

Clinical engineering: a new “bridge” for bioethics?

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Abstract

This case study was based on a performance analysis of the hospital services offered by Dom Orione Hospital, in Araguaína/TO, Brazil, as a result of the structuring of the department of Clinical Engineering in the institution, in which 70% of the services provided are aimed at patients from the Brazilian Unified Health System. The increase achieved in the amount of care provided and in the quality of services offered points to the social nature of this institutional structuring process, noting both its convergence with the principles and values espoused by bioethics, whether from the clinical perspective regarding the social theoretical model, or as it suits the assumptions that guide the Brazilian Unified Health System itself.

Keywords: Right to health. Bioethics-Engineering. Resource allocation. Biomedical engineering. Technology-Total quality management.

Resumo

Engenharia clínica: nova “ponte” para a bioética?

Este estudo de caso baseia-se na análise de desempenho de oferta de serviços hospitalares no Hospital Dom Orione, em Araguaína, Tocantins/Brasil, em decorrência da estruturação do departamento de engenharia clínica na instituição, na qual 70% dos atendimentos são destinados a pacientes do Sistema Único de Saúde. O incremento alcançado na quantidade de atendimentos e na qualidade dos serviços ofertados aponta para o cunho social desse processo de estruturação institucional, assinalando tanto sua convergência com os princípios e valores defendidos pela bioética, seja na perspectiva da clínica ou no que tange à vertente teórica social, quanto sua adequação aos pressupostos que orientam o próprio Sistema Único de Saúde.

Palavras-chave: Direito à saúde. Bioética-Engenharia. Alocação de recursos. Engenharia biomédica. Tecnologia-Gestão da qualidade total.

Resumen

Ingeniería clínica: ¿un nuevo “puente” para la bioética?

Este estudio de caso se basa en el análisis de desempeño de los servicios hospitalares del Hospital Dom Orione, en Araguaína/TO, Brasil, como resultado de la estructuración del Departamento de Ingeniería Clínica en la institución, en la que el 70% de los servicios prestados están dirigidos a los pacientes del Sistema Único de Salud. El aumento de la cantidad de tratamientos y la calidad de los servicios ofrecidos apunta a la naturaleza social de este proceso de estructuración institucional, teniendo en cuenta tanto su convergencia con los principios y valores defendidos por la bioética, desde la perspectiva de la clínica o en lo concerniente a la vertiente teórica social, como su adecuación a los presupuestos que orientan al propio Sistema Único de Salud.

Palabras clave: Derecho a la salud. Bioética-Ingeniería. Asignación de recursos. Ingeniería biomédica. Tecnología-Gestión de la calidad total.

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The “bridge” between Science and ethics envisioned by Potter¹ still in the late 1970s has been slowly consolidated by expanding the field of action of bioethics, which is shown to be an effective tool to promote reflection on conflicts in the health area, both in the clinical perspective and in social terms. This process marks greatly the *Universal Declaration on Bioethics and Human Rights*², that from 2005, signaled unequivocally the close relationship between human rights and health, extending the scope of the discipline to the humanities, particularly philosophy, anthropology and Law.

Although related to conflicts from asymmetries and inequalities asymmetries and inequalities in power in social terms, the comprehensive bioethical reflection also reflected on medical clinic, an area in which bioethics is initially constituted, by including problems related to other fields of knowledge that contribute *pari passu* to medicine in the process of eradicating the disease and promote health. This is the case, among others, of clinical engineering (CE), that in Brazil became mandatory in health care institutions, with the resolution of Agência Nacional de Vigilância Sanitária (Anvisa) (National Health Surveillance Agency) by means of RDC 02/2010³.

Clinical engineering is the subarea of biomedical engineering (BE). According to Bronzino⁴, clinical engineer is the one that graduated in an academic program accredited in engineering and that is involved in applying scientific and technological knowledge in a health care setting with clinical support. The clinical setting is the place where the patients is assisted, and the activities include direct assistance to patients, research and teaching, aimed at improving health care.

The growing importance of hospitals throughout the twentieth century as the main centers related to health care, the increase of the electronic equipment park – some of them with very complex operating principles – and the emergence of new technologies, increasing the range of resources used, made the presence of a specialized professional essential, able to help, from the technical point of view, the medical staff to manage all of these new technologies associated with health care⁵. This professional is the clinical engineer, whose role is to professionalize a hospital medical technology management (HMTM) at a health care facility (HCF), by applying engineering methods to solve problems with equipment and services related to them, provided by health care centers⁶.

Therefore, clinical engineering may be understood by the definition of the role of its professional.

According to the American College of Clinical Engineering (ACCE), a *clinical engineer is the professional that applies and develops engineering knowledge and management practices to health technology, in order to improve the quality of health care for patients*^{7,8}. The activity is also characterized as a branch of engineering that has the purpose of helping and even interfering in the health area, aiming at well-being, safety, cost reduction and quality of services provided to patients, also supporting the multidisciplinary team in the hospital, by applying management knowledge and knowledge of engineering to health technology⁹.

Based on the ethical and technical analysis of the results from the implementation of the clinical engineering services in a hospital, this paper is the case study that exemplifies in a timely manner, the contribution of bioethics in the process of planning, and applying health technology (HT), showing its importance to promote reflection according to principles of the Sistema Único de Saúde (SUS) (Brazilian Unified health System) and the imperatives to build citizenship^{10,11}. Its main objective is to show operational processes of clinical engineering to health care professional and to introduce its jargon in the field of bioethics (appendix), in addition to showing the correlation between technical actions in CE and recommendations and ethical presuppositions, related to the bioethical reflection and to public health, to promote the interdisciplinarity between these areas and stimulate the construction of shared knowledge among professional of these areas.

Brief history of clinical engineering

The history of CE started in St. Louis, United States in 1942 with the creation of course on medical equipment maintenance by the American army. This course consequently led to the implementation of an equipment maintenance school for equipment of the army itself in Denver/Colorado^{12,13}. In the following decades, from 1960 to 1970, the intensity in the use of Technologies in medical equipment, such as ultrasonography, blood chemical analyzers and tomography – increased enormously. Although this technology might improve the diagnosis and improve the process to detect diseases, its growing use started to worry the professionals involved. Risks have been identified such as the difficulty to make tests, the high cost of equipment, and mainly gaps in the legislation on safety, which was not sufficiently specific to ensure that its use would really produce the expected effects^{13,14}.

In the beginning of the 1970s, surgeon Cari Walter, from Harvard Medical School, reported an alarming fact: about three people were dying a day, that is, 1,200 a year in the USA due to electrical shocks related to the use of medical equipment^{15,16}. Although these data have not been proved, the controversy showed the need to pay more attention to medical equipment, particularly to the electrical safety¹³. In order to have an idea of the importance of this, at that time in the USA, it was allowed to design, manufacture and sell equipment as delicate and invasive as a pacemaker with no previous authorization from the government or any other supervisory agency^{13,17}. Moreover, most equipment did not have even a operation and maintenance manual.

After identifying the problem, even if not proved yet, it is shown to be potentially dangerous and thus the American government required the Food and Drugs Administration (FDA) to elaborate norms for registrations, sale, inspections and scientific reviews in addition to suggesting improved practices in the manufacturing process. The solution presented by FDA at that moment was to classify medical equipment as medications and submitting them to evaluation and liberation for use to the same approval criteria for medications. Soon the proposal was shown to be inappropriate, since the delay for approval, certification and liberation for commercialization stimulated equipment manufacturers to certify their products using less rigorous processes, which caused a double problem: in addition to not ensuring the quality of the equipment, it also created a false illusion of confidence.

The certification of FDA exemplifies this process, by means of which it is observed only if the equipment worked according to what was described in the manual, prohibiting the sale of equipment adulterated or dismembered equipment without verifying its safety and efficacy. This showed that the FDA regulation presented serious failures and needed to be changed, in addition to also signaling the need for a specific governmental legislation¹³. In May 1976, a law was passed on medical equipment, requiring that two thousand American manufacturers indicated safety and efficacy of their products in protocols and manuals before submitting them to FDA approval¹³.

It is worth mentioning that, still in the 1970s, this professional category was created and the first clinical engineer was certified. The professional became responsible for managing hospital equipment, training those who used these technologies in the

institutions, performing repairs, verifying safety and performance, in addition to evaluating technical specifications for acquisition¹². Engineers did not substitute physicians, but evaluated the technology, controlled the process of automation and adjusted communication systems to help physicians to engage in clinical activities^{13,18}.

In the following decade, the role of the clinical engineer was consolidated and expanded, no longer being only the technician responsible for maintenance of hospital equipment, and becoming the professional that should actively participate in the technology transfer areas and technological evaluation, as well as managing these activities^{13,19}. Thenceforth, and increasingly, clinical engineering began to incorporate functions related to strategic planning to acquire HT, as well as all aspects related to its use, subsequently comprising several attributions such as technical advice to clinical research, involving equipment and collaboration with the hospital ethics committee in issues referring to the use of HT.

In Brazil, activities related to clinical engineering have been restricted to corrective maintenance (repair) for a long time, thus, delaying the consolidation of the wider and more qualified process of HMTM²⁰. The perception of the importance of this area only emerged in 1989, when Ministério do Bem-Estar Social e o da Previdência Social (Ministry of Welfare and Social Security) estimated that from 20% to 40% of medical equipment in the country were deactivated due to lack of repair, lack of spare parts, lack of supplies and even due to lack of installation²¹. With a technological park estimated at US\$ 5 billion, this amount of equipment not in use represented an estimated loss from US\$ 1 billion to US\$ 2 billion¹³. In addition to the waste resulting from this huge percentage of unused equipment, it was verified that when maintenance was carried out, it was just done by manufacturers.

This severe situation directly affected the hospitals, and several of them tried to create internal maintenance teams, however, bumping into persistent problems, such as lack of trained human resources and of spare parts (due to the monopoly of manufacturers and to the bureaucracy to import parts). These difficulties that institutions all over the country have make the need to create and formalize CE groups¹³. The proposal corroborated the initiative of 1987, idealized in the state of São Paulo, which unified the public services and established HMTM policy that integrated the research that was part of the development, regularization and for all team

that was part of the research, development. The project has to received small the project was from a multidisciplinary results that implanted a maintenance network in multinational project groups which accounts for the implementation of the maintenance network and technologic management^{13,21}.

Between 1993 and 1995, the Ministério da Saúde (Ministry of Health) funded the creation of annual specialization courses in CE, implemented in universities: Universidade de Campinas (Unicamp) (University of Campinas), Universidade de São Paulo (USP) (University of São Paulo), Universidade Federal da Paraíba (UFPB) and Universidade Federal do Rio Grande do Sul (UFRS) (University of Rio Grande do Sul). The fact that in 1994 the American College of Clinical Engineering – ACCE – started certifying Brazilian engineers trained to perform the specialty occupation also contributed to consolidate the activity.

Ins this period, a central technical reference was established at “Centro de Engenharia Biomédica” (CEB) (Center of Biomedical Engineering) at Unicamp, which has been in existence since 1883, aimed at collecting technical documentation and legislations, norms and regulations of manufacturers of medical equipment, both national and foreigner, of governmental and non-governmental associations of the USA and European countries, to provide this material to national health care institutions¹³. Lastly, in 1994, the Associação Brasileira de Normas Técnicas (ABNT) (Brazilian Association of Technical Norms) approved the Norma Brasileira Comissão Internacional de Eletrotécnica (Brazilian Standards regarding the International Electrotechnical Commission), which is based on international parameters, provides for safety of the electromedical equipment^{13,22}.

Still at that time, the Brazilian government issued a series of decrees setting a deadline of up to 36 months for manufacturers and retailers of household equipment to certify their products in laboratories accredited by Instituto Nacional de Metrologia, Normalização e Qualidade Industrial (Inmetro) (National Institute of Metrology, Standardization and Industrial Quality), for the proper registration with Vigilância Sanitária (Health Surveillance), considering determinations of NBR IEC 601.1 and additional ones^{13,22}.

The analysis of the measures aimed at standardizing the production and the sale of equipment, as well as ensuring its safety, shows the growing awareness of the importance of clinical engineering in the last decades of the XX century. Nevertheless,

the need to formalize and implement this service for all health facilities that have equipment for diagnosis and treatment was just explained in the RDC (resolution of the executive board) Anvisa 2/2010³, that deals particularly with the technical regulation for the implementation and the use of HT, establishing minimum requirements for managing health technologies in HCFs. From the edition of this resolution, specialization courses in this area have been implemented, focused on training personnel to meet the requirements of planning, control and maintenance of HT in healthcare institutions, such as post-graduation courses in biomedical engineering – *lato sensu* in clinical engineering –, course offered by Faculdade Gama da Universidade de Brasília (UnB) (Gama College of the University of Brasilia)²³, from which this case study was conducted.

The analysis carried out in this study was based on the list of disciplines offered in the specialization course, considering aimed at both enabling students to face technical challenges of their professional life and to provide specific knowledge of CE and content related to ethical reflection in health. This case study was presented in the discipline of bioethics ministered in January 2014, and was conducted from January to March, when it was presented as a course conclusion thesis of the specialization in CE that originated this article. The discipline comprises traditional theoretical proposals of clinical bioethics^{1,24-32} and new social marks of the field, based on parameters of citizenship and of human rights^{2,33-40}. The bioethical reflection is important to contextualize, particularly for the students, the activities of clinical engineers in the social mark of the health area.

Method

This case study⁴¹ resulted from the analysis of technical (operational) and technological (management tools) actions proposed to structure the clinical engineering department of Hospital Dom Orione (HDO), based on the principles and concepts used by clinical and social bioethics. Based on the premise that this department would have HMTM focused on the patient as the main attribution, the study examines technical results obtained by this structuration, carried out from January to December 2013, as well as its economic repercussion, considering how this process is linked to basic concepts and principles of bioethics in health care that guide ethics in health and the fundamental principles of the current legislation in the area.

Characteristics of the place studied

Founded in 1976, HDO – “Casa de Caridade Dom Orione” is a charity social assistance in health care⁴². It is located in the North of Tocantins state, in the city of Araguaína, and has 70% of its health care assistance focused on SUS patients, offering medical specialties such as obstetrics, neonatology, heart surgery among others.

According to the 2010 Census, the population of the municipality estimated for 2015 is 170,183, with literacy rate of about 90%⁴³. It is the regional center, with direct influence on a population group of about 1 million people, considering a radius of 300 km in the state of Tocantins and areas of the state Maranhão and Pará.

HDO provides medical and hospital services of medium and high complexity with 224 beds, 9 of them are adult ICU, 18 are neonatal ICU, 20 are in the neonatal intermediate care unit and 5 kangaroo beds. It has a surgical center (SC) with five operating theaters, one of them is exclusive to heart surgeries. The obstetric center (OC) has four delivery rooms, one of them is a post-anesthetic recovery room, with four beds, in addition to a pre-delivery room with seven beds. The hospital also has a Medical Specialty Center, with 22 medical and surgical offices. It also has a center of diagnosis and therapy comprising a clinical laboratory, electrocardiogram, digestive endoscopy, physiotherapy, speech language therapy, ultrasonography, Extracorporeal lithotripsy, anatomical cytopathology laboratory, cardiocography, radiology and the only digital hemodynamic-angiographic laboratory in the state.

The working process that brought about this study started with the survey and detailed analysis of the situation of the CE services at HDO, aiming at identifying weaknesses and deficiencies that would prevent the full use of the institutional technological park. The parameters to measure the use of equipment were: *uptime* of equipment (that is, time in use – the amount of time a piece of equipment is developing its activities uninterruptedly), rate of preventive maintenance and rate of corrective maintenance. Three sectors have been selected in which the professional performance is directly related to the use of equipment: obstetric and surgical centers and adult and neonatal ICUs.

The collected information was systematized and from these results, a structuring plan was elaborated in priority order, considering administrative attributions, attributions in research and development and attributions in services as shown below.

• Administrative attributions

- 1) Planning: determining objectives, goals, policies, programs, resources and reestablishing procedures;
- 2) Organizing: organization structures, outlining relations, describing positions and profiles and developing organizational and procedural manuals;
- 3) Integrating: selecting, guiding, training and developing areas of performance;
- 4) Managing: delegating responsibilities, motivating, coordinating, overcoming differences, foreseeing and promoting changes;
- 5) Assessing: establishing the information system, determining efficiency standards, measuring and providing feedback to other results.

• Attributions in research and development

- 1) Helping the implementation of new medical techniques and procedures that involve engineering aspects;
- 2) Helping in medical or clinical researches related to engineering;
- 3) Designing and supervising the construction and the tests of equipment with special purposes;
- 4) Helping in medical and clinical researches related to engineering;
- 5) Conducting a continuous study, research, developing and design of methods used in health care;
- 6) Developing methods to calibrate and adjust tools;
- 7) Developing applied research.

• Attributions in services

- 1) Maintaining the optimal functioning of biomedical instruments, thus ensuring safety both of the patient and of the operator;
- 2) Planning the acquisition of hospital medical equipment, aiming at incorporating technology⁴⁴;
- 3) Coordinating the acquisition process;
- 4) Managing the maintenance of hospital medical equipment from the acquisition to be discarded;
- 5) Planning and following changes in the physical structure of EAS;
- 6) Interacting with the medical and paramedical staff to identify problems and find solutions;

- 7) Help clinical specialists and investigators in the definition of problems in clinical areas and services, analyzing and proposing solutions;
- 8) Acting as the technical part in committees;
- 9) Helping to improve and maintain the quality control of methods and tools;
- 10) Representing the institution beyond its walls in aspects related to engineering;
- 11) Forming human resources;
- 12) Helping in the investigation of accidents involving equipment in the hospital;
- 13) Educate the technical staff for an optimal use of resources.

Each one of these types of attribution was analyzed according to the quality management method *Plan, Do, Check, Act* (PDCA)⁴⁵, which guides technical action in several areas, including CE. The PDCA method defines the needs to plan, do (develop), verify (check) and act, being subdivided in distinct stages and specifying what should be done in each stage.

Results obtained in the survey on the situation of the technological park at HDO were treated according to the 5W proposal. The 5W2H is the *check-list* of activities that need to be developed by the company employees to solve the problems identified and to improve the quality of the services. Based on the mapping of the activities to establish what will be done, who will do what, how long will it be done, in which area of the company it will be done, listing all reasons why this activity should be done. Afterwards, this table should also include how the proposed activity and its approximate cost should be in this table⁴⁶. The objective of the process of HMTM is to promote efficiency, efficacy and effectiveness^{47,48} of the services regarding the optimal functioning of the equipment required for the exams, diagnoses and treatments.

Analytical principles of bioethics

From the survey of the technological park and of the management strategies to implement the department of clinical engineering at HDO, an exploratory study was conducted, focused on verifying whether technical actions had produced ethical results, whether described by different bioethical currents or the recommendations by the instruments of HD and by the regulations governing SUS.

As the study has been conducted in a hospital, the bioethical analysis of technical aspects

considered the perspective of clinical bioethics, particularly focusing in the principlist theory and the notions of beneficence, nonmaleficence, justice and respect to autonomy. The beneficence is related to the availability of equipment, making it possible to maximize exams and treatments indicated to patients; nonmaleficence was characterized by correct exam and treatment results, from the preventive and corrective assessment of the equipment; the principle of justice considered maximizing the access of the population to the technological park and to essential resources for exams and treatment consistent with the assumption of health universalization; and the autonomy focused particularly on the professional dimension, considering the effective possibility of performing exams and treatments prescribed, aiming at the subdivision “personal” and “professional”, proposed for the term in *Descritores em Ciências da Saúde* (DeCS) (Health Sciences Descriptors)⁴⁹.

The importance of principlism for the analysis of actions taken has not eclipsed other bioethical formulations of a social nature, considered equally important tools to evaluate the ethical dimension of the actions taken. Thus, principles of equity in the access of health care services, guarantees of health protection, promotion and recovery, defined in several currents of bioethical reflections have been contemplated as analytical frameworks³²⁻⁴⁰, in addition to notions of efficiency, efficacy and effectiveness of services, indicated in several international tools aimed to ensure human rights in general^{2,50} and particularly the right to health⁵⁰⁻⁵³.

Results

The structuring of the CE department at HDO has shown technical results, which are relevant and measurable. Table 1 shows socioeconomic, operational and technical impacts created from the structuring of the CE department and of the technological park of the institution, that directly or indirectly correlate to bioethical principles and concepts, consistent with the current health legislation.

First, it is highlighted that operational results assessed by HMTM action carried out by CE verified by the improvement in sectors analyzed in this study, considered the most relevant to apprehend the process of analysis and improvement of the service structure of the institution. Gains in *uptime* and, consequently, the increase in the number of surgeries in the SC are achievements, which provide

indications to prove benefits that the structuration brought to HDO. Other important results have also been obtained: 1) increased *uptime* of the rooms in the obstetric center (OC) and, consequently, less waiting time for caesarian sections; 2) increased *uptime* of ICU beds for adults and newborns; and 3) reduction of 55% of expenses with HMTM in the institution.

These aspects related to technical improvement of health care at HDO, obtained due to the implementation of CE actions, makes significant gain in quality of health care for patients, considering that the larger amount of available hospital beds also makes the access easy and helps to consolidate the right of the citizen to health. It is important to explain that the increased *uptime* of ICU beds for adults and newborns does not affect only the users

of HCFs, but it reflects on the clinical staff, who feels more relaxed. When the occupancy rate of hospital beds reaches 100%, it tends to cause instability in the professionals, who feel pressured by the situation, particularly because ICUs are fundamental for patient’s life support.

Having in mind that, even if 70% of health care services are carried out in the institution are for SUS patients, improvement in health care by means of CE actions are in accordance with bioethical principles, as they are turned to groups and segments that are economically and socially more vulnerable. They also respond to constitutional principles and legal requirements that regulate the health system in Brazil, that advocate the universality and integrality, the right to access to all users to all levels of health care.

Table 1. Convergence chart among principles and concepts of bioethics and actions of CE

Item	Convergence Chart	
1	Action	Make an inventory of care and support equipment, verifying its functional and operational state
	Operational/Technical and Economical Results	The inventory has had a large operational impact, since a lot of equipment that would be discarded are in use again and in perfect state, and, in contrast, equipment that was working and gave wrong results and thus have been through comprehensive technical analysis, followed by maintenance, calibration and disposal, when necessary.
	Principles	Nonmaleficence, beneficence, protection, effectivity
	Justification	Principles and concepts were contemplated for two reasons: 1) there was extremely necessary equipment that was idle, due to the lack of minor adjustments and amendments, which increases the time patients wait for an exam; and 2) results of exams performed with this equipment were not reliable, causing misdiagnosis, and consequently, wrong prognosis of those patients.
2	Action	Task force to solve problems with medical equipment (ME) and other ineffective technologies
	Operational/Technical and Economical Results	This action was started after the inventory, which showed that about 28% of the technological park was ineffective. Technical actions planned according to the importance of the equipment to accomplish the mission of the institution reduced this index to 4% in only 30 days.
	Principles	Beneficence, health promotion, health recovery, efficacy
	Justification	With the active recovery of technologies in the institution, the length of time for patient care was extremely reduced in all areas of care.
3	Action	To create, with <i>software</i> , planning for preventive, predictive and corrective maintenance of the technological park
	Operational/Technical and Economical Results	Several positive operational, technical and economical results were achieved by means of this action, but the most important was that about 29% of <i>uptime</i> of equipment. Other dominant factors were: corrective maintenance rate dropped from 77.5% to 24.8%, and preventive and predictive maintenance rate increased from 22.5% to 75.2%.
	Principles	Justice, health promotion, health recovery, efficiency
	Justification	Due to the increase of <i>uptime</i> of equipment, access to health care was promoted also contributing to a better cost-effectiveness of the management.
4	Action	Adjust the structure referring to calibration equipment
	Operational/Technical and Economical Results	The technical aspect was extremely prioritized by taking this action (partly), since it ensures results in HT.
	Principles	Beneficence, nonmaleficence, efficacy, health promotion and health recovery

Item	Convergence Chart	
4	Principles	By ensuring the reliability of results, any maleficence to the patient are avoided, whether physical, by means of life-support or monitoring equipment, or psychological and mental by means of equipment for complementary exam.
	Action	Developing and implementing evaluative indicators to manage maintenance contracts
5	Operational/Technical and Economical Results	Operational and technical results were widely achieved, since, with the supervision, it is possible to assess the quality of the services.
	Principles	Promotion, beneficence, nonmaleficence and justice.
	Justification	Ensure that equipment which are responsibility of other management team have the same established standard security.
6	Action	Establishing evaluation methods of assistance and support equipment, as for security in the hospital setting.
	Operational/Technical and Economical Results	It will be guaranteed that all and every equipment that have a direct or indirect interface with the patient will be assessed with electrical insulation equipment.
	Principles	Nonmaleficence, professional autonomy.
	Justification	It was ensured that, after technical interventions, any equipment of the institution had a perfect electrical isolation, not causing any risk of electrical chock to the patient.
7	Action	Do an action planning of the CE department, when the need to implement and/or incorporating new technologies, via multidisciplinary team.
	Operational/Technical and Economical Results	After starting this action, several operational, technical and economical results will achieve much higher levels than the current ones.
	Principles	Health promotion, protection and recovery, beneficence, nonmaleficence, professional autonomy, efficiency, efficacy and effectivity
	Justification	The main attribution of CE is life cycle management of HT, when technical and technological aspects that excel for quality are considered during acquisitions, installations, installations and training of HT, qualitative and quantitative aspects will be extremely optimized.

Discussion

Since Potter’s pioneer formulation, bioethics aims at discussing the contrast between ethics and technique, stimulating health care professionals to be attentive to ethical aspects of the relationship with patients. This file of study proposes that the ethical discussions extends to beyond deontology, covering aspects which are indistinguishable from health, such as those characterized in human rights and in the very definition of citizenship. Results obtained in this case study allow us to point out that, as for clinical engineering, the contrast between ethics and technique based on a false dilemma, since the two aspects may be in compliance, and even complementarily, to ensure the efficiency, efficacy and effectiveness of SUS.

It is a fact that CE is primarily applied to hospitals, which affects the analysis of this work. However, the restriction to this *locus* does not intend to be an apology of health recovery as the only form of treatment to be offered by SUS, that is, to defend the exclusivity of the hospital-centric model and of processes exclusively centered in hospital care. Nevertheless, if health recovery mechanisms are

essential for the full operation of SUS, maximizing the use of HT in the Brazilian HCFs by means of CE actions may optimize the use of the national technological park by promoting a lower cost-effectiveness ratio in hospitals and in other institutions focused on health recovery, thus contributing to a better use of resources.

If the merit of SUS in the implementation of actions in the Programa Saúde da Família (PSF) (Family Health Program)⁵⁴ is unquestionable, prioritizing actions focused on health promotion and prevention such as state policies, on the other hand, we should know that other recovery measures related to the hospital settings should not be disregarded. Even if all factors that currently predispose most of the Brazilian population to illness were completely eliminated, such as lack of infrastructure water catchment, treatment and distribution, lack of a sewage treatment system, lack of waste treatment policies, as well as economic and social inequities regarding education, housing and transport services, health recovery services cannot be totally disregarded. Whether it is a fall from a bicycle or an emergent surgery, hospital health recovery services – undoubtedly – are part of the health care process.

Based on this finding, it is important to think that each and every health system Works with limited resources that may be more or less scarce, considering the morbi-mortality rates of the population that should be assisted. In the Brazilian case, whether due to lack of allocation or due to management failures⁵⁵, it is a desolate picture, particularly when the evaluations of the performance index of SUS (Idsus) are considered. It used 24 indicators to measure assistance in all Brazilian municipalities, considering a scale from 0 to 10, which have been available on the website of the Ministry of Health since 2012: *In the first evaluation, the Brazilian score is 5.47*⁵⁶.

Thus, the processes implemented by CE in institutions are shown to be extremely important since they maximize the association of gains in cost-effectiveness of health technologies; stimulate the extensive use of technological resources; avoid waste and provide resources for a universal access to the system, including at medium and high levels of complexity. It is worth mentioning that the reduced spending on HMTM transcends the simple economic sphere associated with making a profit; since the health system works with limited resources and, at times, scarce, it is directly associated with distributive justice in health.

In addition to operational and economic results shown in this work, that converge with bioethical principles and with what is recommended by the current health legislation, other technical results obtained due to this technology management in CE also contribute to the same principles, such as: correct application of public resources in HT; guidance about the direction of the institution as for the requirement for a technical manager for HMTM of HT applied at HDO; technical guidance to the clinical staff at HDO and innovations in HT; discarding of HT with no registration at Anvisa; notification to Anvisa regarding HT failures, contributing to techno-surveillance; technological assistance in HT for the Hospital Infection Control Committee (HICC) of HDO; operational training in HT for the clinical staff and nurses of HDO.

It is also worth mentioning that, in practice, actions to structure equipment shown in this study are not restricted to places whose results are described (SC, ICU and OB), but are extended throughout the technology park of the institution, since, in addition to monitoring and life support equipment, structuring process of CE service extended to those who need complementary examinations: ultrasonography, radiology, clinical analysis, sterilization center,

etc. Thus, considerations about promoting principles of beneficence, not maleficence and justice, as well as notions on protection, equity, efficiency and effectiveness of HTs implemented at HDO, should be taken even more comprehensively than shown in the analysis of sectors of the institution presented in the convergence chart.

It is also considered that the regulation of SUS prioritizes the promotion and protection to the detriment of recovery, which is the access mode mentioned on third place in the Magna Carta (Federal Constitution), although it is where most resources are invested. This analysis has shown how the implementation of CE in HCFs may contribute to avoid waste frequently identified in the instance management aimed at the restoration of health (hospitals), allowing that saved financial contributions would be made available to promote and protect health. Thus, it may be stated that, even indirectly, CE actions meet proposals of the World Health Organization (WHO), such as the Ottawa Charter⁵⁷ and the Lalonde Report⁵⁸, as well as the Brazilian health-care reform^{41,59} and its main repercussions, from the previously mentioned article number 196 from of the Constitution¹⁰ and Law 8.080/90¹¹, which define the access to healthcare as a fundamental right of citizenship.

Final considerations

The case study undertaken from the implementation of an improvement plan of the department of clinical engineering at Hospital Dom Orione in Araguaína/TO not only shows expected technical results due to the introduction of survey processes and analysis of the institutional technology park as well as it also shows the correlation between this technical activity and the recommendations and requirements of international treaties on human rights and in the health area, as well as the Brazilian legislation, related to widely guaranteeing access to healthcare for the population.

More specifically, bioethics allows us to observe a clear convergence among actions adopted and some of the analytical frameworks of the field, considering both concepts formulated by the principlism^{1,24-32} and those from domestic laws and international documents, related to extending guarantees to health and to social dimension^{2,33-40}. Both bioethical perspectives are contemplated by the implementation of CE in HCFs, particularly when the process performs the necessary technical steps,

not limited to simple maintenance. Thus, the association between bioethical reflection and the technical activity of CE is made evident, consolidating the bridge of knowledge to promote ethics in health in the clinical perspective and in the global dimension. Even considering methodological limitations of a case study, which reduces the possibility of generalizing results⁴¹, undeniable gains in effectiveness achieved in the implementation process of the CE department in the institution and its direct association with clinical and social bioethical principles^{1,2,24-40} denote the importance of stimulating further studies to improve and increase the understanding of such process.

Regarding this association, it is still fundamental to point out that the initiative to introduce the bioethical reflection among the disciplines of CE is shown to be right since it helps the future professional to understand the big Picture in which its profession is inserted, thus being able to understand not only as a sequence of technical processes and steps to be carefully followed, but also, as an organic and dynamics process to improve and strengthen the institution, that enables HCF to effectively promote SUS principles and values^{60,61}.

Accordingly, it is worth mentioning that training in bioethics helps clinical engineers to know the extension of their professional role, enabling them to work in ethical committees and to take part in research projects of the institution. Bioethical reflection may also make them more apt to work side by side with the other members of the health team, helping to meet the objective of SUS of ensuring access to quality health care for all the population.

Facing the auspicious results verified by offering the discipline of bioethics to classes specializing in clinical engineering, it may be inferred that it would be also helpful to extend the teaching of this discipline to other engineering courses (such as environmental, forest, and fishing engineering), as well as to veterinary medicine and to animal husbandry, which also deal with bioethical dilemmas and that would benefit from a closer contact with the reflection, concepts and values discussed in this field. Lastly, it is worth mentioning that the approximation to the engineering would also benefit the bioethics as it would incorporate to the reflection, the technical support and worldview of another area of knowledge and, thus, it would further consolidate the interdisciplinary vocation of the field.

This article is based on the monography presented in the lato sensu specialization in clinical engineering, offered by the post-graduation program in biomedical engineering at Faculdade UnB Gama (FGA), Universidade de Brasília (UnB).

Referências

1. Potter VR. Bioethics: bridge to the future. Englewood Cliffs: Prentice Hall; 1971.
2. Organização das Nações Unidas para a Educação, a Ciência e a Cultura. Declaração Universal sobre Bioética e Direitos Humanos. [Internet]. Unesco; 2005. [acesso 22 jan 2016]. Disponível: <http://bit.ly/1TRJFa9>
3. Agência Nacional de Vigilância Sanitária. Resolução de Diretoria Colegiada nº 2, de 25 de janeiro de 2010. Dispõe sobre o gerenciamento de tecnologias em saúde em estabelecimentos de saúde. [Internet]. Diário Oficial da União, Brasília, 25 jan 2010. [acesso 22 jan 2016]. Disponível: <http://bit.ly/KuiJLK>
4. Bronzino JD. Clinical engineering: evolution of a discipline. [Internet]. In: Bronzino JD. The biomedical engineering handbook. vols. I & II. Boca Raton: CRC Press; 1995. p. 2499. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2cowvaU>
5. Mendes EV. A evolução histórica da prática médica: suas implicações no ensino, na pesquisa e na tecnologia médicas. Belo Horizonte: PUC-MG/Finep; 1984.
6. Calil SJ. Papel do engenheiro hospitalar nas unidades de saúde. RBE. 1990;7(1):325-30.
7. Beskow WB, Garcia R. A informação como vetor estratégico no gerenciamento de centros de engenharia clínica. Anais do I Congresso Latino-Americano de Engenharia Biomédica. Mazatlan. 1998;634-7.
8. American College of Clinical Engineering. About ACCE – Clinical Engineer. ACCE; 1992. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2byMTD1>
9. Leite HJD. Nota de aula na disciplina Gerenciamento em EMH. Módulo V. Lato Sensu Engenharia Clínica. Brasília: UnB; 2013.
10. Brasil. Constituição da República Federativa do Brasil, de 5 de outubro de 1988. [Internet]. Diário Oficial da União. Brasília; 5 out 1988 [acesso 6 set 2016]. Seção 1. Disponível: <http://bit.ly/1bIJ9XW>
11. Brasil. Lei nº 8.080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. [acesso 22 jan 2013]. Disponível: <http://bit.ly/1luhiIN>

12. Gordon GJ. Hospital technology management: the tao of clinical engineering. *J Clin Eng.* 1900;15(2):111-7.
13. Ramirez EFF, Calil SJ. Engenharia clínica: parte I: Origens (1942-1996). *Semina Ci Exatas/Tecnol.* 2000 dez;21(4):27-33.
14. Christiansen D. Which crisis?: the energy crisis; the health care crisis. *IEEE Spectrum.* 1973;10(4):23.
15. Friedlander GD. Electricity in hospitais: elimination of lethal hazards. [Internet]. *IEEE Spectrum.* 1971;8(9):40-51. [acesso 22 jan 2016]. DOI: 10.1109/MSPEC.1971.5218422
16. Dalziel CF. Electric shock hazard. [Internet]. *IEEE Spectrum.* 1972;9(2):41-50. [acesso 22 jan 2016]. DOI: 10.1109/MSPEC.1972.5218692
17. Jurgen RK. Electronics in medicine: a mixed blessing: technology does lots more, but at a price. [Internet]. *IEEE Spectrum.* 1977;14(1):78-81. [acesso 22 jan 2016]. DOI: 10.1109/MSPEC.1977.6367644
18. Hershberg PI. The EE's place public health. *IEEE Spectrum.* 1972;9(9):63-6.
19. Goodman CS. HTA 101: introduction to health technology assessment. [Internet]. Bethesda: US National Library of Medicine; 2014. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2byUZLP>
20. Beskow WB. Sistema de informação para o gerenciamento de tecnologia médico-hospitalar: metodologia de desenvolvimento e implementação de protótipo. [tese] Florianópolis: Universidade Federal de Santa Catarina; 2001. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2bznfe6>
21. Wang B, Calil SJ. Clinical engineering in Brazil: current status. *J Clin Eng.* 1991;16(2):129-35. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2bCEXh3>
22. Associação Brasileira de Normas Técnicas. [Internet]. ABNT Catálogo. ABNT 60.601.1 (NBR-IEC); 2010. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2bz0e5S>
23. Universidade de Brasília. UnB Gama. [Internet]. Especialização em engenharia clínica. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2byXiyq>
24. Beauchamp TL, Childress JF. Princípios de ética biomédica. São Paulo: Loyola; 2002.
25. Diniz D. Henry Beecher e a história da bioética. [Internet]. *O Mundo da Saúde.* 1999;23(5):332-5. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2c5CTIM>
26. Goldim JR. Justiça. [Internet]. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2bPsRog>
27. Goldim JR. Princípio da beneficência. [Internet]. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2byZA0N>
28. Goldim JR. Princípio da não-maleficência. [Internet]. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2c8t6c6>
29. Goldim JR. Relatório Belmont. [Internet]. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2bTfQcG>
30. Kottow MH. Introducción a la Bioética. Santiago: Universitária; 1995.
31. Loch JA, Kipper DJ. Uma introdução à bioética. *Temas de Pediatría Nestlé.* 2002;73:12-9.
32. Pellegrino ED, Thomasma D. For the patient's good: the restoration of beneficence medical ethics. Cambridge: Oxford University Press; 1988.
33. Oliveira MF. Feminismo, raça/etnia, pobreza e bioética: a busca da justiça de gênero, anti-racista e de classe. In: Garrafa V, Pessini L, organizadores. *Bioética: poder e injustiça.* São Paulo: Loyola; 2003. p. 345-63.
34. Schramm FR. Bioética sin universalidad?: justificación de una bioética latino Americana y Caribeña de Protección. In: Garrafa V, Kottow M, Saada A, organizadores. *Estatuto epistemológico de la bioética.* México: Universidad Nacional Autónoma de México/Red Latinoamericana y del Caribe de Bioética de la UNESCO; 2005. p. 165-85.
35. Diniz D, Guilhem D. Bioética feminista: o resgate político do conceito de vulnerabilidade. *Bioética.* 2009;7(2):181-8.
36. Anjos MF. Teologia da libertação e bioética. In: Privitera S. *Dicionário de bioética.* Aparecida: Santuário; 2000.
37. Segre M, Ferraz FC. O conceito de saúde. *Rev Saúde Pública.* 1997;31(5):538-42.
38. Garrafa V, Porto D. Bioética, poder e injustiça: por uma ética de intervenção. *O Mundo da Saúde.* 2002;26(1):6-15.
39. Porto D, Garrafa V. Bioética de intervenção: considerações sobre a economia de mercado. *Bioética.* 2005;13(1):111-23.
40. Porto D, Garrafa V. A influência da Reforma Sanitária na construção das bioéticas brasileiras. [Internet]. *Ciênc. saúde coletiva.* 2011;16(Supl.):719-29. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2bzg7mF>
41. Gil AC. Métodos e técnicas de pesquisa social. 3ª ed. São Paulo: Atlas; 1991. p. 78.
42. Brasil. Ministério da Saúde, Secretaria de Atenção à Saúde. Portaria nº 122, de 13 de fevereiro de 2013. Define as diretrizes de organização e funcionamento das Equipes de Consultório na Rua. [Internet]. [acesso 20 set 2016]. Disponível: <http://bit.ly/2dZKFMF>
43. Instituto Brasileiro de Geografia e Estatística. Censo Demográfico 2010. IBGE; 2010. [acesso 1 fev 2016]. Disponível: <http://bit.ly/1IgZcXk>
44. Silva Jr. JA, Tavares FA. Modernização no processo de compras: aprendizados, oportunidades e inovações. [Internet]. III Congresso Consad de Gestão Pública, painel 40. Banco do Conhecimento Consad. [acesso 23 jan 2016]. Disponível: <http://bit.ly/2bziyWC>
45. Periard G. O que é o 5W2H e como ele é utilizado? [Internet]. [acesso 4 fev 2014]. Disponível:

<http://bit.ly/1vZqQHv>

46. Schramm FR, Escosteguy CC. Bioética e avaliação tecnológica em saúde. Rio de Janeiro: Fiocruz; 2000.
47. Glowacky LA. Avaliação de efetividade de sistemas concentradores de oxigênio: uma ferramenta em gestão de tecnologia médico-hospitalar. 2003. [dissertação]. Florianópolis: Universidade Federal de Santa Catarina; 2003.
48. Organização das Nações Unidas. Declaração Universal dos Direitos Humanos. [Internet]. [acesso 31 jan 2016]. Disponível: <http://bit.ly/1qwxB4V>
49. Biblioteca Virtual em Saúde. Descritores em ciências da saúde. [Autonomia Pessoal; Autonomia Profissional]. [Internet]. [acesso 4 fev 2014]. Disponível: <http://bit.ly/1ch8cXi>
50. Associação Médica Mundial. Declaração de Helsinki. [Internet]. Finlândia; 1964. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2bSogSd>
51. Hellman F. Declaração de Helsinque versão 2013 é adotada na Assembleia Geral da Associação Médica Mundial. [Internet] Sociedade Brasileira de Bioética 19-10-2013. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2bCsRHQ>
52. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Belmont Report: ethical principles and guidelines for the protection of human subjects of research. [Internet]. U.S. Department of Health & Human Services; 18 abr 1979. [acesso 22 jan 2016]. Disponível: <http://bit.ly/1m4nLEE>
53. Organização Pan-Americana da Saúde. Organização Mundial da Saúde. Organización Panamericana de la Salud promoviendo la salud en las Americas. Opas/OMS; 1998.
54. Brasil. Ministério da Saúde. Atenção primária e promoção da saúde. Secretaria de Políticas de Saúde; 2001.
55. Carvalho GA. Saúde pública brasileira precisa de mais recursos do Governo Federal. [Internet]. Saúde + 10. [acesso 2 out 2013]. Disponível: <http://bit.ly/2c0yb8L>
56. Brasil. [Internet]. Ministério da Saúde. Índice de Desempenho do Sistema Único de Saúde Idsus; 2012. [acesso 18 jun 2012]. Disponível: <http://bit.ly/2eSLE0o>
57. Organização Mundial da Saúde. Carta de Ottawa. Primeira Conferência Internacional sobre Promoção da Saúde. Ottawa; nov 1986. [Internet]. [acesso 24 jan 2016]. Disponível: <http://bit.ly/2bVDHbN>
58. Lalonde M. A new perspective on the health of Canadians: a working document. [Internet]. Gouvernement du Canada/Minister of Supply and Services/Ministry of National Health and Welfare; 1981. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2bC9z1W>
59. Pingarrilho C. Breve história da reforma sanitária brasileira, 2010. [acesso 22 jan 2016]. Disponível: <http://bit.ly/2bBVyX3>
60. Brasil. Ministério da Saúde. 11ª Conferência Nacional de Saúde. Efetivando o SUS: acesso, qualidade e humanização na atenção à saúde com controle social. Relatório Final. Brasília; 15-19 dez 2000. Brasília: Ministério da Saúde; 2000.
61. Brasil. Ministério da Saúde. Secretaria Executiva. Sistema Único de Saúde (SUS): princípios e conquistas. Brasília: Ministério Público; 2000.

Participation of the authors

Demetrius Poveda Marques structured the clinical engineering service to which this case study refers, prepared the technical analysis of the actions performed, wrote the monography on which this article is based and also helped to revise the article. Dora Porto defined and taught the discipline of bioethics in the clinical engineering course - lato sensu of UnB, guiding the bioethical reflection mentioned in the monography, revised its final version and took part in the examination board and elaborated the manuscript based on the document.

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Appendix

Glossary of Clinical Engineering

CE = clinical engineering

BE = biomedical engineering

HMTM = hospital medical technology management

HCF = health care facility

HT = health technology

HICC = hospital infection control committee