Any hospital must have a global safety management system. The safety system in Shisong Cardiac Centre is the result of: needs analysis, assessment of the best solutions, continuous monitoring and verification, updated measures implemented in accordance with the evolution of knowledge.

Some safety measures have already been implemented:

- Risk symbol labels (toxic, corrosive, irritant, explosive, radiations…) upon all the risks zone or devices.
- Behaviors protocol for each risk zone (Cathlab, medical gas store, sterilization…)
- Presence of extinguishers in every critical local and near of the mains doors…in such a way that the distance between the extinguisher and any person in the place is less than 25m
- Escape route and exit are all least than 35m
- The medical gas pipeline has been realized so that there are mains circuit breakers for each service and also secondary ones in critical area. These circuit breakers are near of extinguishers and easily reachable.

Fig.6: *<u>Operating Theatre (during equipment maintenance session) 1</u>*

Fig.7: *<u>Operating Theatre (during equipment maintenance session) 2</u>*

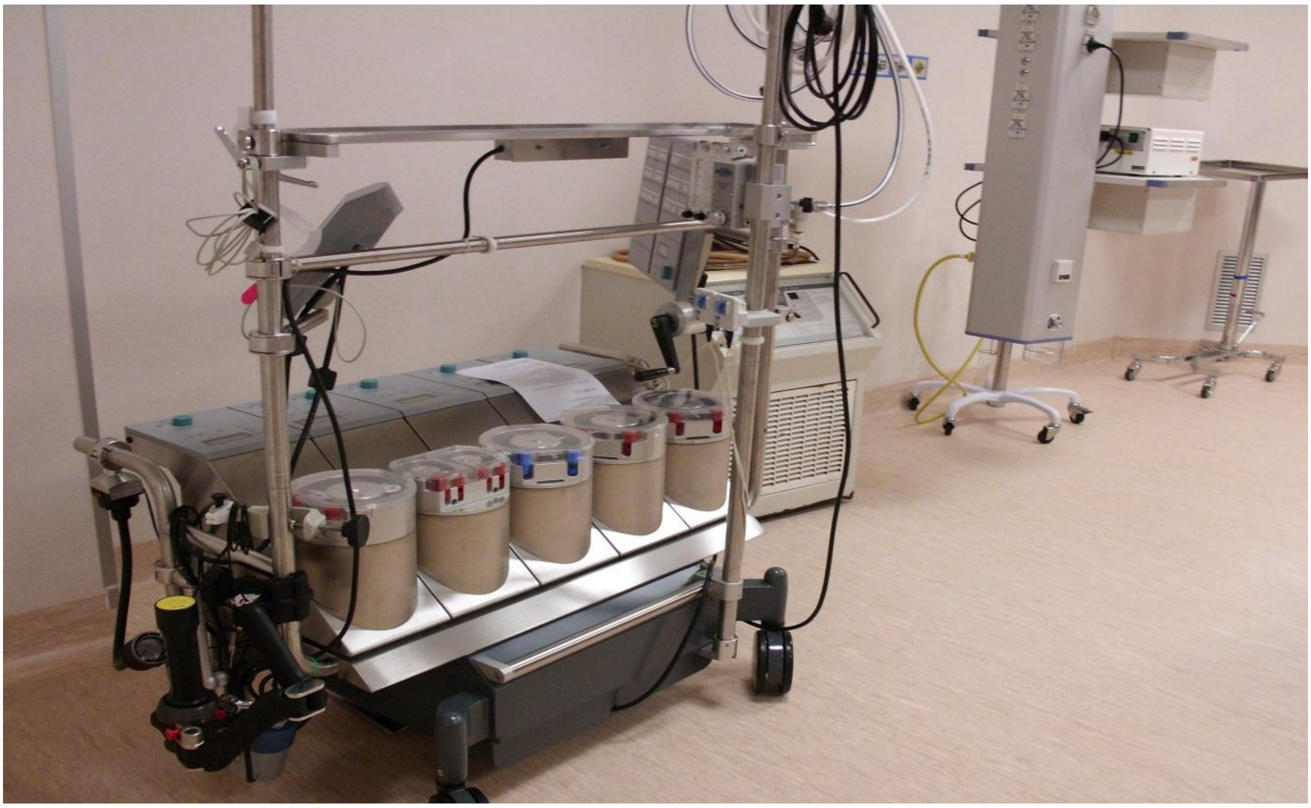


Fig.8:Operating Theatre (during equipment maintenance session)3

Fig.9: Catheterization laboratory during a maintenance session

II.4.2-Medical gas pipeline system

A medical gas pipeline system is designed to provide a safe and effective delivering of the required medical gas from the source of supply to the patient through a pipeline system and via a terminal unit.

In Shisong Cardiac Centre medical gas pipeline, each gas is supplied from a separated system. It's essential that all parts of system are gas specific and to ensure that there no possibility of cross connection between systems. Each gas pipeline system is identified univocally by a color system UNI EN 1089-3 (black and white for medical air, white for oxygen, blue for nitrous oxide…)

The safety of this medical gas pipeline system depends of:

-Identity: gas specific connections are used throughout the system (connectors, terminal unit,)

-Adequacy of supply: it depends of the accurate assessment of the demands and the choice of the appropriate plant of medical gas pipeline.

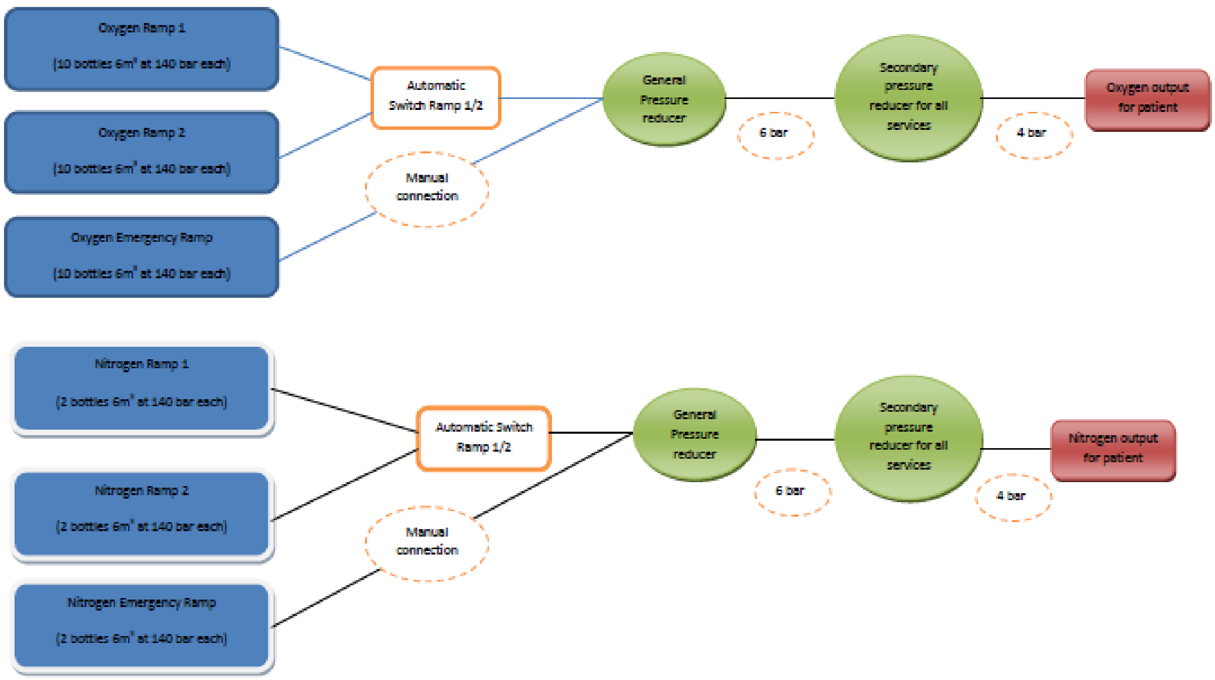
-Continuity and quality of supply: it's achieved by the specification of a system which has duplicated components (valves, manometers…), alarm system and which is connected on an emergency power supplier. Provision of a functional, reserve and emergency gas supply. The whole medical gas pipeline system used is certificated according to the normative UNI EN 737-3, UNI EN ISO7396-1, UNI EN ISO 7396-2.

In our case the medical gas central consists in:

- 2 ramps(left and right) for normal use, made of 10 bottles of 6m^3 Oxygen pressurized at 140 bar
- 1 ramp for emergency made of 10 bottles of 6m^3 Oxygen pressurized at 140 bar
- 2 ramps(left and right) for normal use, made of 2 bottles of 6m^3 Nitrous oxide pressurized at 140 bar
- 1 ramps for normal use, made of 2 bottles of 6m^3 Nitrous oxide pressurized at 140 bar

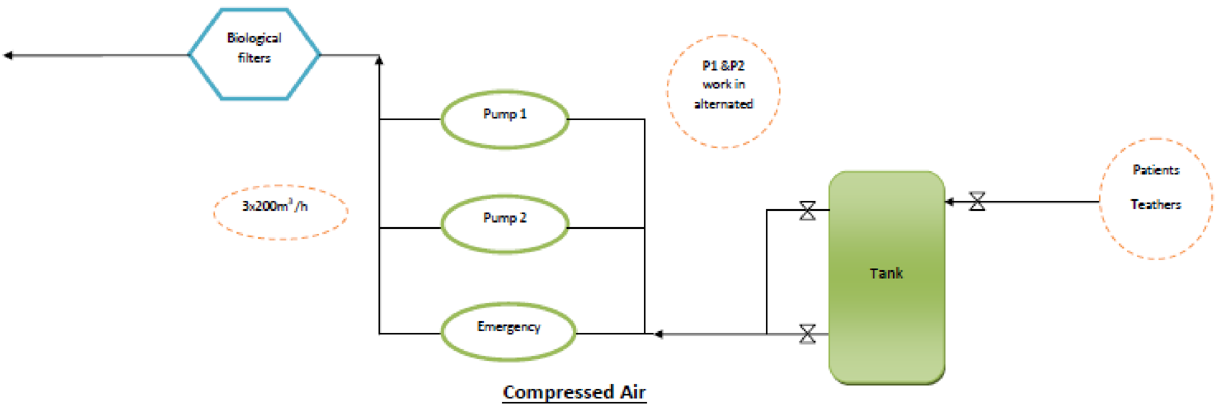
The right and left ramps are connected together in both case of oxygen and nitrous oxide, in order to switch automatically to the other ramp when gas pressure decrease under a defined pressure in the ramp in use because of lack of gas in bottles.

SIMPLIFIED SCHEMA OF OXYGEN AND NITROGEN

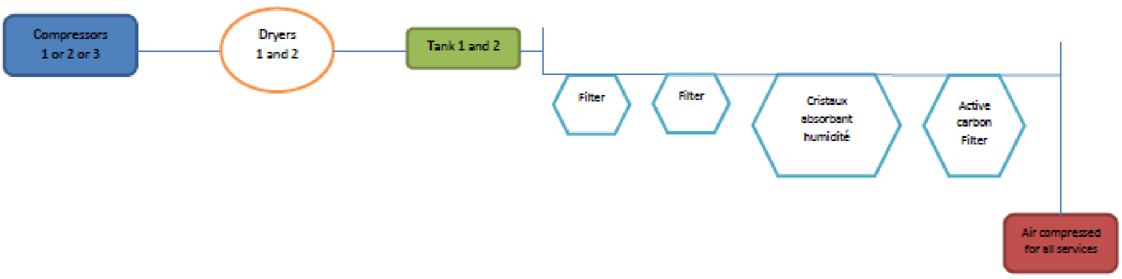


SIMPLIFIED SCHEMA OF VACUUM AND COMPRESSED AIR

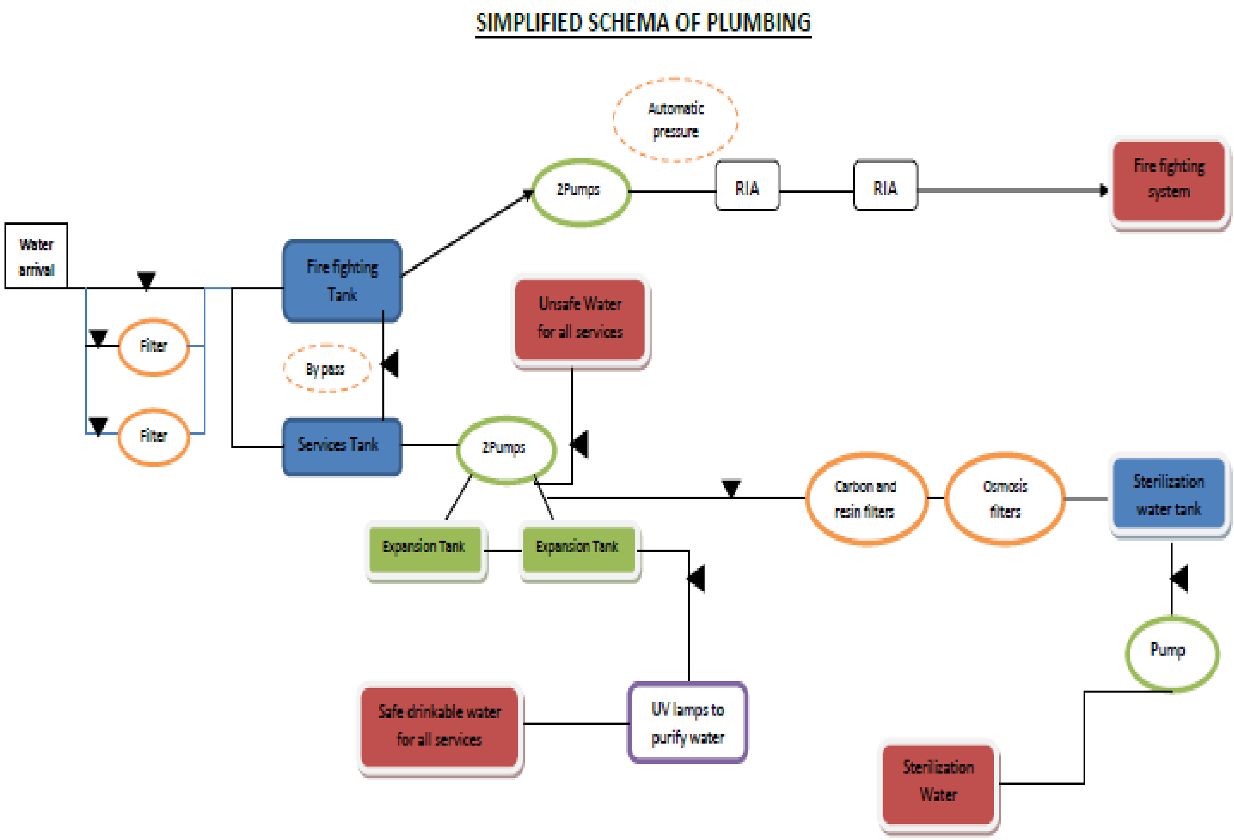
Vacuum



Compressed Air



II.4.3-Plumbing



II.4.4-Wiring

For electrical systems, medium-voltage electricity is supplied by the Territorial Distributor.

Ratings supply medium-voltage:

- Power supply 10 kV
- Frequency distribution of 50 Hz
- IT distribution system

The facilities of IT type are isolated from the ground (they are also called floating because in the absence of a reference, they have an indeterminate value of voltage to ground). They are used where it is deemed necessary to have specific benefits as follows.

1-Operator safety against direct or indirect contact (missing the return through the earth, current cannot flow through the operator's body if in contact with an active part).

2-Continuity of service even in case of a first earth fault

3- Elimination of "hot spots" that can generate in some environments, danger of fire or explosion.

4- Easier grounded metal carcass. The legislation CEI 64-8 allows for the circuits of IT type, higher value of ground resistance

5-Ability to program the maintenance of ground insulation for the electrical installations

Nominal value in low voltage supply

-voltage 400/230 V distribution

-frequency distribution of 50 Hz

-distribution system TN-S

-Three phase with neutral

Ratings for power utilities preferred to feed in absolute continuity through uninterruptible absolute

Input	**Output**
Nominal voltage 400/230 V	Nominal voltage 400/230
Variable voltage +/-10%	Sinusoidal waveform
Nominal frequency 50 Hz	Nominal frequency 50Hz
Power factor 0.8 to 0.97	

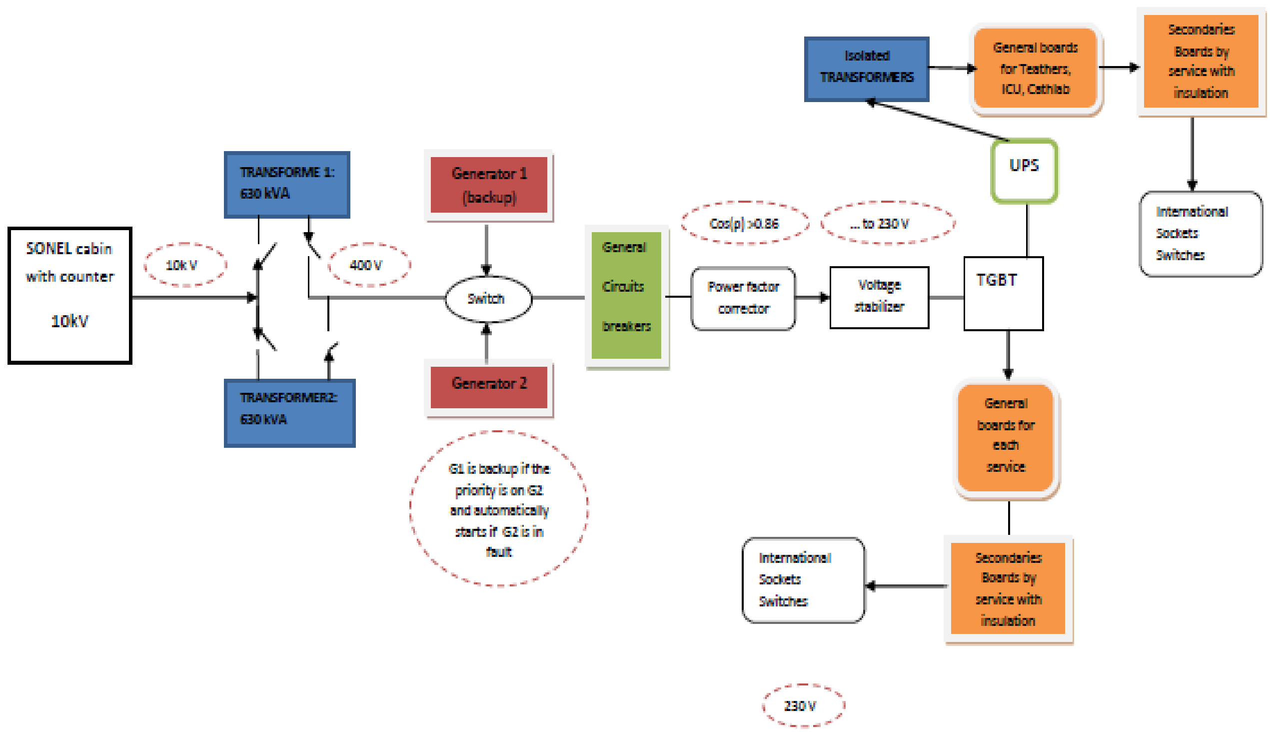
The services for which it's provided a power supply without interruption are identified as:

-Monitoring of medical gases

-Medical equipment in intensive care units and surgical groups

-General lighting and medical equipment inside the operating rooms and maternity wards and Intensive care

SIMPLIFIED SCHEMA OF ELECTRICAL INSTALLATION



II.4.5- Air conditioning

Microbiological transmission in healthcare setting is inevitably a very potential risk. Proper air conditioning of medical care facilities is helpful in prevention and treatment of diseases especially for hospitals like Shisong Cardiac Centre with surgical and cardiovascular activities. The factors determining the need for air conditioning in this hospital facilities are:

(a) The need to restrict air movement between various departments.

(b) The specific requirements for ventilation and filtration to dilute and remove contaminants in the form of microorganisms, viruses, odors, hazardous chemical substances. Infectious bacteria are transported by air. It has been shown that absolute filters remove 99.9 per cent of all bacteria present in hospitals.

(c) Different types of temperature and humidity requirements for various areas.

The temperature and humidity conditions in hospital environment can inhibit or promote the growth of bacteria and activate or deactivate viruses

(d) Control of air quality and air movement.

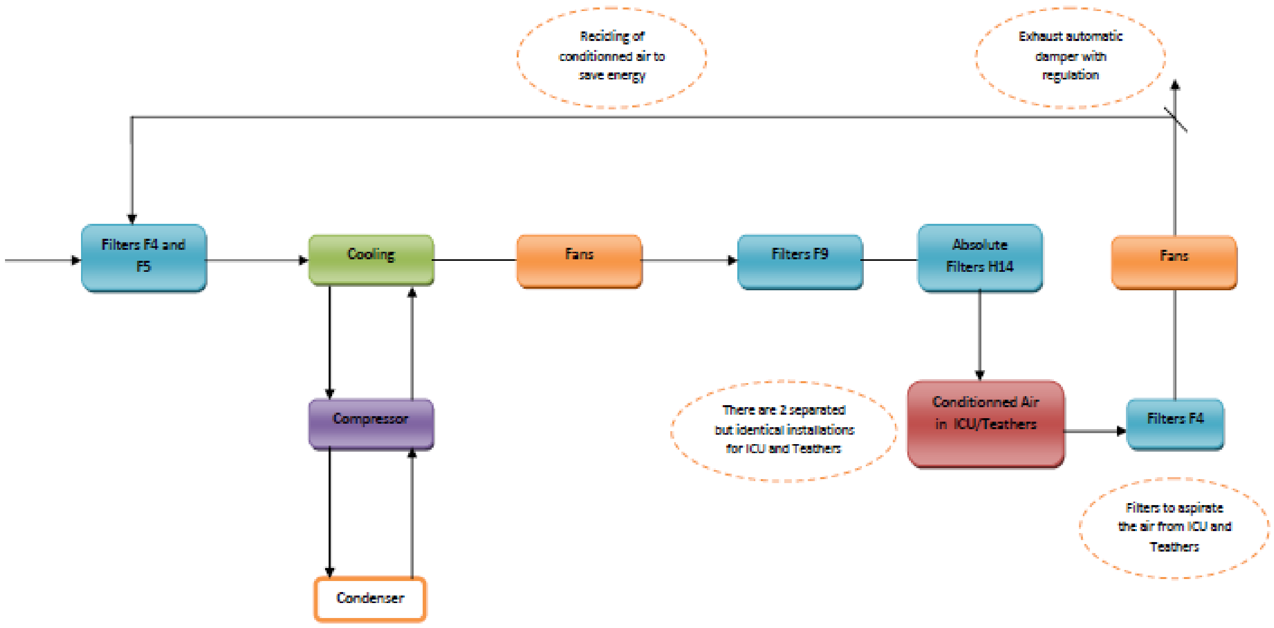
Ventilation systems are used to provide air virtually free of dust, dirt, odor, and pollutants.

The primary task of the ventilation system in our operating room is to provide an acceptable indoor climate for personnel and patients, to remove odor, released anesthetic gases and to reduce the risk of infection in the operating area. The greatest amount of bacteria found in operating rooms comes from the surgical team and is a result of their activity during surgery.

Our air conditioning system is designed and configured to provide:

- Almost 90 000 m^3 of air per hour
- In the 2 operating room and catheterization laboratory 15 air changes per hour
- In intensive care 8 air changes per hour

SIMPLIFIED SCHEMA OF AIR CONDITIONNING



III-Problematic of management of health technologies in developing countries

III.1-Situation analysis and the case of Cameroonian's Healthcare System

Cameroonian's Healthcare System

The recent administrative organization of Cameroon, decree No. 2008/376 of November 12, 2008 has divided the Cameroonian health care system into 10 regions, 58 departments, 360 municipalities.

The Cameroonian health care system referring to the decree n° 95/040 of March7, 1995 is headed by the ministry of health and is organized into three levels: central (strategic), intermediate (technical), peripheral (operative).

Each level has three types of structures: institutional management structures of health ministry, health facilities and structures of representation of people.

The country has 178 health districts, with 162 district hospitals of which 154 are functional, and 2043 public and private health facilities mostly concentrated in urban areas. Only 54% of the population has access to health facilities within 5 Km.

Insufficient quantitative and qualitative human resources, persists despite recruitment efforts in recent year. This situation is aggravated by concentration in urban areas to the detriment of rural areas. The ratio of medical personnel is 2 per 10000 inhabitants in 2009 [14].

Level	Administrative structures	Skills	Health facilities
Central (strategic)	Central services	political leadership, development of policy and strategies	General reference hospitals, university hospitals
Intermediate (technical)	Provincial delegations	technical support to districts and programs	Provincial hospitals
Peripheral (operative)	Health district	Implementation of programs	district hospitals, district medical centers, health centers

The development of health sector and the quality of health cares in all the countries of the world are incontestably today related to acquisition and the performance of materials or equipment of high technology. These medical devices indeed increase the possibilities of diagnosis placed at the disposal of the clinicians and other actors of health. For the least advanced countries, in particular Africa, the acquisition of these materials, remains expensive. In spite of the authorized creditable financial efforts these last years by these countries, with the support of the partners from developed countries and of many humanitarian associations, the report is not glittering.

The difficulties experienced in transfer of medical technology to developing countries are aggravated by partial and incomplete understanding of the cultural, social, economic, and institutional factors affecting technology development, transfer, dissemination and use.

Developing countries have a relatively modest park of medical devices, badly often maintained obsolete or off-service. Studies of the World Health Organization, reports of stage, projects of health initiated in developing countries record results that are not with the height of the authorized investments [15].

The constants are that:

- The majority of the equipment placed at the disposal works only during a limited time
- The technical possibilities of the equipment placed at the disposal are not always well exploited
- A coherent policy for the acquisition and the homogenisation of the park of medical equipment remains to be defined
- Insufficient ability to unite technological equipment possibilities and adequacy to local conditions

The probable causes of these constants are:

- Insufficiency of Training or limited qualification of the biomedical devices users
- Provisioning delays
- Limited funds and sustainability of the hospital
- Distance of specialized services of maintenance
- Problems of energy provisioning
- Insufficient know how in health technology assessment of those in charge of the acquisition of Equipment
- Insufficient use of information and communication technologies for reporting and data reporting

In the specific case of Cameroon, the ministry of health has developed over several years, with the support of partner organisations, various approaches to the management of healthcare technology oriented towards the peripheral level. It was noted that support and the assignment of formal responsibility, together with a system of supervision and control allow better performances and a higher availability of healthcare technology.

During 2004 the ministry of health initiated a « National Study of Maintenance Needs for Medical Equipment » in order to have at its disposal basics information for the development of a National Policy on Healthcare Technology

This study, undertaken on a representative sample of institutions at all levels of the health system in Cameroon, together with other experiences has resulted in a number of important observations regarding the management of healthcare technology [16].

To illustrate the situation:

35 % of equipment is not functioning

10 years is the average age of equipment in current use

70 % of equipment malfunctions are caused by users

75 % of buildings are in a poor state

<0.5 % of the equipment value is allocated to the annual maintenance budget at district hospitals, against 6 % recommended by international directives

50 % of provincial hospitals do not have a maintenance department

80 % of district hospitals do not have a maintenance unit

70 % of service providers and suppliers of medical equipment are not considered professionals

2.8 % is the annual rate of population growth in Cameroon, which indicates the general need to expand the healthcare system, in particular the use of healthcare technology

Insufficiency of Training or limited qualification of the biomedical devices users

According to the World Health Organization, around 95% of medical technology in developing countries is imported. Astonishingly, almost 40% of equipment in these countries is not in use [17]. This is either due to a lack of maintenance, lack of suitable training or because the equipment is too sophisticated. This void has a great impact on the effective provision of healthcare in developing countries.

The training is essential, indispensable for:

- Use all the equipment features
- Perform routine maintenance and maintain the equipment operational
- Train internally other personal

The training can be separate in: training for users and training for maintenance. The study of Jean Sagbo et al 2007 reveals that number of training for users is more than the double of the one of maintenance. It states also that 56% of healthcare structure’s personal declare that only sometimes the structure has internally skills for the use of all the features of equipment and to maintain them operational, 20% declare that their structures don’t have skills for the optimal use and maintenance of equipment.

Regarding the trainings, they are usually done when the equipment is bought. When the equipment is given in 62% cases there no training (this being a big problem knowing that much critical equipment is given).

Beyond this, the problem is that very few training are maintenance oriented and the personal in charge of maintenance often don’t have access to user’s training. This carelessness about maintenance personal training leads to lives and financials losses because of the non reliability and small life cycle of equipment.

Limited funds and sustainability of hospital

The need for funding of hospitals in Cameroon is high. In reality very few or almost none of these hospitals have an objective budget line for preventive or corrective maintenance.

Jean Sagbo et al, in their study notes that 42% of healthcare structure administrators surveyed, said to not have specific budget for equipment maintenance. This can be cause by the very low financial sustainability of most of the hospitals. The financial needs necessary to maintain or increase the quality and quantity of medical cares is very superior to the healthcare financial incomes from patients. In Cameroon for instance the health expenditure per capita was 122 USA$ per capita in 2009.

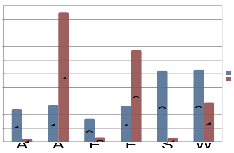


Fig.10: Continent Health Expenditure

Distance from specialized services of maintenance

The access to specialized maintenance is very difficult because of distance from specialized technicians. Very specialized maintenance has to be done by manufacturers technician but because of the distance between manufacturers (European or American companies) the most of the time local administrators rely on maintenance structures can only be found in local principal cities in this case they are very expensive, latency are long and sometimes there is not insurance of getting the equipment repair.

Problems of energy provisioning

Energy provides services to meet many basic human needs, particularly heat, motive power (e.g. water pumps and transport) and light. Business, industry, commerce and public services such as modern healthcare, education and communication are highly dependent on access to energy services. Indeed, there is a direct relationship between the absence of adequate energy services and many poverty indicators such as infant mortality, illiteracy, life expectancy and total fertility rate.

Modern energy sources, such as electricity and petroleum-based fuels, generally provide only a small part of the energy used by poor rural people. This is mainly because they are too expensive and sometimes it’s difficult to achieve regular supplies to isolated rural communities.

Around half of all people in developing countries are dependent for fuel on wood, dung and crop residue, collectively known as ‘traditional biomasses. While the use of traditional energy sources is not necessarily undesirable in itself, concerns have been raised over how they are currently being used. Concerns over traditional biomass fuels are:

- Efficiency: current practices tend to have low efficiency (~10%)
- Economic burden: time spent on collecting and using traditional fuels represents a significant burden
- Environment: use of fuel wood for energy can exacerbate deforestation, which often has effects such as loss of wildlife, soil erosion and increased flooding
- Health: cooking on traditional stoves is a major source of concentrated air pollutants, including respirable particulate in smoke and gases such as carbon monoxide and nitrogen oxides. For instance according to the World Health Organization (WHO), long-term exposure to smoke can increase the risk of a child developing acute respiratory infection by between 2 and 4 times. The WHO estimates that 2.5 million women and young children in developing countries die prematurely each year as a result of breathing the fumes from indoor biomass stoves.

As their economies will develop over the next few decades, the demand for energy services in developing countries is expected to increase considerably, especially in rural areas. Meeting energy demand in developing countries thus presents a significant challenge.

The optimum choice of technology for energy supply has to be specific to each location and depends on a number of factors including resources availability, affordability, and local capacity to access, use and maintain the technology. This means, it depends on the services and uses desired in each locality, as not all technologies are adequate and cost effective for particular end uses.

However, technology is not the only consideration, other factors are for instance:

- local preferences, attitudes and perceptions
- benefits, such as the creation of jobs associated with supporting industries

The options for energy supply in developing countries can be :

- Electricity: clean and efficient at the point of use, extending electricity grids is capital intensive and requires on-going maintenance.
- Small scale hydropower systems: these tend to have high capital costs but relatively low maintenance costs, a long service life, high operational reliability (given water availability) and low environmental impact.
- Solar energy systems (photovoltaic and solar thermal): they have few environmental impacts, but initial costs can be high. Maintenance and replacement may be difficult in isolated communities.
- Small scale wind energy systems: they tend to have high capital costs but low running costs. Supply is intermittent and so energy storage is necessary for reliability.
- Biogas and liquid bio-fuels (alcohols and vegetable oils): these tend to have low capital costs and are beneficial depending on products
- Improved biomass systems: this is focused on enhancing the use of biomass through technologies such as improved cooking stoves, aimed at increasing efficiency , reducing air pollution and providing energy that can be transform or store in the case of improved hospital waste incinerators.
- Hybrid systems: these provide a mix of energy sources for electricity generation and can frequently reduce costs, and ensure a reliable supply (e.g. wind and electricity grid extensions, waste incinerators and electric power…)

Insufficient know how in health technology assessment of those in charge of the acquisition of Equipment

One factor that appears to limit the operational time and life cycle of medical equipment in Africa and of course in Cameroon is his original state or characteristics. This is explained by the lack of involvement of technical staff during the equipment purchasing process (purchase and donation). 50% of technical managers and maintenance officers declare to not be involved during the development of the investment budget and certify that their involvement in this area is only to sign documents based on established priorities.

Indeed, if skilled maintenance personal doesn't get involved in the choice of material, it is normal that equipment's adequacy to the local needs and technical capabilities is sometimes nonexistent. Thus, the initial quality or state of the equipment appears as a factor limiting its lifetime.

In sum, work planning and forecasting required in the acquisition of medical technology, is really to improve.

Insufficient use of information and communication technologies for reporting and data reporting

The study on *"Stresses of biomedical technology management in Africa"* Jean Sagbo et al 2007, reveals that 80% of those in charge of health technologies management in healthcare structures didn't use any software of health technologies management. Among the 20% that have this kind of tool, many people say they do not use it for lack of sufficient training in the use of this complex software, computer knowledge or adequacy of nomenclature to the local situation. This lack of tools and lack of skills to exploit it explain the difficulty of the existence of an updated inventory. This situation limits the possibility of monitoring equipment in terms of maintenance and relevance of acquisitions, renewals of materials (list of needs not conform to the actual needs, absence of evidence on the facilities state, depreciation…)

III.1.2-Concept of appropriate technologies

The technological and human means available at health institutions represent today the essentials factors for an improvement of the offer of health services. The concept of appropriateness of a technology is highly relevant in health car technology management. The president of Cameroon, Mr. Paul Biya said in his speech to Cameroonian people: "We shall make effort to provide to our country health care system the capacity to response to the real needs of population by giving to the health institutions the necessary means of personnel, technology and medicines"

The appropriateness of a technology implies that technology meet for instance the followings requirements:

- manageable by local technical staff
- give an acceptable product in terms of accuracy and reliability
- solidity and durability in the climatic and environmental conditions of use
- can be used safely in the context provided (protection measures)
- can be easily disassembled for cleaning or maintenances operations
- Purchase costs, management, maintenance and repair must be sustainable according to anticipated resources available.
- Existence of adequate and conform facilities (water, electricity, spare parts…)
- Subject to regular quality control procedures
- Address to health problems resolvable at that level of the health system

In the purpose of improve the efficiency of the health care system by using appropriate technologies, a "Health Care Technology policy of Cameroon" have been realized since march 2009. This "Healthcare Technology Policy of Cameroon" present various areas of weakness in equipment management in the Cameroonian's Healthcare System. We can list:

1. Problem of identification of appropriate technology (failure to respect standards, choice of unsuitable equipment and materials)
2. Planning (lack of inventory, incoherence)
3. Acquisition (poor preparation of specifications, failure to respect specifications)
4. Use, maintenance and management (weak competencies, lack of support, management by crisis)
5. Budgetary provisions (insufficient funds for the management of healthcare technology)
6. Availability of qualified personnel
7. Governance (weak discipline in the management of resources, lack of contract management, insufficient transparency and control)
8. Regulatory mechanisms (lack of policy, non-existence of rules, failure to respect rules)
9. Hygiene and waste management

IV- Shisong Cardiac Centre clinical engineering service

IV.1-Staffing model

The Clinical engineering service can provide a great help to health services if its size is determined properly, i.e. when the number of staff member is proportionate to the activities and equipment that must be handled. It is not easy to deduce from analysis of already operating clinical services unique criteria to design a clinical service for there is a great diversity in services offered by clinical engineering services depending on the type of hospital and outside tech service available... More than thirty parameters including the amount of equipment, their types and ages, the complexity of use, complexity of maintenance have been found in a first attempt to list the variables that affect the workload of clinical engineering services.

The great variability of organizational structures and the number of employees also stems from the lack of strong standards regarding the frequency and accuracy of execution of periodic inspections and preventive maintenance of equipment in use and also from the great variability about the tasks assigned to the various clinical engineering services.

General parameters such as number of beds, the total value of equipment, the number of devices, devices types and ages, complexity of use and maintenance, can be used for the sizing. [18]

Basically the number of staff operators required depends on:

- How sophisticated the equipment is
- How much equipment is present
- the value of your equipment inventory (the value of your stock of equipment)
- the time it takes to attend to faults
- the number of equipment items not working
- maintenance management
- number of beds

The staff structure needed varies also by:

- The type of hospital: it can be teaching, community, psychiatric, specialty or urban, rural, governmental or a part of a multi-hospital system.
- Availability of outsourced technical support.

There are some rules of thumb for the number of staff members required. They can be useful when there is no other information available.

- One BMET (biomedical equipment technician) for every 100 -150 beds was a good ratio in early 1990s. But as more and more outpatient services are performed, this number has become less reliable.
- Another ratio that has been used is 1 BMET for every 400 items of equipment. This works out reasonably well in a large facility that has many thousands of devices (devices that can be classified in family example: families of the pumps).
- Other ways of staffing that have been used are one BMET for every special service such as intensive care, radiology, clinical laboratory
- One BMET for every 1,000.000$ USA of biomedical devices…

For the staffing 1 supervisor and 1 administrative each 8 or 10 BMET is appropriated.

The best tools for determining staffing needs are workload data and historical maintenance information. The reports of work orders provide information about type of equipment that usually needs to be repair or check and the amount of time required for different repairs or checks. One can consider preventive maintenance or scheduled work to determine the number of staff hours that are required. However preventive maintenance must be viewed realistically because almost no hospital can accomplish all the preventive maintenance that the manufacturers recommend.

An appropriate preventive maintenance program and scheduled works must be developed to avoid too little or too much expenditure of human resources.

There are many approaches to staffing a clinical engineering service but one aspect, however, is qualifying and decisive for the design of a clinical service: the definition of the activities that the clinical service should perform.

The proposed model of clinical engineering service for the Shisong Cardiac Center takes into consideration activities like: update inventory, acceptance testing, verification of failures, Training of medical staff and technical personnel, security checks, functional checks, procedures and planning purchases, management of maintenance contracts, first maintenance, scheduled maintenance, corrective maintenance, research and development, health technology assessment

An important feature of the model based on planned activities is the ability to estimate the staff required depending on the workload expected. This assessment requires the definition of activities that must be performed and parameters on which to estimate its workload.

The various levels of a Clinical Engineering Service can be for instance:

• First Level:

Updating inventory, out of use checks, acceptance testing, training of health operators and technical, security controls, preventive maintenance, reporting.

• Second Level:

Perform all the activities listed above and also functional checks, corrective and scheduled maintenance program, procedures and planning of purchases, management of knowledge resources, research and development, reporting.

IV.2-Survey results and interpretation

IV.2.1-Methodology

According to *Claudio Lamberti et al 1997* model, to each activity are set parameters that determine the correspondent workload. The most significant parameters appear to be the number of equipment (NE) and their global replacement value (RV) [19,20]

Clinical Engineering Service Activities	Parameters with which activities are related
Inventory Update (IU)	NE
Acceptance Tests (AT)	NE RV
Out of Use Checks (UO)	NE
Health Operators Training and Updating (HO)	NE RV
Technical Training and Updating (TT)	NE RV
Security Checks (SC)	NE RV
Functional Checks (FC)	NE RV
Scheduled Maintenance (SM)	NE RV
Corrective Maintenance (CM)	NE RV
Maintenance Contracts Management (MC)	NE
Health technology assessment(HT)	NE RV
First Intervention (FI)	NE
Communication and Reporting (CO)	
Administration and Books keeping (BK)	
Incident Investigation (II)	NE RV
Store House Management (SH)	NE

Table 2: Dependence of Clinical Engineering Service activities from Number of Equipment and their Renewal Value

The dependence on the parameters of the workload associated with each activity can be expressed as the product of that parameter to an appropriate coefficient, if the activity depends on both two parameters, then his workload is an expression of the linear combination of both two parameters. For instance the workload of a second level skilled operator (T), expressed in annual workload hours (AW_T) is given by:

$$AW_T = IU_T + AT_T + UO_T + HO_T + TT_T + SC_T + FC_T + SM_T + CM_T + MC_T + HT_T + FI_T + CO_T + BK_T + II_T + SH_T + GT_T$$

Where $IU_T = NE * W_{IU}$

With NE number of equipment, W_{IU} *coefficient associated to a second level skilled operator for that specific activity.*

$AT_T = NE * W_{AT} + RV * W_{AT}$ *with RV renewal value of equipments,* W_{AT} *coefficient associated to a second level skilled operator for this specific activity. The others are calculated in the same way*

So the number of second level skilled operators is given by:

$N_T = AW_T : HW_T$ *with* HW_T *as annual hour of work on the contract*

The estimated values of the coefficients are determined basing on experience and with data of similar hospitals. This is why it is essential a qualitatively and quantitatively valid data collection. Assigning a value of 0 to the coefficients some of the activities listed above can be removed of the calculus.

The number of administrative personnel is deduced assigning one person for each eight persons of the technical staff (technician or engineer)

An estimation of coefficient values has been made on the basis of experience and the data of some Italian Clinical Engineering Services.

Clinical Engineering Service Activities	**Hours (NE=1)**		**Hours (VR=516,460 euro)**	
	Eng.	**Tech.**	**Eng.**	**Tech.**
Inventory Update (IU)	0.015	0.15	0	0
Acceptance Tests (AT)	0.02	0.25	2	25

Out of Use Checks (UO)	0.03	0.2	0	0
Health Operators Training and Updating (HO)	0	0	4	3
Technical Training and Updating (TT)	0	0	6	6
Security Checks (SC)	0.015	0.15	1.5	15
Functional Checks (FC)	0.015	0.15	1.5	15
Scheduled Maintenance (SM)	0.025	0.4	2.5	40
Corrective Maintenance (CM)	0.02	0.8	2	80
Maintenance Contracts (MC)	0.075	0.15	0	0
Health technology assessment(HT)	0.1	0.05	14	5.5
First Intervention (FI)	0.02	0.2	0	0
General management & technical consulting	0.4	0.3	4	3

Table 3: Coefficients of the workload for an engineer and a technician in terms of number of hours per year and standardized to an equipment and a billion lire of value (516,460euro)

IV.2.2-Results and interpretation

Data of the Shisong Cardiac Center

Number of Equipment: 935 (medical devices + furniture related)

Global renewal value: 1,596,200 euros (= 3.09 x 516,460)

Contract Workload of an Engineer (skill level II): 44 hours/week x 48 weeks = 2112 hours

Contract Workload of a Technician (skill level I): 44h/w x 48 weeks =2112 hours

Clinical Engineering Service Activities	Yes=1 No=0	Eng. Hours	Tech. Hours
Inventory Update (IU)	1	14	140
Acceptance Tests (AT)	1	25	311
Out of Use Checks (UO)	1	28	187
Health Operators Training and Updating (HO)	1	12	9
Technical Training and Updating (TT)	1	19	19
Security Checks (SC)	1	19	187

Functional Checks (FC)	1	19	187
Scheduled Maintenance (SM)	1	31	498
Corrective Maintenance (CM)	1	25	995
Maintenance Contracts Management (MC)	1	70	140
Health technology assessment(HT)	1	137	64
First Intervention (FI)	1	19	187
Books keeping & reporting (BK)	1	50	30
General management & technical consulting (GT)	1	386	290

Total hours Engineer and Technician (AW_T)	854	3244	HW_T=2112
Number of Engineer and Technician (N_T)= AW_T **:** HW_T	0.40	1.54	
	Eng.	**Tech**	**Administrative**
Clinical engineering service staff	**1**	**1**	**0**

The data collected in the Shisong Cardiac Centre using *Lamberti et al 1997* model deduced from data of various Italian's healthcare Institutes consent us to deduce theorical results concerning the annual workload for each activity.

These results are obtained considering Shisong Cardiac Centre in a European environmental context. The fact is that from the experience on the field, there are many activities not relevant in Europe that becomes very critical in Shisong because of the environmental context, energy supply and people culture.

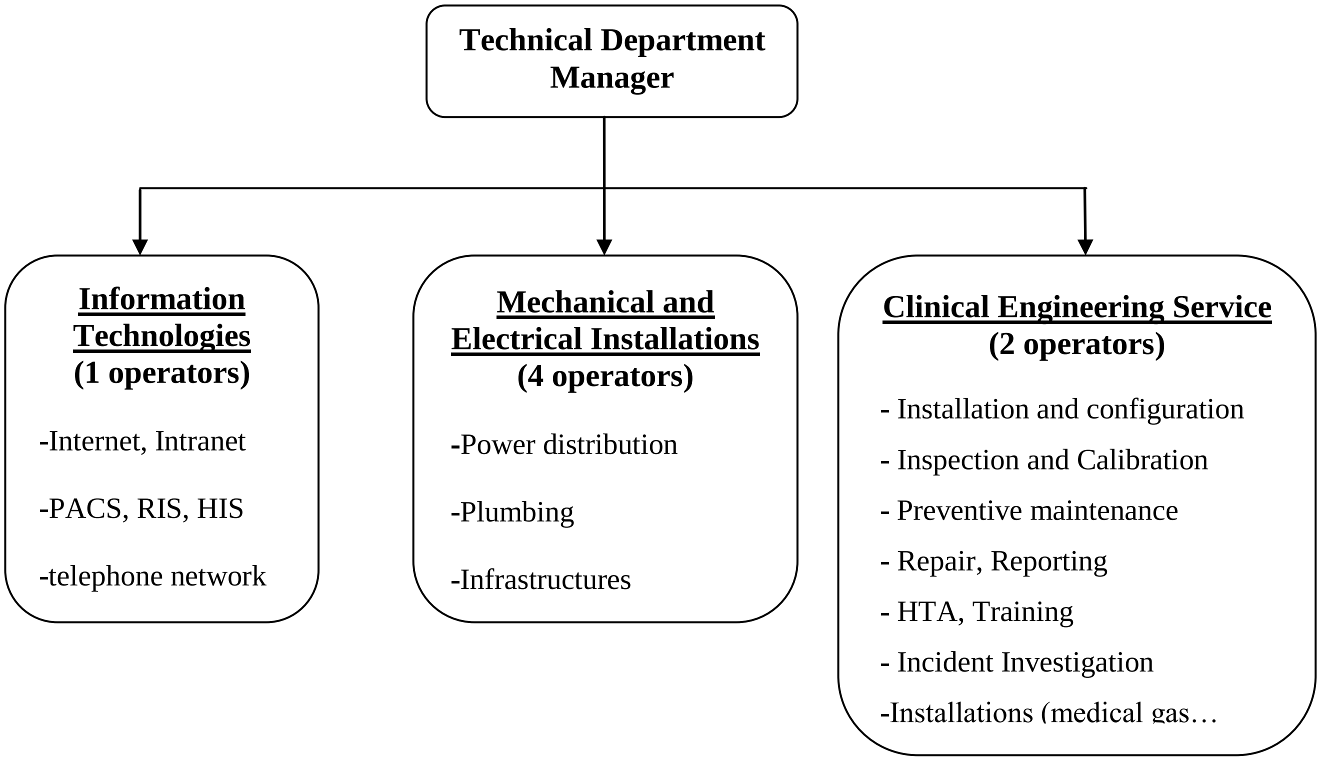
It has been noticed that some activities made time to time in Europe (once per semester) becomes routine activities (once per 2 weeks). It's the case of the preventive maintenance "cleaning of devices", training of medical operators or clinical service personnel, functional checks…

From the results (engineer: 0.40; technician 1.54), it's possible to define two type of staff:

- A staff of 2 technicians
- A staff of 1 technician and 1 engineer

In this specific case of Shisong cardiac centre many activities that can be outsourced in Europe as (some corrective maintenance, functional checks, trainings, installations…) are insourced. On the other side the clinical engineer should then act as engineer and as technician in order to have all the activities completed. The challenge in this case being to have operators very versatile and qualify to realize technician's tasks as well as engineer task. Knowing that the costs are different if the employee is engineer or technician it's wise to choose a staff with one technician and one engineer.

This schema can be an appropriate organization chart for Shisong technical engineering service for the first years.



Proposed Technical Department Organization Chart

IV.3- Biomedical equipment Policies and procedures

The Shisong Cardiac Centre is a small hospital in terms of patient's capacity, and number of biomedical devices. On the other side this hospital has many advanced technology for highly specialized clinical activities in a context of remote area of a developing country. This means that factors as: distance from specialized maintenance services, provisioning delays, limited funds and energy provisioning become very critical in the choice of health technology devices management strategies. It has been identify 6 strategic axes for a good medical equipment management at Shisong Cardiac Centre.

IV.3.1-Definition

Policies: statements of principles and values that guide organizational activities. Effective policies are flexible, coordinated, comprehensive, ethical, and clear

Procedures: defined and established methods used to achieve a specific objective

IV.3.2-Equipment Identification System

Devices are labelled and identified in a simple way for the first years: univocal intern code

- Furniture, which have a red label with code SCC-1-XXX upon. SCC stand for Shisong Cardiac Centre, -1- is an indicator for Furniture and XXX is the SCC identifying number for that specific furniture
- Biomedical devices which are attached yellow labels with code SCC-0-XXX, -0- identifies the device as biomedical, and XXX is the inventory number for the specific devices

For example: SCC0307 identifies an anaesthetic machine and SCC1010 identifies a plastic trolley.

Some devices are connected in order to have biomedical system, or just mechanical system. There isn't a system of codification for systems. The simple and quite efficient way to identify which equipment is connected to another one is column "connected to" in the equipment database. This allows us to know precisely which devices are connected together during functioning.

IV.3.3-Biomedical equipment inventory management

The biomedical equipment inventory is one of the most useful strategies for the management of many high-technologic medical devices in a remote area. The strategy employed here is to realize a very practical database of the entire medical devices. All the devices inserted are characterize by attribute such as serial number, model, date of installation, age, preventive maintenance, software version, incident reports and actions realized to repair …

The database must satisfy some requirement like:

- be updatable and modifiable only by the clinical engineering service
- be always update in order to present almost the exact situation of all the devices present in the Shisong Cardiac Centre
- be always available for the clinical engineering service
- be available even in remote

These requirements permit to be very specific during communication with technical helpdesk or manufacturers about maintenance repair, software upgrade or any other problems.
For instance in case of software upgrading or just user interface configuration it's very important to know exactly which version of software is currently present, which model of device, serial number, in order to interface well with may an application specialist of a manufacturer or technical helpdesk team. This is very important in situation of limited funds or time.
For the starting up a specific, very simple and efficient inventory is used (Annex A).
This current inventory in realize in Excel software and devices are identify by their univocal intern code and characterize by attributes such as: Inventory number, connected to, description, brand, model, serial number, supplier, contacts, conditions, unit, room, electrical test, functional test.

IV.3.4-Inspection and Preventive maintenance

Many developing countries currently take a corrective approach to the maintenance of medical equipment. This approach:

- is expensive
- requires a highly trained staff

This approach achieves only mediocre efficiency because maintenance is performed after major damage has been caused. Massive resources are the needed to restore the equipment.
Planned preventive maintenance is regular and repetitive work done to keep equipment in a good working order and to optimize its efficiency and accuracy. These activities involves regular, routine cleaning, lubricating, testing, calibrating and adjusting, checking for wear and tear and eventually replacing components (Annex G).
An appropriate preventive maintenance program and scheduled works must be developed to avoid too little or too much expenditure of human resources.
The strategy that can be used for planned preventive maintenance is productive preventive maintenance. Productive preventive maintenance refers to:

a-The proper selection of equipment to be included in planned preventive maintenance.
Decisions must be made to reduce costs; inexpensive units are not necessarily included in the planned preventive maintenance programme. The major consideration is ratio cost of maintenance/time life deviation (time life deviation means the difference between the life time and life time standard expectancy in our environmental conditions expressed in financial cost), the renewal cost of the device, and the frequency of use of the equipment.

A simple way to determine the benefit is based on the positive effect of maintenance on the useful life of utilities and equipment. Extending the life of assets(expressed as the prolongation factor) means that replacement occurs less frequently and this leads to savings in capital costs. The savings are then compared with the expenses for maintaining the assets. [21]

Annual savings = [(1-1/prolongation F.)/life expectancy without maintenance] x renewal Cost
Prolongation factor= life expectancy with maintenance / life expectancy without maintenance

b-Training of medical operators to preventive maintenance and realization of standard procedure to follow in order to avoid incident or devices damage
Preventive maintenance should start with users, and the bulk of the work should be their responsibility. The first preventive maintenance for every medical device is the proper use of it during clinical activities, for instance: the procedure of turning off a computer for image processing in angiography, monitor or simply avoid water leakage inside a device. Many specific control procedure must be performed daily before, during or after clinical activities, with joint activities involving the user and a technician engineer at the end of a define period of time.
Example: daily control of the temperature in Laboratory Unit.
Highly technical repairs or expensive repairs, which are the engineer's responsibility, may be scheduled every three or six months.

IV.3.5-Training

Trainings are critical and very core activity in a remote context in other to avoid incidents as seen in the paragraph before. A good training leads operators to be aware of the sources of risk, behaviours in case of incident but most of all, a well-trained personal using appropriate technologies guaranties a good level of performance (qualitative and quantitative) in health care. Training means also safety for operators, less damage for medical devices, more efficient work and a better output.
A good strategy will be to organize training with this priority:

- for every new device as soon as acceptance test are completed
- for every critical devices (devices with high safety risk for operators and patient, expensive devices)
- for very used equipment or procedure in order to increase the efficiency and efficacy

IV.3.6-Incident reporting and repair

A very great importance is gave to incident and repair reporting because the S.C.C is located in a remote zone with many advanced technologies, which are not always cover by manufacturer guarantee. The need of precise, complete reports of incident and repair procedures done to solve the problem is very high.

Basically when a problem occurs these steps are followed:

- Verbal then written report of the incident. This includes the definition by the user of urgency degree of corrective actions: Job orders (annex B)
- Clinical engineering investigation: this imply visual checks, complement of incident description including the circumstances, non-usual conditions of use, settings, alarms, this in collaboration with the user present during the incident
- Then all the information are analysed, hypothesis are made and corrective actions are taken.
- If the problem is not solve then the local Clinical engineering service contact the helpdesk service, the manufacturer or any other professional.

When the problem is solved all information are elaborated so that at the end: incident causes, interpretations and correctives actions are well known and archived. These reports are very precious resources of the knowledge management, training of users or technicians (Annex C).

IV.3.7-Health technology assessment in Shisong Cardiac Centre

One challenge of managing refurbished or just used devices is to know when invest in maintenance or invest in replacement. This is the case of Shisong Cardiac Centre

One basic question is what kind of benefit one can expect when investing in maintenance.

Predominantly qualitative expectations are connected to an improved quality of health care, safer treatments and even to reducing morbidity and mortality. It has been proved that rational maintenance can produce benefits too.

Comparative Cost Effectiveness of Maintenance: One classical approach to assessing cost effectiveness is to compare costs incurred by in-house services with the hypothetical costs of exclusive involvement of private service providers would cause. The productivity and overheads of the in-house service must be taken into account. The method is relatively easy to apply, if a good record system is in place.

The disadvantage is that it does not give direct clues about the question, whether to support a maintenance system or to prefer a replacement strategy in our case.

Interest-Related Cost Effectiveness: this theoretical approach is related to the fact that idle equipment (those waiting for repair) represents a non-productive investment. By recording the time idle and the investment value of equipment, losses can be calculated using the current average interest rate of money invested. This approach gives a more direct picture of, for instance the actual losses experienced by neglecting maintenance.

For the working level at health facilities, this kind of abstract analysis is of little help.

In view of the apparent weaknesses of those methods, a more problem-oriented formula is proposed to be used at Shisong Cardiac Centre

Life Expectancy Related Cost Effectiveness: A general effect of maintaining and repairing physical assets is, the prolongation of their useful life. Increased life expectancy can significantly reduce replacement expenditures and modifies lifecycle costs. In others words, this would mean comparing the accomplishable (efficiently maintained) life expectancy of a device with its life expectancy under poor maintenance conditions.

But how can such expenditure in developing countries be determined?

Sufficient and reliable data are not available because of the lack of relevant records. The only alternative would be to carry out surveys.

The savings (S) during the lifetime of an item achievable by rational maintenance can be calculated as follows [22]:

Re-investment costs (Rc), Difference between maintained and unmaintained life expectancy (D) Unmaintained life expectancy (U)

$$S = (Rc \times D)/U$$

The expenditures for maintenance must not exceed these savings. Otherwise one must consider either replacement instead of maintenance, or to reduce maintenance cost.

The expenditure ceiling for each device can be calculated as below

$$\text{Annual maintenance cost ceiling} = S/\text{Maintained life expectancy}$$

The following example with an electrical washing machine illustrates this

maintained life expectancy = 8 years

unmaintained life expectancy = 5 years

Re-investment costs approx. 4000 (simple model, approx. 10 kg capacity)

S = 4000x3/5 = 2400

Maintenance cost = 2400/8 = 300

Maintenance Cost in % = 300x100/4000 = 7.5% of the replacement cost per year

In other words, the hospital should not spend more than 7.5% of the value of that washing machine per year (overall costs including personnel).

It should be noted that relatively high maintenance expenditures shortly after installation and when approaching the end of useful life may occur.

If the best choice is to replace instead of maintain, criteria such as full cost (purchase, transport, training of operators, installation…) , availability of spare parts, availability of technical support in-house or outsourced, compatibility with the other technologies still used…financial and health benefits obtainable will be evaluated.

V- Future Improvements

Criticality Indicator

It seems very important to develop a particular intern devices indicator of criticality (Ic). This will be useful to identify which devices to focus more on, or to prioritize in maintenance or management.

This criticality indicator will be function of parameters such as full renewal cost with indirect costs of purchase (Rc), rate of use in medical activities (Ru), financial income related (Fi), level of technology complexity (Tc) from which it's possible to know if the devices can be fully maintain in-situ or not, frequency of failures (Ff)

This will required to collect data in-situ in order to obtain an average value for each parameter.

The Ic could be a weighted average of these parameter or have a non-linear relation with these parameters.

Conclusion

To set up a clinical engineering service in a highly specialized hospital like Shisong Cardiac Centre means:

- Identify exactly which activities has to be done by the clinical service (devices inspection, preventive maintenance, repair, training of operators, health technology assessment, functional test, safety test…)
- Size and staff the clinical engineering service according to the workload assessed. In our case using Lamberti et al model of staffing
- Inserted clinical service staff in an appropriate way within the already existent hospital organization chart. In our case the clinical engineering service is a part of technical department. Because of limited funds, the reduced size of the hospital…the scope is to have biomedical technician able to intervene also in other technical issues like electrical, mechanical, informatics.
- Identify the possible weaknesses in medical equipment management, undertake preventive and corrective actions.

The mains weaknesses in this case are:

- Absence of outside technical support because of the remote location of the hospital and lack of technician experts. Because of this the strategy of having valid back up when possible is used. Back up devices usually are gifted and old equipment still functioning and enough safe to guarantee a good quality of result even if it's for a limited period. Furthermore, various training have been organized in order to have at least one technician skilled for preventive maintenance, and various repairs for each type of devices.
- Training of technician and health professionals: training is very relevant in the case of Shisong Cardiac Centre for it's a fact that the more people are trained the less errors and incidents occur. The procedure to implement is the analysis of causes of every incidents and the documentation of the right corrective actions. The training becomes a dynamic process evolving with new equipment purchase and reported incidents or failures.

The analysis of clinical engineering issues at the Shisong Cardiac Centre shed light on the fact that for developing countries to have appropriated medical technologies, right policies and procedures of management, skilled technicians can lead to great improvement in healthcare system even in condition of limited funds.

Annex

A- Inventory of Biomedical devices at the Cardiac Centre

BIOMEDICAL TECHNOLOGIES DATA COLLECTION FORM

Form filled in

in Shisong ☐
for technical devices inventory

back at the headquarter ☐
for evaluating existing technology

notes/on the market ☐
for suggesting "ideal" technologies

Person who is filling in the form: ____________ Date: ____________

General data

Typology: ____________ Stationing: ____________

Producer: ____________ N° in the inventory: ____________

Model: ____________ Serial number: ____________

Country: ____________ Place/department: ____________

Department/place: ____________

State of conservation: ____________ State of use: ____________

Other/description: ____________

Economical data

OWNERSHIP

Purchased by TSSF ☐ Provider/where: ____________

Donation ☐ Donor/where: ____________

Regenerated ☐ Provider/where: ____________

Owner not TSSF ☐ Owner/where: ____________

PRICE (specify the type of currency): ____________ Real/estimated: ____________

AGE (in years): ____________ Real/estimated: ____________

Possible guarantees/contracts/technical assistance: ____________

Contact / person: ____________

Technical data

Mechanical functions (hydraulic/oil/gas/cylinder): ____________

Electrical functions (battery/electrical grid): ____________

Voltage: ____________ Power: ____________

Installation requirements if any: ____________

Replaceable parts: ____________

Available from: ____________

Consumables: ____________

Available from: ____________

Characteristics / functional description: ____________

Instructions available ☐

Medical equipment Database

Inventory ID				
Serial Number				
Model				
Description				
Connected to				
Brand/manufacturer				
Supplier				
Contact				
State of use				
Unit				
Room				
notes				
Electrical test				
Functional test				

B-Jobs order

JOB ORDER N°					
Type of equipment	Electrical ☐	Biomedical ☐	Informatics ☐	Priority High ☐ Normal ☐ Low ☐	Unit
Equipment Id code or Serial number					
Description of the problem or Job					
Name of the		Date and time		Date and time	

applicant		of start		of end	

C- Incident and repair report

INCIDENT AND REPAIR REPORT				
Univocal code /Serial Number	Type of device	Unit	Date and time of failure	Technician signature
Description of the failure				
Hypothetical causes of the failure				
Corrective Actions				

D- Daily checks

DAILY CHECKS OF TECHNICAL INSTALLATIONS

MEDICAL GAS CENTRAL									
Date	**Pressure Left O_2**	**Pressure Right O_2**	**Pressure Emergency O_2**	**Pressure Left N_2O**	**Pressure Right N_2O**	**Pressure Emergence N_2O**	**Taps and pipes checks**	**Technician name and Notes**	**Technical coordinator name and signature**
Mon.									
Tues.									
Wed.									
Thur.									
Fri.									
Sat.									

AIR COMPRESSED CENTRAL									
Date	Status on the control board	Oil level Comp. 1,2,3	Check of dryer 1,2	Check of line filters 1,2	Cleaning Air filter Comp. 1,2	Cleaning Air filter	Hours of work Comp. 1,2,3	Technician name and notes	Technical coordinator name and signature
Mon.									
Tues.									
Wed.									
Thur.									
Fri.									
Sat.									

VACUUM PUMP CENTRAL									
Date	Oil level pump 1	Oil level pump 2	Oil level pump 3	Check and cleaning of filters	Hours of work Pump 1	Hours of work Pump 2	Hours of work Pump 3	Technician name and Notes	Technical coordinator name and signature
Mon.									
Tues.									
Wed.									
Thur.									
Fri.									
Sat.									

WATER CENTRAL STATION									
Date	Sterilized water pressure	Fire fighting Water pressure	Toilet water pressure	Visual Check of tanks levels	Visual check of mains filters			Technician name and Notes	Technical coordinator name and signature
Mon.									
Tues.									
Wed.									
Thur.									
Fri.									
Sat.									

AIR TREATMENT UNIT (ATU)									
Date	**Visual check of ATU 1**	**Visual check of ATU 2**	**Alarm control ATU 1**	**Alarm time ATU 1**	**Alarm control ATU 2**	**Alarm time ATU 2**		**Technician name and Notes**	**Technical coordinator name and signature**
Mon.									
Tues.									
Wed.									
Thur.									
Fri.									
Sat.									

GENERATORS									
Date	**Check of gasoil tank level**	**Check of oil level**	**Cleaning of oil filter generator 1**	**Cleaning of oil filter generator 2**	**Cleaning of air filter generator 1**	**Cleaning of air filter generator 2**	**Generator in priority 1 or 2**	**Technician name and Notes**	**Technical coordinator name and signature**
Mon.									
Tues.									
Wed.									
Thur.									
Fri.									
Sat.									

GENERATORS									
Date	**Quantity of oil refilled in generator 1**	**Quantity of oil refilled in generator 2**	**Number of starts generator 1**	**Number of starts generator 2**	**Working hours generator 1**	**Working hours generator 2**		**Technician name and Notes**	**Technical coordinator name and signature**
Mon.									
Tues.									
Wed.									
Thur.									
Fri.									
Sat.									

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Figure 10: http://apps.who.int/nha/database/DistributionReportPage.aspx

Table 2,3: C. Lamberti, A. Panfili, G. Gnudi, G. Avanzolini, *A new model to estimate the appropriate staff for a clinical engineering department*, J Clin Eng 22(5) page 335-341, 1997

Extra-Academic Formation

May 2010 DRAEGER MEDICAL, MILANO - ITALIA

Configurazione, manutenzione preventiva e correttiva base dei sistemi per ventilazione respiratoria e anestesia: Evita 4 edition, Savina, Fabius GS

July 2010 SORIN GROUP, MIRANDOLA (MO) - ITALIA

Set up & handling, hardware structure, calibration, testing and troubleshooting, maintenance of heart lung machine Stockert III

October 2010 – Febuary 2011 ISTITUTO CLINICO SANT'AMBROGIO, MILANO-ITALIA

Intership in Clinical Engineering Service

October 2010- AICARR SEMINAR MILANO -ITALIA

Impianti termici e di climatizzazione per le strutture sanitarie: corso base teorico-pratico

February 2011 - March 2011 SIEMENS MEDICAL BRUSSELS - BELGIO

Technical Training for Configuration, diagnostic of trouble, preventive and corrective Maintenance of Angiography System: Axiom Artis and Axiom sensis xp

April 2011– May 2011, SHISONG CARDIAC CENTRE CAMERUN-CENTRAL AFRICA

Intership in Clinical Engineering Service, Shisong Cardiac Centre with "Associazione Bambini Cardiopatici nel Mondo"

June 2011 AIR LIQUIDE MEDICAL, BOVEZZO (BS) - ITALIA

Gestione e manutenzione dei ventilatori polmonari MT75

July 2011 HOSPAL GAMBRO, MEDOLLA (MO) – ITALIA

Prisma acute dialysis machine: Configuration, Maintenance

July 2011 METALARREDINOX, VERDELLINO (BG) - ITALIA

Corso manutentivo per Lava padelle e Lava strumenti

September 2011 CISA, POMEZIA (RM) - ITALIA

Maintenance and use of Steam Sterilizer Machine HB6410 , Autoclaves

September 2011 MEDRAD, CAVA MANARA (PV) - ITALIA

Manutenzione degli iniettori Mark V Provis

October 2011 SORIN GROUP, MIRANDOLA (MO) - ITALIA

Use and Maintenance: Autologous transfusion system: Electa Concept

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