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POLICY AND MANAGEMENT OF MEDICAL DEVICES FOR THE PUBLIC HEALTH CARE SECTOR IN BENIN

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Key words: Healthcare technology management cycle, value-based pricing, essential medical devices list

Abstract

Developing countries have very limited resources for procurement and management of medical devices. Usually, the resources that they do have, however, are not used in appropriate and optimal ways. Initial results of a study, supported by NUFFIC and conducted in Benin, are reported, identifying factors that adversely affect the healthcare technology management cycle of planning, budgeting, selection, procurement, distribution, installation, training, operation, maintenance and disposal of medical devices. Poor device management results in low overall community health effectiveness.

The study included surveys using semi-structured interviews with policy makers from the Ministries of Health and Finance and Economy, health facility managers, equipment users, maintenance technicians, managers of medical device companies and representatives of external support agencies.

Key factors identified so far include: high acquisition costs; lack of insight of the government on medical device market prices; lacks of capacity to monitor reasonable prices from suppliers; lack of insight in the cost/performance ratio of various brands of medical devices; an unequal distribution of devices among health care facilities; an unbalanced allocation of resources for acquisition of devices; infrastructure, and maintenance. Other key factors included the insufficiency of human resources with appropriate capacity to manage the equipment, the unavailability of spare parts, and the lack of an annual maintenance budget. In a nutshell, the lack of good medical devices national policy and management practice.

Preliminary results will be presented, starting with a list of essential equipment and of reference prices for the most widely used devices. The latter will allow health sector authorities to monitor financial diversion that may occur during procurement activities, while the former will serve as a reference to assess availability of fully operational devices at different health care facilities. The project aims to provide a basis for the development of basic legislation, empowering the Benin government to assure more cost-effective use of its resources for medical devices.

For a variety of reasons, the potential benefits associated with the use of medical devices purchased for the public health care sector of Benin are not fully realized. To improve upon the current situation, the magnitude of the problem and its contributory causes should be examined more systematically. Existing tools, such as value-based pricing, development of an essential medical devices list and technology assessment may be used, but should be tailored to the specific context of the country. Participatory approaches are more likely to produce more sustained effects than simple regulations.

Introduction

Healthcare technologies offer many benefits and have greatly enhanced the ability of health professionals to prevent, diagnose and treat diseases[11]. They are one of the essential elements for the delivery of health services. The use of technology in health care systems in developing and transition countries faces a great number of difficulties. Since about 95% of the healthcare technology used in these countries is imported[30]; mismatches occur because the technology development process has not usually considered the needs and realities of the target environments. These mismatches in the technology transfer process to countries with financial and technical constraints are often of great significance. Thus, in Benin, medical devices and equipment represent a significant proportion of national health care expenditure. Each year, more than 10,600,000 US$, (about 20%)[20] of the national health budget, are spent on procurement of medical devices and equipment for healthcare facilities. Despite this great amount of money spent each year on an ever-increasing array of medical devices and equipment, not enough attention is paid to how the equipment is selected or how it is used and maintained. The management of medical devices is not yet recognised as an integral part of public health policy. Planning, follow up and maintenance of the equipment are inefficient and ineffective [12, 13, 14, 15, 16, 17, 18, 19, 20, and 21].

This study, supported by the *Netherlands Organisation for International Cooperation in Higher Education* (NUFFIC) and conducted in Benin by the Ministry of Health and the University of Abomey-Calavi in collaboration with the Athena Institute, Vrije Universiteit Amsterdam aimed to identify factors appearing between 1998 and 2007 that adversely affected the healthcare technology management cycle i.e., planning, budgeting, selection, procurement, distribution, installation, training, operation, maintenance and disposal of medical devices. The results will allow us to identify the reasons underlying the mismanagement and critical maintenance system of medical devices in Benin and to formulate recommendations to improve the system. The first part of this paper gives background information on the country, its health system and an overview of its healthcare technology management situation. The second part describes the methods and materials used and the third part presents the results, followed by discussion, comments and recommend-dations in the final section.

Background information

Benin: The country:

Located on the West coast of Africa, the Republic of Benin is small (114,763 square kilometers), with a coastline on the Gulf of Guinea nestled between Nigeria, Niger, Burkina Faso, and

Togo (Figure 1). The population, estimated at 7,839,914 in 2006, includes a multitude of ethnic and linguistic groups. Benin remains one of the world's least developed country and has been ranked 163 of 177 on the United Nations Human Development Index (2005). Demographic and health indicators are given below (Table 1).

Figure-1: Map of Benin

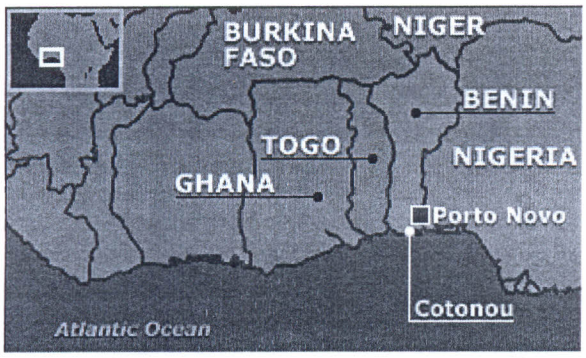


Table-1: Selected demographic and health indicators of Benin
Sources: Human Development Reports: 2007/2008, Benin Demographic and Health Survey 2006; Benin Health Statistics Directory 2006

Indicators	
Population in 2006	7,839,914
Human Development Index	0.437
Country rank	163/177
GPD per capita (Purchasing Power Parity US$)	1,141
Life expectancy at birth (years)	55.4
Public expenditure on health (% of GPD) in 2004	2.5
Health expenditure per capita (PPP US$) in 2004	40
Infant mortality rate per 1,000 live births	67
Maternal mortality ratio per 100,000 live births	474
HIV/AIDS prevalence (%)	2.0
Adult literacy rate (% ages 15 and older)	34.7

The health system:

The public healthcare system of the country has been reorganized according to the decentralization policy and consists of three levels: **central** with the National Referral Hospital (600 beds), **intermediate** with six (06) Province (Departmental) Hospitals and **peripheral** with thirty four (34) Health Zones, twenty eight (28) functional District or Zone Hospitals (in average 85 beds each), seventy seven (77) Communal Health Centers, four hundred eighty nine (489) Arrondissement Health Centers and five hundreds sixty two (562) Village Health Units and other private health facilities. Apart from that, the health system also has the following public hospitals: The Mother and Child Hospital, The National Center for Tuberculosis Treatment, the National Hospital for Psychiatry, the National Hospital for Gerontology, The Tuberculosis Treatment Center, Two Buruli Ulceration Treatment Centers, The Leprosy Treatment Center[12] etc…

Healthcare Technology Management and Maintenance

The application of organized knowledge and skills in the form of devices, medicine, vaccines, procedures and systems development to solve a health problem and improve quality of lives is the recent definition given by WHO of the term *health technology*[4]. When used in this paper, the term healthcare technology means the different types of devices or equipment used in health facilities. Its encompasses: medical equipment for clinical use; hospital furniture; vehicles; service Supplies; plant; communication equipment; fire fighting equipment; fixtures built into the building; office equipment; office furniture; training equipment, walking aids and workshop equipment.

Healthcare technology management and maintenance remains one of the main challenges of the developing countries healthcare systems in general and, of Benin particularly. Thus, although many financial resources are used for procurement of devices, not enough attention is paid to their future. While some of the equipment were donated, a significant portion was purchased with loans provided by bilateral and multilateral agencies and will have to be paid back with great sacrifice[26]. One of the root causes of the equipment idleness is the lack of good management. It is important to point out that despite the several initiatives undertaken by the ministry of health to improve the *healthcare technology management cycle* no significant changes have been noticed[13, 14, 15, 16 and 17]. Many facilities, especially Zone Hospitals, continue to lack the basic technologies they need to provide quality care to their patients, because equipment is unavailable, inoperative, misused or inappropriate. The situation is most severe in the Communal and Arrondissement health facilities far from the first referral hospitals. This has far-reaching implications for the prevention and treatment of disease and disability and often leads to a waste of scarce resources.

Materials and Methods

The study was carried out in the Ministry of Health, 321 healthcare facilities of the southern part of the country, the Ministry of Economy and Finance, some representatives of external support agencies in Benin and ten managers of medical device companies. It consisted of surveys undertaken in 2006 and 2007 and of desk research (content analysis) and, a short survey based on data collected from 1998 to 2007. We aimed to determine the factors that adversely affect the healthcare technology management cycle (planning, budgeting, selection, procurement, distribution, installation, training, operation, maintenance and disposal of medical devices) in Benin.

Desk research and short survey:

This study focused on the procurement management of medical devices in the Republic of Benin and aimed to identify the main weak points in the procurement management system of medical devices from 1998 to 2007. It was based on data colleted from documents (such as national procurement magazines and health equipment procurement and bidding contracts from the Ministries of Health and Economy and Finances), and on interviews and friendly discussions with ten managing directors of private companies supplying medical devices in Benin.

A comparative study was done concerning the selling prices of ten medical devices items procured by Benin Ministry of Health further to international tenders. The steps were i) We selected ten medical device items from the available essential medical device list according to their importance. ii)We determined their mean reference selling prices (based on their specifications) from 10 managers of medical device companies in Benin according to the prices the devices were sold in their shops and the prices the same devices were sold to the private health facilities. iii) We identified the mean prices at which the same devices were sold to the Ministry of Health following an international tender process, in three periods between 1998 to 1999; 2001 to 2004 and 2005 to 2008 when the procurement evaluation process has been changed and improved. iv) We compared the mean prices at which they were sold to the Ministry of Health to the mean reference selling prices provided by the companies.

Surveys

Two surveys were carried out in 321 healthcare facilities of the six southern departments (provinces). The first, entitled "management and maintenance of healthcare technology", was conducted in 2006 in 11 health centers and hospitals. It aimed to identify the weaknesses in the healthcare technology management and maintenance system in order to make recommendations for its improvement. Data were collected through observation visits, interviews and questionnaires. The second, entitled "healthcare technology assessment in the southern Benin public healthcare facilities" was carried out in 310 health centers and hospitals between 2006 and 2007. The first objective was to determine the extent of disparity between what medical devices/equipment were planned and what was actually available in each selected health facility to facilitate procurement for the poorly equipped health facilities of the essential medical devices. The second objective was to identify weaknesses in the whole Benin healthcare technology management cycle. Data were collected through observation visits and reading reports, interviews, and questionnaires (inventory sheets). The steps were i) We did equipment inventory of all the public healthcare facilities in southern Benin; ii) We compared the healthcare equipment in these facilities to the Ministry of Health Essential Medical Device List of each health facility level iii) We did needs assessment of each healthcare facility using asset assessment soft ware ITODJU-EQUIP. Finally, interviews were held with a range of stakeholders including policy makers from the ministries of Health and Finance & Economy, healthcare facility managers, equipment users (physicians, nurses, midwives, lab technicians, X-ray machine technician ....) and, maintenance technicians.

Results:

The results of the study are summarised in Tables 2 to 5 and graphs 1 to 3. Tables 2, 3, 4 and graphs 1, 2 and 3 show the mean reference selling prices of selected medical devices in comparison with the price of the same devices as sold to the Ministry of Health from 1998 to 1999, 2001 to 2004 and 2005 to 2008. The ten equipment studied were: 1) blood pressure device 2) spectrophotometer 3) electric suction unit 4-) Electrocardiograph 5) X-ray apparatus 6) hot air sterilizer 7) autoclave 8) ventilator 9) anaesthesia system and 10) blood bank refrigerator.

The letter X that may be a, b, c, d, e, f, g, h, i or j represents respectively the selling price in (FCFA: Benin currency) of each equipment to the Ministry of Health, through tenders. The letter Y that may be A, B, C, D, E, F, G, H, I or J are respectively the reference selling price (FCFA) of the same equipment

Desk research and short survey:

Table 2: Comparison of the mean reference selling prices of medical devices to the price paid by Ministry of Health, 1998 to 1999.

Equip No	Selling price (FCFA) to the MoH by tender (X)	Reference selling price (FCFA) (Selling price to the private hospital by the same supplier) (Y)	(X)/(Y) Ratio
1	a	(A= 0.32a)	3.13
2	b	(B= 0.25b)	4.00
3	c	(C= 0.35c)	2.85
4	d	(D= 0.42d)	2.38
5	e	(E= 0.47e)	2.12
6	f	(F= 0.42f)	2.38
7	g	(G= 0.45g)	2.22
8	h	(H= 0.35h)	2.85
9	i	(I = 0.30i)	3.33
10	j	(J = 0.43j)	2.32
			Mean= 2.75

Graph-1: Comparison of the mean reference selling prices of medical devices to the prices paid by the MoH

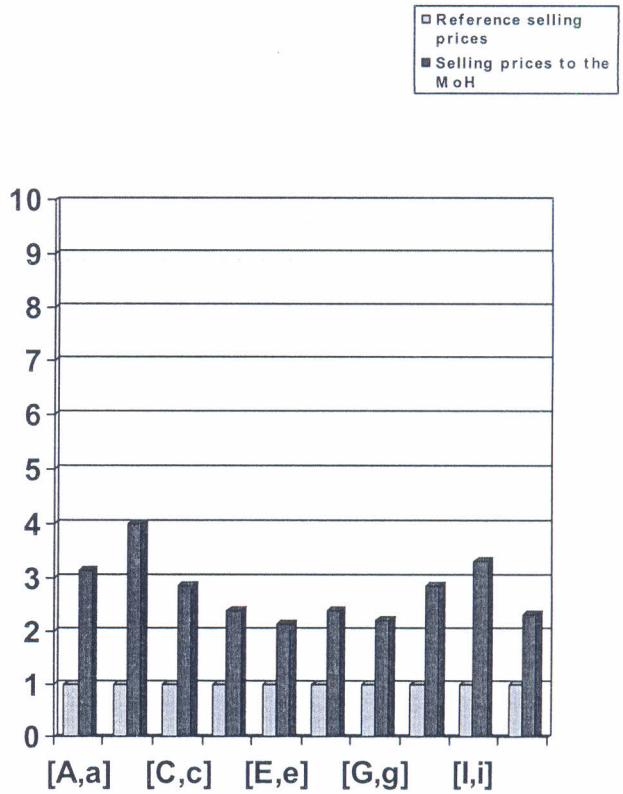


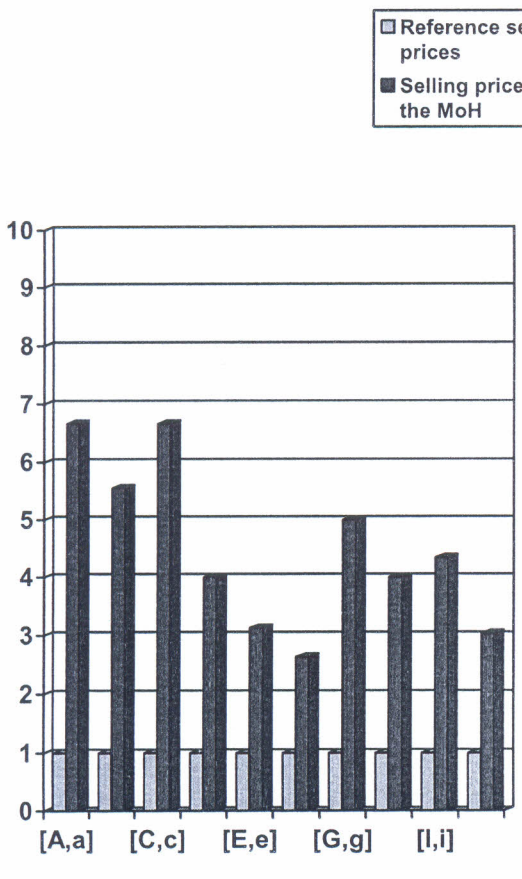
Table 3: Comparison of the mean reference selling prices of medical devices to the price paid by they have been sold to the Ministry of Health, 2001 to 2004.

Equip No	Selling price (FCFA) to the MoH by tender (X)	Reference selling price (FCFA) (Selling price to the private hospital by the same supplier) (Y)	(X)/(Y) Ratio
1	a	(A= 0.15a)	6.66
2	b	(B= 0.18b)	5.55
3	c	(C= 0.15c)	6.66
4	d	(D= 0.25d)	4.00
5	e	(E= 0.32e)	3.13
6	f	(F= 0.38f)	2.63
7	g	(G= 0.20g)	5.00
8	h	(H= 0.25h)	4.00
9	i	(I = 0.23i)	4.34
10	j	(J = 0.33j)	3.03
			Mean= 4.50

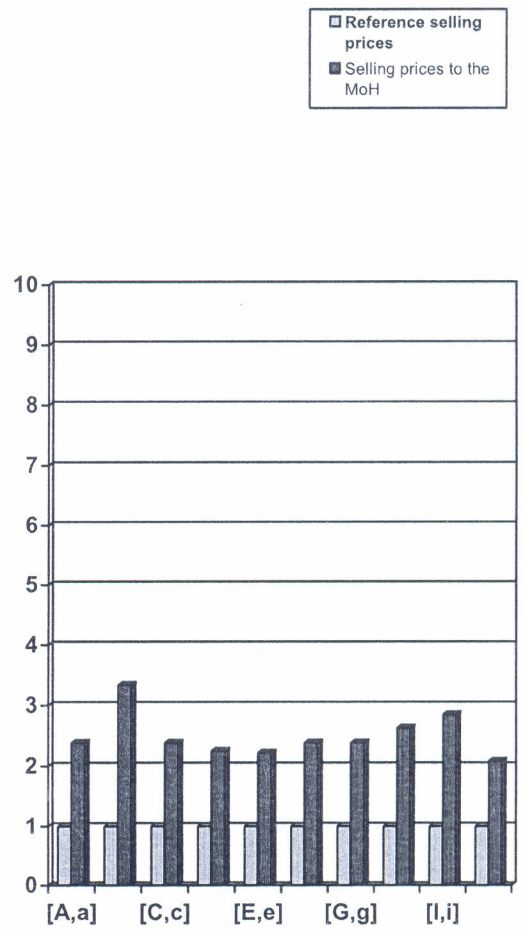
Table 4: Comparison of the mean reference selling prices of medical devices to the price they were sold to the Ministry of Health, 2005 to 2008.

Equip No	Selling price (FCFA) to the MoH by tender (X)	Reference selling price (FCFA) (Selling price to the private hospital by the same supplier) (Y)	(X)/(Y) Ratio
1	a	(A= 0.42a)	2.38
2	b	(B= 0.30b)	3.33
3	c	(C= 0.42c)	2.38
4	d	(D= 0.40d)	2.25
5	e	(E= 0.45e)	2.22
6	f	(F= 0.42f)	2.38
7	g	(G= 0.42g)	2.38
8	h	(H= 0.38h)	2.63
9	i	(I = 0.35i)	2.85
10	j	(J = 0.48j)	2.08
			Mean= 2.48

Graph-2: Comparison of the mean reference prices to selling prices of medical devices paid by the MoH



Graph-3: Comparison of the mean reference prices to Selling prices of medical devices paid by the MoH



Surveys1 and 2:
1: Management and maintenance of healthcare technology.
2:Healthcare technology assessment in the southern Benin public healthcare facilities and hospitals.

Table 5: Factors affecting the healthcare technology management cycle in 321 health centers and hospitals in southern Benin.

	Factors
1	Unequal distribution of devices within the centers
2	No after-sales service
3	Inadequate equipment (because of technical constraints like electricity
4	Heavy equipment procured but no location to install it
5	Multiplicity of marks due to the multiple acquisition sources
6	Unavailability of many equipment
7	Misuse of equipment
8	Inappropriate technology for the site, size, capacity of health facility
9	Lack of resources (financial, material and human resources) for maintenance
10	Lack of good maintenance planning
11	Lack of equipment assessment
12	Lack of availability of equipment spare parts
13	Lack of equipment user instruction documents
14	Lack of annual maintenance budget
15	Lack of technical instruction documents
16	No involvement of the equipment users in the administrative acquisition process
17	No asset management tools (software)
17	Lack of follow up of equipment
18	Lack of information on the acquisition cost

The key factors that have been identified so far include the high acquisition costs; the lack of insight of the government on medical device market prices, the lack of capacity to monitor reasonable prices from suppliers, the lack of insight into the cost/performance ratio of various brands of medical devices, an unequal distribution of devices among health care facilities, an unbalanced allocation of resources to acquisition of devices compared to infrastructure, and maintenance. Other key factors identified included the insufficiency of human resources with appropriate capacity to manage equipment, the unavailability of spare parts, and the lack of an annual maintenance budget. In a nutshell, the lack of good medical devices national policy.

Discussion and recommendations

Goods acquisition, especially healthcare technology, represents an important part of any health budget and need to be looked with close attention. Through the results shown in Tables 2, 3 and 4 and, graphs 1, 2 and 3, it is clearly seen that, independently of the procurement years, the devices acquisition costs by the Ministry of Health remain higher than market costs. improved during the years 2001 to 2004 and also from 2005 to 2008, no significant improvements were found regarding the higher cost of medical equipment paid by the Ministry of Health. It is important to deeply understand the real reasons that underlie this phenomenon. Thus, widely surveys need to be done on the behaviour of some stakeholders especially in our next papers on "medical devices procurement management in Benin".

The Ministry of Health still needs a national financial tool like a list of reference prices of the most widely used devices to overcome and to master the increasing medical device prices. It is normal to have the device acquisition costs paid by the government a bit higher than the reference set prices because of financial and administrative fees involved when the suppliers submit tenders. It is acceptable and reasonable to have the average device selling prices comprised between **1.1 to 1.2 times** the set reference prices. But, when the device selling prices are over than that, one can be considered as *a suppliers outbidding*. It is thus urgent for the Benin government to have insight on that fact, to encourage the development of policies and laws regarding a reference price lists document of medical devices. The availability of the reference prices of the most widely used devices will allow the health sector authorities to monitor the usual financial diversion occurring during the procurement activities. It is expected that once this document becomes available, the Ministry of Health could each year save a lot of money which can be used to improve the health of Benin population through other investments.

The results of the two surveys: i) "management and maintenance of healthcare technology" and ii) "healthcare technology assessment in the southern Benin public healthcare facilities" have revealed many weaknesses in the Benin health system through its healthcare technology management cycle. The results show failures in each link of the cycle (planning, budgeting, selection, procurement, distribution, installation, training, operation, maintenance and disposal of medical devices) resulting in low overall community health effectiveness. As recommendations, twenty actions need to be taken by the government to overcome this situation in order to achieve its goal to improve the quality of/and access to health services that taking into account the poor and indigent. It is thus urgent to develop and implement a good medical device national policy which can include the following: i)An improved national list of essential medical devices and equipment based on evidence from the studies; ii) A national policy and plan for medical devices; iii) A national functional regulation authority in medical device empowered with legislation; iv) A document on assessment of medical device needs; v) National regulations based on ISO standards or WHO specifications; vi) National procurement procedure; vii) National policy for acceptance of donations; viii) Negotiated pricing list of each item of equipment; ix) National guide for management and use of medical devices; x) An inventory of suppliers and medical devices in use; xi) The cost of all the equipment of each level of Benin health facility related to the cost of infrastructure; xii) The service life of each medical device or equipment in use in Benin health care facility or hospital in order to plan the replacement at a systematic time; xiii) The list of medical devices which have the highest risk;

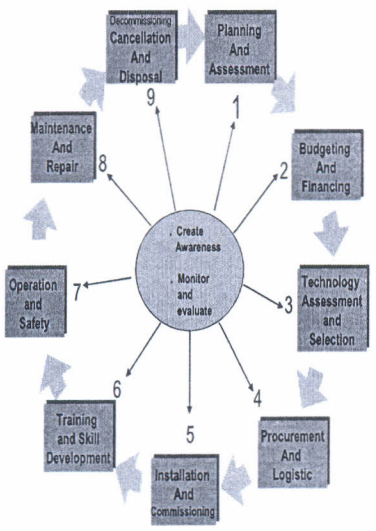
Although the Benin Goods and Services Procurement Code has

xiv) The spare parts which have the highest failure rate in order to plan their procurement; xv) The list of critical equipment and instrument affected by the electrical power outages and power anomalies in Benin hospitals; xvi) Good software based planning and management tools for management and maintenance of medical devices; xvii) A post-market surveillance/vigilance system for alerts, notifications and recalls; xviii) A national budget for devices, using costing, budgeting and financing; xix) Standard operating procedures and best practices that cover every stage in the life span of medical devices; xx) Creation the Direction of Healthcare Technology Management and maintenance within the Ministry of Health.

The following Healthcare Technology Management Cycle could be used as a framework for health equipment management in developing country, providing a guideline for the necessary regulations and systems.

The Healthcare Technology Management Cycle[11]:
An example of a framework for health equipment management in developing country

The Healthcare Technology Management Cycle



Conclusion

Management and maintenance of healthcare technology in developing countries especially in the poor countries of sub-Saharan Africa, remain a challenge. From the planning to the disposal of the devices many actions need to be undertaken to improve the Healthcare Technology Management Cycle. The achievements in the health sector depend on the full involvement of each stakeholder, but the main responsibility is still the government's. They need the political willingness and commitment to recognize the management and maintenance of devices as an integral part of public health policy in order improve the quality and access to healthcare in each country.

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