
Clinical Engineering & Equipment Policy for Sao Paulo State, Brazil

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A comprehensive equipment policy was established for the health system of Sao Paulo State, Brazil. Research, development and regulation issues were integrated with all phases of the equipment life cycle, including: planning, procurement, acceptance testing, commissioning, maintenance, repair, refitting, and decommissioning. This policy was implemented by a multidisciplinary group, which advised and coordinated planning and procurement, created a technology management and maintenance network composed of clinical engineering teams and reference centers, and worked closely with manufacturers, universities and research institutes to improve the quality and increase the variety of domestic medical products in order to substitute for imported devices.

Index Under: Equipment Policy, Planning, Equipment; Healthcare Equipment Policy; Maintenance; Management, Equipment; Procurement, Equipment; Regulation, Equipment.

INTRODUCTION

In 1987, all health services within the state of Sao Paulo, Brazil, began a restructuring process. All public services belonging to federal, state or city governments, as well as philanthropic institutions, were consolidated into a single system. This included about 560 hospitals (with a total of about 85,000 beds), 2100 outpatient health centers, and ten research and manufacturing facilities. At the same time, the administration was decentralized by dividing the state into five divisions, with a total of 63 regions. Greater autonomy was given to the divisional and regional health authorities. Furthermore, the new system gained control over the services provided by the private sector, which used to be paid and supervised directly by the Federal Government's **Social Security Administration** without any input from the state authority. The unified system, together with private institutions, provides care for about 33 million residents of the state of Sao Paulo and several million more people from other states and neighboring countries.

From the beginning of the reorganization, it was clear that healthcare equipment needs required urgent attention. Besides being essential for healthcare delivery, equipment is expensive to acquire, use and maintain, and requires

highly qualified personnel. Poor equipment management has caused enormous loss to healthcare services in Brazil and other Third World countries (Russel, 1982; World Health Organization, 1987).

This paper describes the healthcare equipment policy devised and implemented for Sao Paulo State's public health system since May 1987, and presents the results that have been achieved.

AN INTEGRATED HEALTH EQUIPMENT POLICY

Because of the reorganization, the system had three major roles with respect to technology: 1) as the main consumer, its purchasing power could be used to induce research and development, resulting in quality improvement and introduction of new products; 2) as public health authority, it would be responsible for regulating the manufacture and sale of all devices; and 3) as the main service provider, it should set a proper example for technology management.

A policy for equipment was, therefore, devised integrating the issues of research, development, and regula-

tion with all phases of an equipment's life cycle within a health institution. The policy includes planning, procurement, acceptance testing, commissioning, maintenance, repair, refitting and decommissioning, (Figure 1), with the ultimate goal of controlling capital and operating expenditures while meeting the actual population needs.

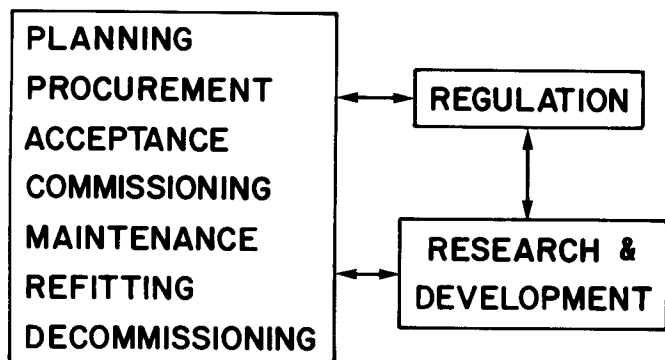


Figure 1
Basic elements of the equipment policy.

To implement this new policy a technical group, known as the "Office of Equipment Advisor" (ASEQ), was created. The ASEQ is staffed with professionals in medicine, public health, nursing, nutrition, clinical and biomedical engineering, architecture, and computer sciences. Subordinated directly to the Secretary of Health, it was responsible for all issues regarding equipment, and served as a link between the Health Secretariat and other sectors of the state government, as well as equipment manufacturers and suppliers.

The activities and achievements of ASEQ in its almost three years of existence are reported below, divided into three parts. The first describes planning methods, procurement practice, and management of major loan projects. The second explains strategies used in the establishment of clinical engineering services and reference units. The last delineates how research, development and quality improvement by domestic manufacturers were encouraged.

PLANNING AND PROCUREMENT

Before the creation of ASEQ, equipment planning was made independently by physicians or surgeons, outside consultants, architects, and nurses, most of whom had little experience with modern healthcare technology. Furthermore, there was no established approval process, so the requesting party could, and often had to present his or her case directly to the highest authorities he or she was able to reach.

The new policy requires equipment planning to be initiated by the chief of the requesting service. The responsibility for approval is scaled according to cost and impact: low-cost items with impact limited to a small population (such as a stethoscope) are managed directly by small

institutions or local authorities who must submit a lumped annual budget to their superior; medium-cost items with regional impact (such as an ECG monitor) are handled by large hospitals or regional directors, who must list all necessities in their annual budget; and high-cost items with wide impact (such as a complete X-ray system) must receive positive recommendations by regional and divisional authorities and can only be approved by the Secretary of Health, after reviewing the justifications put forward in the request. Procurement follows the same rule: local suppliers for low-cost items; limited bidding for medium-cost items; and open bidding for the most expensive items (Figure 2). Thresholds were set around 400 and 6400 U.S. dollars, respectively, but can be revised promptly.

When equipment has to be imported because of the lack of a locally made equivalent, ASEQ requests that the equipment be included in one of the international loan projects available to the Secretariat of Health. These projects are usually managed directly by ASEQ because all procurement and follow-up have to be handled by a single office due to accounting needs and high-cost of the equipment involved. Such equipment involves sophisticated items such as CT scanners, gamma cameras, and radiotherapy units. Although the total amount of loans managed was about U.S. \$220 million, only about U.S. \$15 million worth of equipment was actually delivered by the end of 1989. This was primarily due to the need for innumerable approvals by federal authorities and delays caused by renegotiation of Brazilian foreign debt. Hopefully the rest of the requested equipment will be delivered and commissioned within the next few years.

Whenever requested, ASEQ participated at all levels, helping physicians, nurses and other professionals find an appropriate instrument, update an outdated imaging department, or plan equipment for an entire new hospital. Furthermore, it advised the Secretary on the approvals necessary to purchase high-cost equipment, which have to be planned on a statewide basis.

In order to facilitate equipment planning and approval by all concerned, ASEQ systematically acquired information about domestic and imported equipment. This information is distributed through a computerized database system (known as SISCON) covering all domestic equipment (about one thousand different types and capacities), with standard nomenclature and codes, detailed technical specifications, estimated costs, main suppliers and potential clinical users (Wang, 1988). This database is currently used by over one hundred public health authorities in Brazil and by several other Latin American countries.

Because procurement often used to be managed by administrators, nurses and physicians with little technical background, ASEQ had to develop a standard bidding document with specific requirements about training, warranties, after-sales service and technical specifications. Occasionally, ASEQ also had to coordinate some large procurements and follow-up on them until all equipment was accepted after proper testing by users and clinical engineers or biomedical equipment technicians (BMETs).

ORIGIN/ COST	IMPACT	PLANNING	PROCUREMENT
IMPORTED (LOAN)	REGIONAL DIVISIONAL	JUSTIFIED REQUEST	INTERNATIONAL BIDDING
NATIVE > \$ 6,400	DIVISIONAL	JUSTIFIED REQUEST	CENTRAL/ REGIONAL BIDDING
\$400 - 6,400	REGIONAL	LIST OF NEEDS	REGIONAL BIDDING
< \$ 400	LOCAL	LUMPED BUDGET	LOCAL SHOPPING

Figure 2
Equipment planning and procurement guideline.

In one project, ASEQ had to be involved in every step, from planning to acceptance testing. The **Metropolitan Health Program**, financed in part by the **World Bank**, was established in 1986 to renovate and equip 38 health centers and 3 hospitals, as well as to build 86 new health centers and 5 new community hospitals. A consulting company was initially contracted to plan and supervise the entire equipment process. After concluding 21 new health centers, 38 renovated ones, and 2 renovated hospitals, however, it became clear that the results were unsatisfactory and the cost prohibitive. So in July 1988, ASEQ was called upon to assume full responsibility for the equipment part of the program. By the end of 1989, ASEQ was able to deliver 40 completely equipped health centers and conclude some of the bidding processes needed to equip the five new hospitals and the last renovated one. Actually, all units would have been equipped if there had been no financial shortages and construction delays, as all the necessary technical and administrative preparations had been made. Although the total budget for equipment was only about U.S. \$20 million, this program demanded a large amount of manpower and served as a good test of the competence of the ASEQ staff.

Management and Maintenance

One of the top priorities of the new policy is management and maintenance of equipment. A previous study (Wang, 1986a) indicated that the situation was critical. A large portion of equipment was not functioning because of a lack of repairs or parts. Some units were cannibalized for the repair of others, many needed refurbishing, and

some should be decommissioned due to obsolescence.

Therefore, an equipment management and maintenance program was created with the aim of maximizing equipment availability for healthcare delivery and, at the same time, reducing the costs of maintenance. To achieve this goal, a strategy was adopted to promote and improve in-house management, maintenance and repair of equipment throughout the system by establishing a statewide network of technical services. These are provided by teams with different levels of competence, supported by regional and statewide reference centers. Besides service, these teams also provide expertise for equipment planning and acquisition, implement safety measures, and investigate accidents involving equipment (Wang, 1986b).

In this process, ASEQ acted as a catalyst, and was always willing to help any hospital or regional health authority create its own in-house clinical engineering team, but never to impose it. To make the program more attractive, ASEQ shared some of the start-up costs. This typically includes the hiring and training of an initial team (usually one engineer and up to four BMETs), and the purchase of certain testing and calibration instruments. Meanwhile, the host institution is responsible for supplying tools, facilities and staff, and paying for the operating costs.

The demand has been much larger than the financial resources available and, primarily because of difficulties in finding qualified personnel, ASEQ had to define criteria for establishing a queue of interested institutions. First, higher priority was given to larger hospitals and research institutes. These facilities have higher concentrations of technology and are more vulnerable to breakdowns, thus offering the potential of achieving significant savings. The second criteria was the degree of commitment that the in-

stitution's administration was willing to demonstrate, especially in sharing the initial investments and in providing facilities.

Following the strategy and criteria described above, 14 teams were established, made up of a total of 16 engineers and 21 BMETs. Most of these teams are responsible exclusively for medical equipment, while others also take care of supporting equipment (such as generators, boilers, sterilizers and air conditioning systems) and, occasionally even the physical plant because of the lack of service personnel in many institutions.

Two reference centers have also been engaged. The **University of Sao Paulo's Institute for Electrotechnique and Energy** agreed to give support for radiology equipment, while the **State University of Campinas' Center for Biomedical Engineering (CEB/UNICAMP)** provides assistance on complex electronic equipment, such as ultrasound imaging systems and analytical laboratory instrumentation. These institutions also serve as testing laboratories for certifying new products introduced by domestic manufacturers.

A "Technical Reference Library" for archiving documentation related to healthcare equipment, especially service manuals and corresponding circuit diagrams and mechanical drawings, has also been arranged through CEB/UNICAMP. The purpose is to have, within a single place, back-up copies of all material regarding new instrumentation purchased for the health system, as well as whatever information it has been possible to secure about the existing equipment. If someone loses their own operating or service manual, a copy can be obtained from this reference library.

One of the top priorities of the new policy is management and maintenance of equipment.

In order to train the newly hired people, as well as existing service personnel, over 130 training courses were organized in 1988 and 1989 by ASEQ, mostly with assistance from manufacturers and their distributors. Furthermore, 14 persons were sent abroad to the United States and Japan through cooperative programs with hospitals, corporations and government agencies. This allowed participants to receive in-depth service training and acquire management experience. To compensate, albeit incompletely, for the impossibility of giving all teams the same level of expertise in all areas, ASEQ also took the responsibility for coordinating tasks that needed special skills, exchanging highly specialized technicians between institutions.

Finally, a PC-based, computerized management system (known as SISMAN) has been developed to give clinical engineers an analytical tool for controlling both equipment and all the services they supervise (Wang, 1989). Thus, a certain level of uniformity for cost control and productivity management can be achieved. This computerized system is also currently being used by clinical engineers

in other states of Brazil and in some Latin American countries.

Research, Development and Regulation

Working closely with the **Brazilian Health Device Manufacturers' Association** and the regulatory branch of the Health Secretariat, ASEQ tried to induce improvements to domestic products and decrease the number of imported devices. For this purpose, ASEQ periodically provided the association with projected needs of the health system. This information, together with the required minimum technical specifications and the bidding judgement criteria, allowed the manufacturers to prepare themselves beforehand. Furthermore, by taking into consideration quality certification provided by official laboratories (such as the two reference centers mentioned before) in bidding evaluations, closer working relationships among manufacturers and R&D institutions have been fostered. Based on these initial contacts, many improvements in existing products and new developments have resulted.

DISCUSSION

In spite of the increased awareness of the necessity of management of healthcare technology in the last five to ten years, it is actually quite rare to find a health system that has an established policy for equipment, particularly in a Third World nation (World Health Organization, 1987). Even in developed countries, the notion of comprehensive technology management is only starting to gain ground (ECRI 1989; Blackwell, 1989). Most health systems and hospitals are still only concerned about satisfying accreditation requirements for safety standards and quality control. Increased expectations regarding safety and quality of healthcare, and growing concern about escalating costs, have made it clear that equipment management will become a major issue in the next decade. This is especially apparent as there are data to prove that higher quality care actually is correlated with lower costs and greater market shares (Burda, 1989).

The policy outlined above has been implemented gradually since May 1987. Although considerable progress has been achieved, it is difficult to measure the results, as many benefits cannot be quantified and do not have a direct, immediate impact on the bottom line. Some actually only have long-term effects. There is general agreement among healthcare administrators, however, that the policy has contributed significantly to improved planning, procurement, distribution and replacement of equipment. In addition, better management and maintenance have allowed savings in service costs and increases in productivity, because of reduced down time. Naturally, further benefits will be realized if this policy continues, in spite of future political changes.

Although the policy described here is intended only for the health system of Sao Paulo State, its impact has been

noticed well beyond state borders (Cordeiro, 1990). Several other states of Brazil and some other Latin American countries are applying the rules and methods described here or, at least, using the databases, computerized management system, standard bidding documents, and management models developed by ASEQ.

One fundamental aspect deemed critical to the success of the policy is the integration of all issues related to equip-

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ment. Planning and procurement, which used to be handled solely by public health planners, administrators, and physicians with little knowledge and experience in technology management, benefited by feedback from experienced users and clinical engineers. At the same time, the clinical engineers gained from the purchase of more appropriate devices and equipment, which were also less difficult to service. Furthermore, with the help of testing institutes, manufacturers were willing to bring out better products because of fairer bidding conditions. Also, they were able to simultaneously avoid possible problems with the regulatory authorities.

Another key to success was the multidisciplinary approach used to implement the policy. No single person or discipline can claim to know everything about healthcare technology. Putting together about 25 professionals with differing backgrounds and experience in a multitude of disciplines was a most gratifying experience. Besides learning from each other, the quality and comprehensiveness of the work thus produced exceeded all expectations, and thus made ASEQ widely respected by manufacturers, doctors, users and engineers alike, even when their private interests were sometimes impaired.

The need for and the advantages of in-house clinical engineering teams have been confirmed in countless hospitals and many countries (World Health Organization, 1987; Bloom, 1989), and will not be repeated here. Only some unique aspects are worth discussing. There were two main reasons for choosing a decentralized service network instead of creating a single, large service center that would have been much easier and less expensive to set up and manage. First, because the health system itself was being decentralized, it would have been contradictory to impose a central facility subordinated to the highest authority. Second, and more important, is the political instability of a technical division within public administration in Brazil—it can easily disappear overnight. In contrast, a network of services closely linked to its beneficiaries has a much better chance of surviving frequent political changes, even though some of the teams might have occasional problems. Any administrator who tries to destroy or tamper with a clinical engineering team would have to justify it to physicians and other health workers who have directly benefited from the services, while a politician may be too aloof to care for these issues.

Also motivated by the concern about future survival and success of these teams was the criteria of using the commitment of top administration in establishing the queue for creating clinical engineering teams, as well as the insistence on sharing costs right from the beginning, instead of ASEQ alone assuming the total cost. It appears less likely that an institution or its directors would dismantle something erected with its own investment, unless the result is truly unsatisfactory. Furthermore, it is more likely that the initial team will grow when its superiors are genuinely committed.

In spite of strong and continuous support of the Secretary of Health, many difficulties had to be overcome, even by using extraordinary measures. The lack of a career path for engineers and technicians within the health system and consequently, the lack of a reasonable pay scale had to be corrected through "legal loopholes." A plan for establishing a career for "equipment management and maintenance personnel" was proposed by ASEQ and hopefully will be implemented soon, so as to retain the people already trained and to attract new talents.

The main difficulty encountered was actually the lack of adequate human resources, as there is no regular training program for clinical engineers or biomedical instrumentation technicians within Brazil. Because setting up training courses would take too much time and thus lose credit with administrators, the option chosen was to hire electrical, electronics and mechanical engineers and technicians (the latter graduated from secondary-level vocational school). Selected personnel were trained on-the-job by more experienced persons and through courses arranged with manufacturers and universities. Naturally, for this program and other similar ones being set up in other Brazilian states, a great effort will have to be made to ensure a continuous and adequate supply of manpower.

Even in developed countries, the notion of comprehensive technology management is only starting to gain ground.

Two other difficulties were also encountered: purchase of spare parts and lack of technical documentation. Unless equipment is produced solely by a particular manufacturer, it was discovered that most parts are available elsewhere. So, the only real problem is the availability of funds, which depends again on the support and commitment of health administrators. For rare and imported parts, a provision was made in all new purchase contracts to reserve 6-10% of the total value of each contract for parts, which could be purchased over a period of up to 2-3 years afterward, besides including a clause requiring the sale of spare parts and supplies during the equipment's life expectancy. The issue of technical documentation was taken care of through the establishment of the technical reference library already mentioned.

The economic problems of the country, especially the foreign debt, public deficit and huge inflation rate, also contributed to make ordinary problems more difficult to solve. Foreign loan projects and importation of complex equipment and spare parts were halted several times due to debt moratoriums and renegotiations. Lack of funds prevented the rapid implementation of new clinical engineering teams and fuller use of the reference centers. Finally, significant turnover of clinical engineers and BMETs could not be prevented, because of difficulties in constantly readjusting their salaries according to the inflation rate.

The accomplishments achieved so far, however, have made clear that progress and success are only possible when one knows and is willing to address the actual underlying causes of the problems and not just deal superficially with the symptoms. To blame equipment itself for

Other states of Brazil and some other Latin American countries are applying the rules and methods described here

the problems of cost increases and abuse, as many people have done (Attinger, 1987), is completely wrong and useless, because the devices are only tools and their usefulness depends on why and how they are used. *All the difficulties discussed earlier are merely consequences and not the real roots of problems caused by the introduction of modern technology into healthcare.* The fundamental reasons for the failures in technology management seem to be the following:

- 1) *Lack of training, experience, and awareness among decision makers regarding the management of modern technology.* These people tend to treat equipment in the same way as drugs or buildings, ignoring the essential differences between them. Unlike drugs, equipment needs continuous care, maintenance, supplies, spare parts. Unlike a physical plant, equipment deteriorates and becomes obsolete rapidly, making frequent replacement necessary; furthermore, it requires sophisticated users and service personnel.
- 2) *Equipment is often primarily considered a status symbol rather than a production tool.* Instead of purchasing something that would adequately meet the needs of patients, many doctors insist on acquiring the fanciest and "most advanced" model, regardless of price, performance, and often, real efficacy and safety.
- 3) *Greed and short-sightedness of manufacturers and suppliers.* The attitude of "profit above all" has led large conglomerates to sell excessively complex equipment to hospitals and countries that evidently do not have the technical and financial resources to operate, maintain and update it.
- 4) *Selfishness of the so-called "donation," "aid" and "cooperation" programs.* Sometimes, these are actually promotional schemes designed to stimulate the purchase of large quantities of costly, sophisticated equipment by less-developed countries and poorly man-

aged institutions, without any commitment to, nor even advice on, how to solve subsequent problems with operation and maintenance.

CONCLUSIONS

The experience accumulated through implementation of the healthcare equipment policy for the health system of Sao Paulo state, Brazil, lets one conclude that it is possible to tackle and to begin solving problems related to medical instrumentation. This is especially true in developing countries, where dramatic reports have been made (Russell, 1982; World Health Organization, 1987; Bloom, 1989). Naturally, because of diverse conditions, each hospital or health system will have to find its own solutions. For example, decentralization of management and maintenance activities was adopted in response to political and cultural realities in Brazil, and, thus, might not be appropriate for other systems or countries.

However, it is clear that the fundamental issues discussed above have to be addressed quickly and consciously; otherwise, any effort is doomed from the beginning. It is also believed that a comprehensive approach integrating the issues of R&D and regulation with all phases of equipment life cycles is absolutely essential for any policy designed for a large system, because it allows better control, increased bargaining power, and more effective solutions. Individual institutions should concentrate on integrating all phases of equipment life cycles and incorporating technology assessment to assure that equipment acquired will indeed improve quality at reasonable costs.

Finally, the multidisciplinary approach adopted here should be used everywhere, even in small community hospitals. Those who do not have biomedical or clinical engineers should seek outside consultants whenever their own BMETs cannot help. Healthcare technology management is crucial to the future survival of all healthcare institutions as the introduction of modern technology into healthcare is irreversible and its pace will only continue to grow more and more rapidly.

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