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Editor's Corner

Often do I hear at meetings debates about how many clinical engineers and technicians are needed per some quantifying unit. Quantifying unit like the volume or quantity of assets managed, the replacement or acquisition value of the assets managed, or number of patients' beds, and even per volume of patients discharged. However, seldom the debate reaches the level of how many such qualified personnel a system such as city or country or even the world may need.

Recent surveys attempted to identify the volume of clinical engineering professionals practicing around the world. They resulted either in very low response rate (Calil 2017) reflecting therefore estimate of very small community of CEs practitioners, or as designed by another survey organizers included variety of other than CE engineering professionals such as biomedical engineering other engineering practitioners and technology managers (WHO 2018) that resulted in high volume count of about 800,000 practitioners but could not clearly identified the share of CEs in that count. Knowledge about the gap, if one exists, between the volume of practicing qualified CEs and the volume of the needed CEs can help guide national and global policies, priorities, and program support that are needed to narrow and even eliminate the gap (if one exists) over time.

Following the publication in 1999 of its landmark manuscript about reducing preventable medical errors committed during provisioning of health care (http://www.nationalacademies.org/hmd/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx), the National Academy of Medicine (formerly the Institute of Medicine), published in 2001 their report *Crossing the Quality Chasm; A new Health System for the 21st Century* (http://www.nationalacademies.org/hmd/Reports/2001/Crossing-the-Quality-Chasm-A-New-Health-System-for-the-21st-Century.aspx), and followed up in 2015 with another landmark book about the criticality of getting the correct diagnosis in managing patient conditions and the underappreciated occurrence of diagnostic errors (http://www.nationalacademies.org/hmd/Reports/2015/Improving-Diagnosis-in-Healthcare.aspx). These reports call for urgent and fundamental change to healthcare system design, policies, processes, and the direction for the professionals who have stake in its outcomes. These reports state that patients should be able to count on receiving care that meets their needs and is based on the best scientific knowledge – however that is too frequently is not the case. It furthermore points that health care harms patients and routinely fails to deliver its potential benefits. The 2001 report specifically states that "*Faced with medical and technology rapid changes, the nation's health care delivery system has fallen far short in its ability to translate knowledge into practice and to apply new technology safely and appropriately. And if the system cannot consistently deliver today's science and technology, it is even less prepared to respond to the extraordinary advances that surely will emerge during the coming decades.*"

Clinical engineers, according to ACCE definition I participated in its creation in 1992, are "*professionals who supports and advances patient care by applying engineering and managerial skills to healthcare technology*." (https://accenet.org/about/Pages/ClinicalEngineer.aspx). While there are differences in some of the Clinical Engineers scope of practice between countries their focus is the same – deliver competent technology life cycle skills that support improvement in patient outcomes and wellness.

This calls for clinical engineers to adopt professional guidance about the minimum requirements for education, training, and professional credentialing that will lead to building of competent practitioners' capacity. Capacity that can deliver on the recommendations for plans to correct the above noted deficiencies.

So, while we still debating how many CEs a technology life-cycle program should optimally has or how many CEs the world needs - I believe that it is unanimously clear that in order to deliver the value of our profession to improve global health systems outcomes these professionals must be well prepared, ethically committed, competent and professionally credentialed.

I look forward to your comments.

Together we can lead the move from Health to Wealth!

Dr. Yadin David

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WHO Update Column

By Adriana Velazquez Berumen

Welcome to the initiation of a new column in our Global Clinical Engineering Journal that will serve the readership as additional information source of international health technology interest, as opportunity to exchange comment and collect your feedback, and promote stronger engagement with WHO representative members.

This new added feature will be directed under the expertise of Adriana Velazquez Berumen, Senior advisor on medical devices, Department of Essential Medicines and Health Products, at the World Health Organization in Geneva, Switzerland (*url:* www.who.int/medical_devices/en/ and *e-mail:* velazquezberumena@who.int). Your feedback and promotion and sharing of the information posted in this column are welcome.

At a press conference at the United Nations in Geneva, on July 9, 2019, WHO launched the 2nd WHO Model List of Essential In Vitro Diagnostics (EDL) and the application for the 3rd EDL List has opened. (https://www.who.int/medical_devices/publications/Second_WHO_Model_List_of_Essential_In_Vitro_Diagnostics/en/). The objective of the EDL is to increase access, affordability, availability of these tests globally, to support universal health coverage and better health for all. It includes laboratory tests as well as point of care and the objective is that countries will refer to WHO lists and updated their national reference lists for public procurement or reimbursement.

The process to select these diagnostics included: assess the tests submitted for the 2nd EDL, ,series of consultations, including public comments and final review, analysis and discussion by Members of Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD) and WHO staff .

The full report of the process will present a description of the methodologies, reviews, evidence, references and recommendations of the SAGE IVD members and will be published in September 2019 as part of WHO Technical Report Series. and will be found at: https://www.who.int/medical_devices/diagnostics/selection_in-vitro/en/.

You may find of interest the exciting update about Health Product Profile Directory https://www.who.int/tdr/diseases-topics/product-directory/en/ a free-to-use online resource created and developed by TDR (Special Programme for Research and Training in Tropical Diseases) on behalf of WHO as a global public good to improve the efficiency of efforts to develop new products for neglected diseases and populations as well as threats to global health. It provides a searchable database of the 8-10 key characteristics used to describe desired health products, including medicines, vaccines, diagnostics and medical equipment. Links are provided to access the full Product Profile document where this is publicly available. The Directory was launched in May 2019 and will be continuously updated. You are encouraged to visit the website provided.

Finally, I would also like to share with you additional highlights from the July 2019 WHO Medical Devices Newsletter that describe career opportunities at WHO. In particular, a full time Technical Officer position is open (Position 1902257) where you can find additional information about it such as job description and how to apply as well as about more opportunities at https://careers.who.int/careersection/ex/jobdetail.ftl?job=1902257&tz=GMT%2B02%3A00&tzname=Europe%2FBerlin.

I am delighted with this opportunity to connected with you and to create a new platform for increasing knowledge about and communication between stake holders with interest in health technologies.

Respectfully,

Adriana

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Assistant Multi-Parametric Method to the selection in the Process of Incorporation of Hospital Equipment

By A. M. Marciano[1], L. S. Schneider[2], J. Pedroni[2]

[1]Moinhos de Vento Hospital/ Clinical and Hospital Engineering, Porto Alegre, Brazil
[2]Moinhos de Vento Hospital/ Hospital Engineering, Porto Alegre, Brazil

ABSTRACT

This project aims to demonstrate a multi-parametric method of hospital technology comparison. The main goal was to develop a method to assist the clinical and hospital engineering team, in the process of acquisition and incorporation of medical-hospital equipment, to be used as a tool in the comparison stage of brand options and models of available equipment in the market. The method is composed by groups of criteria or characteristics that can be evaluate referring to the technologies to be compared. This method was applied to compare autoclaves and disinfecting machines that would be purchased to install in a Material Central and Sterilization in a hospital in the south of Brazil. As a result, it was obtained the classifications with the final scoring referring to each brand and model of technology. It also contributed significantly to assist the choice definition of the equipment, considering the hospital and technology profile, as well as the requirements and expectations of the multi-professional technical group of evaluators and users.

Keywords – *Multi-parametric Method, Hospital Equipment Comparison, Selection Assistance, Incorporation Process.*

INTRODUCTION

Where technologies are evolving with great speed, new priorities in the medical device incorporation process are emerging. Medical equipment must correspond to local clinical needs, as well as be accurate and reliable in the environment for which they are used, in order to generate safety and effectiveness for health care.[1] Medical device incorporation as defined by Wang "Is the entire process of absorbing technology into a health system or organization through planning, selection, and acquisition, with emphasis on its dependence on technology policies and continuous feedback from technology management."[2]

The acquisition process of hospital equipment requires a defined criteria to make the comparison possible between different equipment from different brands and models and to the ensure ease of incorporation in the hospital for a specific application. A few items that must compose the technical specifications list of the equipment to be purchased, are the characteristics of use, functioning principle, nominal capacity, physical dimensions, indication mode and parameter record, outputs and inputs, accessories, construction characteristics, safety, etc.[3]

Most hospitals (75%) do not have any decision-making tools such as multiple criteria decision analysis. Table 1 represent the categorization of different criteria used by hospitals to select a medical device by the degree of importance or the applied weight.[4]

TABLE 1. Categorization of Different Criteria used by Hospitals to Select a Medical Device by the Degrees of Importance

Degrees Of Importance	Criteria
Essential	• Technical characteristics • Vendor evaluation • Legal aspect • Safety aspect
Very important	• Current use of technology • Material resources / supplies • Type of qualification / training required
Important	• Costs-effectiveness and economic benefits • Clinical effectiveness • Clinical efficiency
Little important	• Evidence of adverse events, occupational hazards and other risks to users. • Departmental modifications
Irrelevant	• Ethical analysis • Acceptance of technology in institution • Patient and social aspects

An alternative to comparison of hospital equipment is to use a matrix composed by the models of the equipment and its technical characteristics with the possibility of defining the weights of each characteristic and grade. After finding the results of each characteristic and multiplying the weight by of grade given by the specialists in the evaluation, it is possible to obtain the final scoring for each brand and model of the evaluated equipment. The characteristics suggested in this method are reliability, precision, repeatability, safety, maintainability, interchangeability, performance, and cost.[5] Another options of characteristics that could be included in the comparison are the estimated price of parts, the existence of the part in national market, the stock list of the provider, the ease of importing parts, the proximity of the provider, stocking costs, reliability of the provider, and stoppage cost of the equipment by lack of parts.[6]

In the process of the comparison matrix development it was observed that a model should grade, weight, and categorize the features. This comparative matrix has three categories. The technical evaluation is composed of: precision, repeatability, maintainability, safety, performance, reliability and ergonomics. The clinical evaluation category includes the operation features, alarms, and display. And the third category, the financial evaluation accounts for the cost of the equipment, accessories, contract, and cost of the test instruments.[7]

In this line of categorization, there is also a spreadsheet that proposes additional categories that can be evaluated, them being: Safety (by mechanical and electric features), human engineering (design evaluation criteria, ease of maintenance, maintenance instructions, etc.), users experience (clinical engineering, doctors, nurses, and reports from other hospitals that have the referred equipment already evaluated, as a way of benchmarking) and other factors (such as standardization, familiarity). In this method, besides grouping criteria, scoring, and weighing, it is also suggests the weights of categories (0 to 1) and the grades for each criteria (0 to 10).[8]

Health care decisions are complex and involve confronting trade-offs between multiple, often conflicting, objectives. Using structured, explicit approaches to decisions involving multiple criteria can improve the quality of decision making. A set of techniques known under the collective heading, multiple criteria decision analysis (MCDA), are useful for this purpose. MCDA methods are widely used in other sectors, and recently there has been an increase in health care applications.[9]

The technology assessment domain corresponds to the choice and applying of multi-criteria methods in supporting the decision, such as: Analytic Hierarchy Process (AHP), Multi-Attribute Failure Mode Analysis (MAFMA), Elimination and Choice Translating Reality (ELECTRE) among others.[10] Multi-criteria decision analysis (MCDA) concepts, models, and tools have been used increasingly in health technology assessment (HTA), with several studies pointing out practical and theoretical issues related to its use.[11]

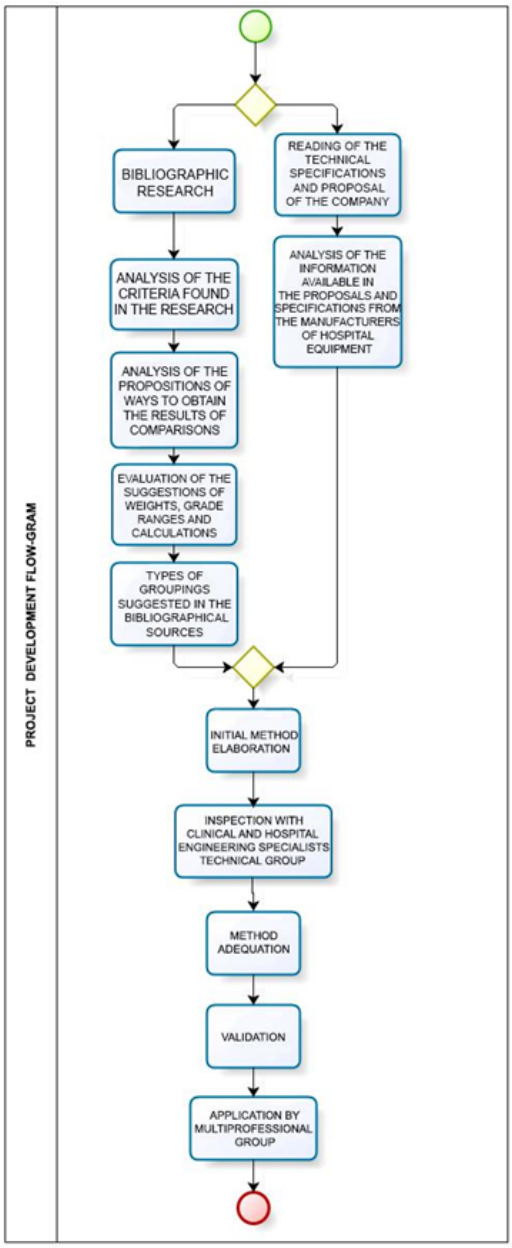
The goal of this project was to develop a multi-parameter method to assist the process of acquisition and incorporation of hospital technologies which can be used as a tool in the comparison stage of brands and models of equipment available. Also, this project would contribute methodically and standardized a more assertive definition of the choice of equipment while considering the hospital profile, technologies evaluated, users, and applications.

METHODS

A. Development of the multi-parametric method of evaluation

The method was developed from the bibliographical research, by reading the technical specifications provided in the technical commercial propositions through the notes from hospital and clinical engineering professionals and is demonstrated in flow-gram in Figure 1.

FIGURE 1. Project development flow-gram



The stages demonstrated in Figure 1 were followed to develop the multi-parametric evaluation method of hospital equipment at the moment of acquisition to help determine the choice of model and equipment settings.

B. Presentation of the criteria (or attributes) and groups (or categories)

Examples of criteria and groups used to evaluate the technologies are demonstrated in Table 2.

The information from Table 2 generated the following model, disposed in an Excel spreadsheet and presented in Table 3.

TABLE 2. Evaluation Groupings and Criteria

Group/Category	Examples of evaluated criteria
Cost	Installation, life cycle, parts, accessories, inputs...
Performance	Productivity related factors
Provider	Structure, profile, team, after sales…
Infrastructure	Infrastructure needs, utilities, electric, water...
Maintenance	MTBF, Tx. Failures, parts stocked…
Operation/Usability	Operation, functions, facility, audiovisual indicators...
Safety	Applied technology, criteria, standards, redundancies...
Technology	Constructive material, applied technology, evolution, component types...

The proposed method, was used to compare the hospital equipment used in Material Central and Sterilization (CME) as support in the choice of autoclaves and washing disinfecting machines. A multi-professional group was created of specialists, composed by the areas of hospital engineering (clinical engineering, production and electric-mechanic) of CME (nursing and administration) and CCIH (nursing), to validate the weights and grades to each criterion, in agreement, considering the types of technology that would be evaluated. Meetings were organized to validate the scores.

TABLE 3. Comparative Spreadsheet Configuration

	Criteria/ attributes	**Group/** category	**Weight**	**Option 1** grade	**Total grade of Option 1**	**Total grade of Option 2,3, ...**
1						
2						
3 ...						

The spreadsheet with the criteria was sent to the three providers that took part in competition. They only had access to the criterion list, not to the groups weights. Excel was used to generate the results with suggested calculations.

Table 4 shows some examples of the criteria and categories used to compare the washing disinfecting machines.

TABLE 4. Examples of Criteria and Evaluation Categories

What is the annual cost of non-contract preventive maintenance and no MP kit in Porto Alegre?	Cost
What is the annual cost of non-contract preventivemaintenance and MP kit in Porto Alegre?	Cost
What is the cost of infrastructure adequacy?	Cost
What is the cost of replacing the gate trim?	Cost
What is the replacement cost of the resistors?	Cost
What is the cost of the controller for the disinfecting machine?	Cost
What is the cost of the water reuse system for the disinfecting machine?	Performance/Efficiency
What is the water consumption per tray (in L)?	Performance/Efficiency
What is the water consumption per complete cycle (in L)?	Performance/Efficiency
What is the average time of the flash cycle including drying?	Performance/Efficiency
What is the average time of the instrumental cycle including drying?	Performance/Efficiency
What is the average cycle time for ventilator material including drying?	Performance/Efficiency
What is the time for daily water heating when the machine is cold?	Performance/Efficiency
What is the size of the inner chamber (height x width x depth)?	Performance/Efficiency
What is the capacity of loading in number of DIN baskets?	Performance/Efficiency
What is the load capacity in number of ISO baskets?	Provider
Does the company have any quality certification? (e.g. ISO 9001, BPF, BPAD)	Provider
Does the company have its own or outsourced technical assistance (representative) in POA?	Provider
Does the warranty cover the door resistances and fittings?	Provider
Do you provide operation manuals in Portuguese?	Provider
Do you provide technical reference manuals?	Provider
Is there another differential related to the technical assistance structure not addressed? If so, please comment	Provider
Will the engineers and technicians attending the HMV have an NR-32 or NR-10 training certificate?	Infrastructure
What is the weight of the equipment? (net weight + charge)	Infrastructure
What is the electric peak power?	Infrastructure
What is the nominal electric power?	Infrastructure
Is there a need for exhaustion?	Infrastructure
Is there a need for a water treatment system?	Infrastructure
Is there a need for an energy stabilization system?	Infrastructure
Is there a need for a compressed air point?	Infrastructure
Does the passageway have the necessary floor dimensions/resistance required for this equipment?	Maintenance
What is the maximum period for delivery of the pieces in Porto Alegre? Inform in numbers of days	Maintenance
What is the maximum time in hours for call after call on HMV POA? (State whether there is difference with and without contract)	
Does the manufacturer recommend preventive maintenance at what intervals?	Maintenance
What will be the technical assistance telephone service?	Maintenance
Does the company have stock for immediate supply of parts for the maintenance of the products offered? Is there any part that you do not keep in stock? (Please attach list)	Maintenance
Allows remote access to services? What infrastructure is needed?	Maintenance
In short, what preventive care will be required for this equipment?	Maintenance
What are the types of maintenance contracts available?	Maintenance
Can the equipment be connected to a material traceability system?	Operational/Usability
Is the control display colourful?	Operational/Usability
Does it have a printer / registration system?	Operational/Usability
Does it send data for external printing?	Operational/Usability
How is the door locking system?	Operational/Usability
How are notifications and alerts displayed /viewed?	Operational/Usability

What notifications appear on the display and are easyto see?	Operational/Usability
What is the layout of the command?	Operational/Usability
What is the layout of the display?	Operational/Usability
What is the construction material of the inner chamber?	Safety
Is the control display touchscreen?	Safety
Are the measuring instruments calibrated?	Safety
Does it have the option of two independent control systems (one for control and one for recording) as well as temperature sensors?	Safety
How is the door security system?	Safety
What is the guarantee of the chamber?	Safety
What is the construction material of the generator safety valve?	Safety
What is the door type?	Safety
What is the spray cover of the spray arms?	Technology
What is the thermal dissipation? (Wall thickness and insulation type)	Technology
What is the construction material of the control panel?	Technology
What is the construction material of the water pump?	Technology
What is the electrical resistance construction material?	Technology
What is the printer type?	Technology

The criteria were listed according to the number of specifications and technical descriptions that these types of equipment present. This was done through the initial proposals received from both the suppliers and the technical knowledge of the multiprofessional team from the hospital (which listed which criteria would be important to evaluate for the technical comparison of these types of equipment). The information or data in Tables 4 and 5 were initially obtained by sending the complete spreadsheets (some criteria were exemplified in Table 4) to the representatives / suppliers of the three equipment brands that participated in the comparison. The spreadsheets were received, filled in, and returned us with the information or data of the equipment.

After receiving the answers from the suppliers, they were evaluated by the multiprofessional group from the hospital according to the information received. These scores were equivalent to the levels of information provided by the manufacturers for each criterion (according to the consensus of this multiprofessional group).

C. Weighing Coefficients

The goal of the replacement of sterilization and thermodynamic equipment was to optimize flow, increase productivity, and thus qualify the service of Material and Sterilization Center, due to the demand in elevation and restricted physical area. For this, the multiprofessional group defined that the criteria / category of performance, and consequently technological characteristics / category (which allows increased productivity with decreasing process times, for example), as well as usability criteria / category (to facilitate the use, avoiding unavailability of the equipment due to doubts of use, difficulty of use and even misuse, were avoided). It was also defined that the post-sale / technical assistance category would have relevance (so that preventive maintenance and corrective maintenance routines were the most assertive and performed by a technical team capable of reducing downtime). We use AHP method to validate the consistency of the weights uses for each criterion.

D. How to transform qualitative criteria to quantitative criteria.

The multidisciplinary group defined analogy to transform criteria with qualitative to quantitative answers. For example, score from 0 to 5, where 0 (equals not shown, non-existent). Score 1 (equals little, or bad, weak, ... up to 5 (equals a lot, good, strong, ...)

RESULTS

With the scores inserted a spreadsheet summarizing the final results was generated (Table 5).

The weight for the cost-related criteria group was 15%. And as explained earlier, the initial goal was to increase productivity, and from this, given relevance to the criteria and groups, that would impact on productivity. The groups with the highest weights (with 15%) were the cost criteria; Performance / Efficiency; Maintenance; Operation / Usability and Technical / Technology. It was also observed that the acquisition and lifecycle prices were similar, varying in a small range, between the three options of models and brands. Thus, incorporation and lifecycle costs would not have a major impact on the

TABLE 5. Final Results of Option Comparison By Category

	Option 1	Option 2	Option 3
Cost Characteristics (installation, life cycle, etc.)	5,8	4,7	5,0
Performance/Efficiency Characteristics (productivity related factors...)	16,2	11,9	12,2
Provider Characteristics (structure, profile, team, after sales...)	8,9	8,4	9,6
Infrastructure Characteristics (structure needs, utilities, electric, water…)	6,0	6,5	4,1
Maintenance Characteristics (access, MTBF, Tx., failures, stock parts...)	4,7	4,4	5,1
Operational Characteristics (operation, functions, access, facility, audiovisual indicators...)	7,5	6,4	6,6
Safety Characteristics (applied technology, redundancies, criteria, standards...)	8,4	7,1	6,5
Technical Characteristics (constructive material, applied technology, evolution, component types...)	16,1	14,6	18,9
Total	73,5	63,8	67,9

organization, if one or the other brand (among those compared) was chosen.

After generating the results an opinion was issued to the Purchases/Supplies sector of the hospital who performed the final scores for each brand/model of participating equipment. The acquisitions were made considering the best scores resulting from this method.

The deal was closed in the third trimester of 2016. The equipment arrived in the first trimester of 2017 and the installing was finalized in May of 2017. The machines are in initial process of use after going through installation, validation, performance, calibration, and operational training of the users and technical team. The technical trainings are scheduled for June/July of 2017.

DISCUSSION

Not only was the method model creation and definition laborious, so too was assigning the criteria (which were very extensive) and receiving the information from the providers/representatives. The companies, in general, don't know all their products' information. All companies needed to request information from their respective industries. These factors took a long time and delayed the comparison process.

It also required a lot of attention, time, and dedication to include the definition of weight average and scores to the criteria. Depending on the weight averages and scores, scales the differences in final scores became very tenuous. It was also necessary to define qualitative scales to support the quantitative scales. However, criteria don't always have data (quantitative) and there are criteria that are qualitative. Therefore, it is necessary to transform them into quantitative data. In some cases it was noticed that some characteristics interface/relate each other with others or that can be associated with more than one group/category.

Table 6 demonstrates the quantity of criteria defined, by group/category to be evaluated in the process of comparison.

TABLE 6. Criteria Quantity Defined by Category

Group/Category	Criteria Quantity to Autoclave	Criteria Quantity to disinfecting washing machine
Cost	22	22
Performance	21	27
Provider	24	25
Structure	18	19
Maintenance	11	9
Operation/ usability	19	18
Safety	14	14
Technology	29	32
Total	158	164

The impacts of the technology sterilization substitutions, washing, and disinfection, will be measured concerning performance, productivity, maintainability, costs and other pre-evaluated criteria and can be certified in practice. Other comparative-method developments, including criteria inspection, groupings, weights, calculations, can be done. Additionally, the influence analysis on the types of technologies to be compared, in criteria and weights that work as a base to the comparison.

To make validations and adjustments possible you must have adhesion according to the technology to be compared. For example, this method was applied in other acquisition processes, as an assistant to the comparison of medical-hospital equipment. It was applied by both the hospital engineering team, to evaluate other technologies like air central and medicinal vacuum, and by the clinical engineering team, evaluating the multi-parametric monitor options and in other cases in which the results can be demonstrated in further projects.

CONCLUSION

The acquisition process of hospital equipment requires defined criteria to make comparison possible between different brands and models, and to point to the selection and consequent definition of which item will be more fit to incorporate in a certain hospital in a certain application.

This project proposed the development of a multi-criterion method to support the acquisition process and incorporation of hospital technologies, to be used as a tool in the comparison stage of brand options and equipment models available in the market.

The project contributed significantly in the assistance of more assertive definitions of the steam autoclave and disinfecting washing machine, while considering the hospital profile, requirements, and expectations from the multi-professional technical group of evaluators and users. It is believed that methods like this must be developed and replicated according to the technology profiles of hospitals as well as their needs and acquisition goals.

CONFLICT OF INTEREST

The author declares not having conflict of interest.

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Analysis of IFMBE-CED 2017 Worldwide Clinical Engineering Survey

By L. Nascimento[1], S. Calil[1], T. Judd[2], Y. David[3]

[1] Department of Biomedical Engineering - School of Electrical and Computer Engineering. University of Campinas, Brazil

[2] Chair, IFMBE Clinical Engineering Division. Associate Editor, Health Technology and Quality, The Permanente Journal

[3] Biomedical Engineering Consultants, LLC, University of Texas School of Public Health

ABSTRACT

Background and Objective: Clinical engineering (CE) professionals are fundamental to the deployment of healthcare technology and the management of its life cycle. As the role of technology grows in healthcare, so does the need for trained CE practitioners and the dynamic nature of the domain requires them to maintain their skills. However, the skills and activities required from clinical engineers around the world are not homogeneous, so the CE Division at IFMBE promoted a global survey to identify a common body of knowledge and body of practices for the profession.

Material and Methods: This survey, based on a previous one conducted by the American College of Clinical Engineering, was aimed at collecting data about clinical engineering practices and the importance of certain competencies for their practitioners.

Results: Survey results indicate the profession still maintains certain traditional characteristics, such as the predominance of professionals with a background in electrical, electronic, or mechanical engineering and the prevalence of hospitals and clinics as employers. Some patterns in the perceived relevance of certain kinds of knowledge among different regions were also identified.

Conclusion: Overall, the survey seems adequate to reveal which skills and activities CEs considered the most relevant, but more responses are required before a solid Body of Knowledge and Body of Practice can be defined.

Keywords – *Clinical Engineering, Body of Knowledge, Body of Practice, Clinical Engineering Survey.*

INTRODUCTION

To reap the full benefits of deploying technology in healthcare delivery, healthcare programs require competent clinical engineering professionals to manage its life cycle. As the technology's role rises over time so does the need for trained clinical engineering practitioners. Clinical Engineering (CE) is today one of the most dynamic professions in the world.[1] This dynamic state challenges CE professionals to maintain their skills and stay current with the continuous progress of healthcare technologies. From the early stage of innovation throughout the rest of the technology life cycle, clinical engineers not only have to keep a constant update of their knowledge and expertise needed to develop their activities but also to periodically add, adapt, and learn new competencies and methodologies due to introduction of new and innovative technologies. Clinical engineers must sustain and further

build their contribution to safe, efficient, and optimal life cycle stages and patient outcomes.[2]

While Maintenance Management, Equipment Specification, and Acquisition composed the basic set of knowledge for clinical engineers in the seventies and eighties, the current basic set is composed of more than 18 subjects and it is still growing. Table 1 compares the increasing number of subjects during the last 18 years.

TABLE 1. New Subjects Added to the Set of Knowledge of clinical engineering in the Last 18 Years (based on personal observations)

1970 – 1980	1990 – 2015
• Medical Equipment Management • Safety • Procurement • Education • Individual Product Management • Individual Thinking	• Medical Equipment Management → Technology Management • Safety → Risk Management • Procurement • Education • Disaster Preparedness • Cost Control (TCO. LCC) • Technology Assessment • Telemedicine (Homecare) • Project Management • Contract Management • Mobile Healthcare (Events. Transports. Group Assistance) • Home Care • Quality Management • Information Technology (Interoperability) • Human Factor Engineering • Forensic Analysis • Artificial Intelligence • Systems Integration And Management • Soft skills (Writing. Communication. Supervision) • Team Practicing

LCC = life cycle costs; TCO = total cost of ownership

There are very few recent studies describing worldwide activities developed by CEs. Most surveys were either done a long time ago[3,4] or are recent, but regional. To our knowledge, there are no recent publications on surveys conducted to investigate CE activities worldwide. In 2004, a comprehensive CE survey[5] was developed to address two points via two questionnaires. The first one investigated the structure, personnel, responsibilities, and resources of the CE departments all over the world. The second questionnaire was to investigate trends and current CE practices. To identify such practices, respondents were requested to check a list of several activities such as equipment management, quality control, risk management, education, and training. The resulting analysis from the 174 valid answers received, indicated that the main problems were lack of highly qualified personnel (because of the lack of quality academic programs), limited funding for technical training to maintain staff competencies for all equipment types and continuous pressure to reduce costs by increasing department efficiency. Additionally, the authors also concluded that despite the efforts for activities harmonization among CEs regarding the management of healthcare technology in hospitals all over the world, this subject remains non-uniform, with great variations in terms of structure, personnel, responsibilities, resources, and outcomes.

Starting in 2004, the BIOMEDEA project (a European-wide initiative) promoted the organization of three meetings aiming at the development and establishment of consensus on European guidelines and protocols for the harmonization and accreditation of high quality Medical and Biological Engineering and Science programs and for the training, certification and continuing education of professionals working in the health care systems.5 The third meeting took place through an international symposium on an important issue of quality assurance in biomedical/CE: patient safety.

In 2005, a meeting co-sponsored by the University of Stuttgart and the International Federation for Medical and Biological Engineering – IFMBE,[6] produced several documents, which included an "Agreement for Mutual Recognition of Qualifications for Clinical Engineers". A white paper produced by the Clinical Engineering Division – CED/IFMBE7 described its contents. A further document was also produced: the "Protocol for the Training of Clinical Engineers in Europe."

Both were very important and valuable documents; however, some obstacles stopped the progress of such initiatives:

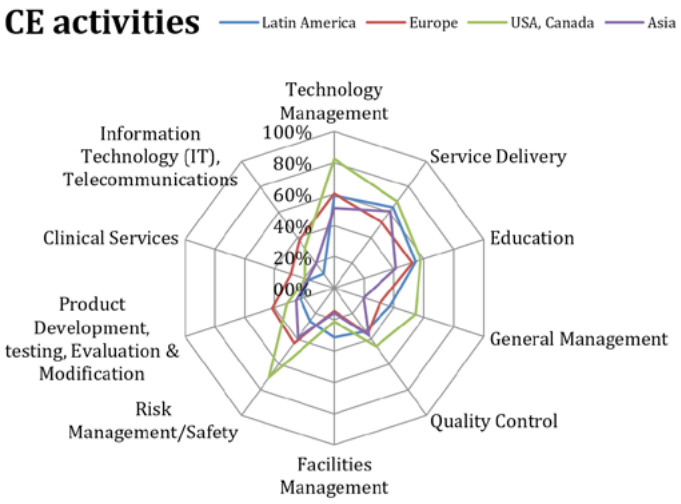
1. There were no further discussions to carry on the work and the documents became just a source of consultation.
2. The documents were heavily based on the CE model adopted by the American College of Clinical Engineering (ACCE), meaning that it was an American model to be adopted in Europe.
3. The document aimed the CE in Europe and even though its development lacked further studies to understand the kind of CE activities practiced in many of the European countries.
4. The document contents would serve only as a source of consultation for countries outside Europe and it did not fill the need to find a worldwide harmonization for knowledge among CEs.

Then, also in 2005, CED/IFMBE launched a survey aiming to learn about the CE activities in different countries.[8,9] The objective was to identify and develop a worldwide network of CEs and understand their activities. This survey looked for characteristics such as age, time of experience in the CE area, type of employer, primary position and all the activities developed within the work.

The results of this survey indicate some similarities among activities in several parts of the world. Figure 1 shows the results of the 2005 survey and it indicated that Technology Management was practiced by a range of 55% (Asian CEs) to 85% (North Americans and Canadian CEs) of the respondents. As another example, risk management practices varied from 39% (Latin Americans CEs) to 70% (North Americans and Canadians CEs). Such similarities can be the basis for developing stronger international cooperation among clinical engineers and CE professional organizations. This set of activities can also be the basis to understand the core of CE practices worldwide and develop a core of knowledge to be taught by any academic unit that aims to train CEs. It can also be used by countries/societies that already have or are planning to develop a CE credentialing or certification system.

This was, however, a primary set of data. To have a more reliable set of the knowledge needed by CEs to develop not only their daily activities but to empower them to propose and develop advanced projects within the CE area, it was necessary to have a better understanding of the CE profile and practices worldwide. The results of the 2005 survey are outlined in Figure 1.

FIGURE 1. The results of the 2005 survey showing that, according to the respondents, Technology Management is one of the activities practiced by a range of 55% (Asian CEs) to 85% (North American and Canadian CEs).



Ten years later, in 2017, sponsored by IFMBE/CED it was possible to develop and launch a worldwide project called "Body of Practice and Body of Knowledge – BoK & BoP." This project, led by senior CEs from around the world, developed data collection tool (a survey), included additional questions designed not only to identify the CE activities practiced at their place of work but also what set of competencies is important for better development and successful outcomes from such activities.

This survey was based on a similar tool used by the ACCE to identify the profile and practices of CEs working in USA and Canada.[10]

METHODS

The topics and format of the questions were either extracted or modified from a survey kindly provided by the ACCE and Eng. Frank Painter. The original survey was used by ACCE to determine the current knowledge and skills needed for competent CE practice mainly in the United States and Canada. As the ACCE survey, this one was divided into five sections, aiming at collecting different pertinent types of information.

The first part of the survey – "Contact Information", asked for identification and general data about the respondent. such as name, company, country and email address. In this part, only the country's name of the respondent was mandatory.

The second part – "Job Information," was focused on acquiring data about the CE employer and educational background. It included questions about the type of employer, about how respondents describe their profession, the primary nature of their current position, their academic background (engineering or other), and about the existence of CE certification in the country.

The third section – "Knowledge", presented a list of 28 knowledge topics and asked the respondents to rate the importance of those topics (Minor, Moderate, or High Importance) in the development of their activities.

The fourth part – "Responsibilities," presented eight classes of activities (Technology Management, Service Delivery Management, Product Development Management, IT/Telecommunications, Education, Facilities Management, Risk Management/Safety, and General Management). A list of multiple skills related to each one of these classes was then presented. and respondents were asked to rate how important (No, Minor, Moderate, or High importance) each skill is to develop each of the "Responsibility."

The final section of the questionnaire – "Work Activities", asked the respondents to indicate the percentage of time they dedicate to each one of the eight classes of activities presented in the previous part.

During the data analysis process, weights were assigned to the levels of importance indicated in the responses: for the knowledge topics where the answers had three rating levels; 0 (zero) was assigned for "Minor," 1 for "Moderate," and 2 for "High" importance.

For the responsibility topics. where four rating levels were presented. 0 (zero) was assigned for "No," 1 for "Minor," 2 for "Moderate," and 3 for "High."

Though there are several ways to present the data in this article, it was decided to show the result by geographical region: Latin America, Oceania, Asia, Middle East, Europe, Africa and, USA and Canada.

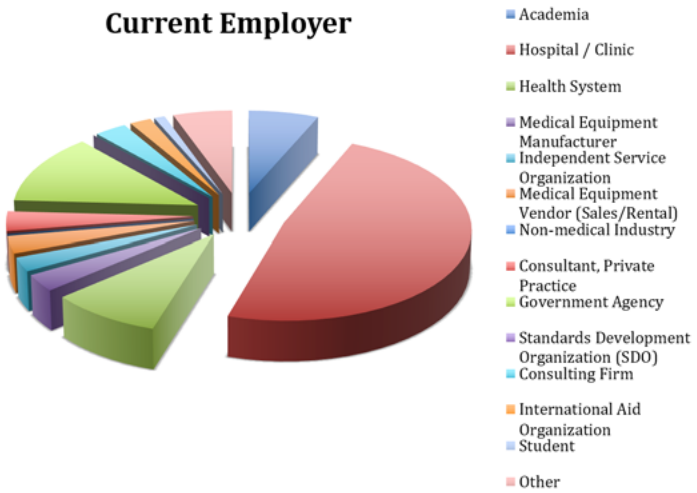
The survey was developed and presented to the invited participants with Google Forms and 574 invitations were sent by email.

RESULTS

From the 574 invitations to respond to the survey, 199 responses were received from 35 countries. From those; 35% came from Latin America, 20% from Oceania, 14% from Asia, 11% from the Middle East, 10% from Europe, 6% from Africa and 4% from USA and Canada. Though it was below the expected number of responses, the results can already present important information regarding the objectives of the BoK & BoP project. Due to the very low number of responses from USA and Canada (7 responses), here it will be left out of the resulting graphics but will be at a later point compared with the 2015 ACCE survey.[8] The African Region also has few responses (12 responses) but is presented due to the very small number of CEs working in that region. The total number of respondents with an electrical/electronic/mechanical engineering (B.Sc.) degree is around 65%.

As identified in the 2005 survey, the vast majority of CEs (48%) are employed by hospitals or health clinics. Government agencies are ranked in the second position as employers according to 12.5% of the respondents (Figure 2).

FIGURE 2. Percentage of the types of employers of clinical engineers worldwide.



Respondents were also asked how they see themselves as professionals. Nine different names that could define the profession were given (including the options "Others") and the question was presented as: "Which of the following names do you believe best describes your profession?" Around 48% describe themselves as CEs and 18.1% as healthcare technology managers.

Asked about the primary nature of his/her present position, the three first positions selected worldwide were Management (45.7%), Service Delivery (15%) and Professional Support (14.1%). However, this question also raised interesting information: Management was the first position in all regions but it was placed second in Oceania (34.15%) and Service Delivery (41.5%) was placed first.

Due to the small number of responses from each region, one can argue that such results lack reliability. However, by comparing this information with those obtained in 2015 (the USA and Canada BoK survey,8 with 472 respondents), the picture regarding Technology Management is the same, being in the first position. According to the respondents, there are great variations for other positions depending on the region. This can be seen in Table 2 where Latin American CEs responded (70 responses) that Professional Support is the second position while in the Middle East (21 responses), as Oceania (41 responses). Service Delivery is the second position.

TABLE 2. Final Results of Option Comparison By Category

	Africa	Asia	Europe	Latin America	Middle East	Oceania
Management	41. 67%	42.86%	50.00%	54.29%	42.86%	34.15%
Research	0.00%	7.14%	10.00%	4.29%	0.00%	2.44%
Manufacturing	0.00%	0.00%	0.00%	1.43%	0.00%	2.44%
Teaching	25.00%	10.71%	0.00%	7.14%	9.52%	2.44%
Consulting	16.67%	14.29%	10.00%	8.57%	0.00%	0.00%
Service Delivery	8.33%	3.57%	10.00%	4.29%	28.57%	41.46%
Professional Support	8.33%	17.86%	10.00%	15.71%	14.29%	14.63%
Other	0.00%	3.57%	10.00%	4.29%	4.76%	2.44%

One of the most important questions and the one that directly helps to achieve the objective of this project asked respondents to indicate, in a list of background knowledge topics, the level of importance of each one for his/her daily duties and responsibilities. Three levels of importance were presented (Minor, Moderate and High Importance). To present the results, the data processing was already explained in the chapter "Methodology" previously.

Interesting observations can be made by looking at the results presented in Figure 3. Though not with the same level of importance, there are coincident "Knowledge" rating tendencies. All respondent regions rated General Medical/Nursing Equipment above moderate importance. The same happens to the "Knowledge" regarding Computers, Networking and IT. On the other hand, "Knowledge" regarding Telecommunications is below moderate to all regions. The same happens for Chemistry and Implants.

FIGURE 3. Level of importance of background knowledge for clinical engineers to develop their daily work activities.

PACS = picture archiving and communication system

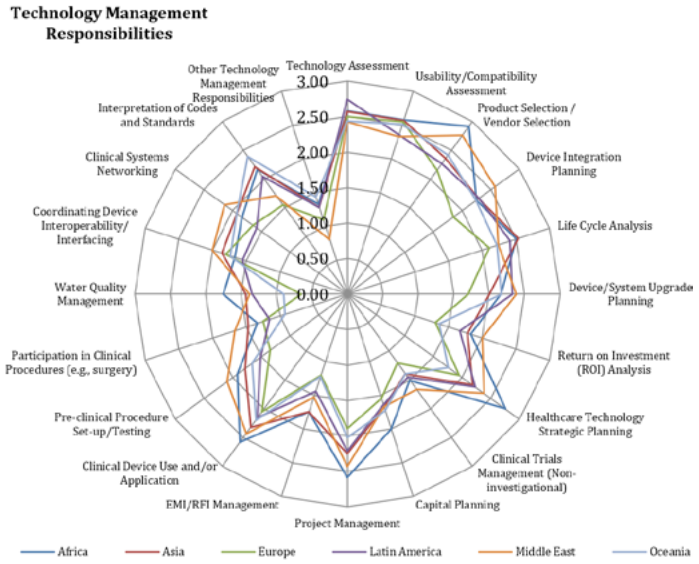
Other comments can be made about these results but, the most important one is to see that a primary profile of the Body of Knowledge for CEs all over the world can already be traced, based on the rate tendency.

This survey, as well as the 2005 survey7 and the one promoted by ACCE9, pointed out that the position of technology manager was the one held by most clinical engineers worldwide. Presented with 20 different

activities within the scope of this position, they were asked to rate the importance of each activity (High, Moderate, Minor and No) to develop their work. The process used to present this information was already explained in the Methodology chapter.

Again, Figure 4 shows a great number of coincident tendencies regarding the activities. Taking as an example the activity Life Cycle Analysis, all regions rated it between Moderate and High importance. On the other hand, the activity Clinical Trials Management is rated as Minor to Moderate importance within the responsibilities of their work. As mentioned before, despite the low number of respondents, the importance of the activities among the regions follow the same pattern.

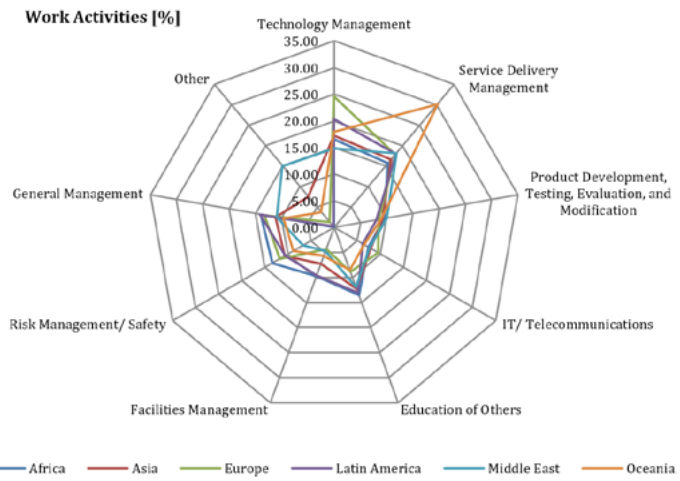
FIGURE 4. The importance of activities for clinical engineers within the technology management domain.



EMI = electromagnetic interference; RFI = radio frequency interference

Figure 5 presents the percentage of time CEs spent on each work activity during the work. Confirming what was pointed out on Table 2, most of the CEs from the Oceania region spent their time on service delivery (30%) while CEs from other regions spent between 15% and 18% on this activity. Important work profiles can be noticed here; while CEs from the European region spent 11.7% of their time on Risk Management Safety, this percentage is reduced to 6.7% by CEs in the Middle Eastern region. Another activity that presents a great difference in the percentage of dedicated time is Education of Others. While in Latin America CEs declared that this activity consumes 13% of their time, in the European and Oceania regions it drops to 8.5%.

FIGURE 5. Percentage of time spent by clinical engineers on each activity during work.



EMI = electromagnetic interference; RFI = radio frequency interference

The reasons for such percentage differences in some activities may be due to the group of respondents within each region, interpretation of the question (Survey was done only in English) or cultural behavior. One may understand that Education of Others meant a short but formal lecture and others may understand that just the fact of orienting a new technician on repairing medical equipment is part of the time dedicated to education.

The kind of activities the CEs develop for each work activity was also explored, as shown in Figure 5. A total of 18 different activities composing the Risk Management/ Safety work activity was presented to be rated according to its importance to the development of the work.

Figure 6 shows a few differences in the importance of each activity given by the respondents according to the region. While in the Oceanian and European regions the respondents considered Forensic Analysis as low importance, all other regions considered it above moderate. The

majority of other activities were rated between minor to moderate importance.

FIGURE 6. The importance of each activity within the Work Activity Risk Management/Safety.

DISCUSSION

One of the most challenging tasks when designing mainly a worldwide data collection tool in the form of a survey is to develop a question that has the exact meaning to all respondents. Due to language and culture differences as well as different academic systems and job titles, people tend to respond according to the regional characteristics, which cause some distortions in the analysis of the results. Some of the data obtained can be corrected by a simple translation to English while others would be necessary to have a deeper understanding of the country's academic system.

Adaptations from the ACCE survey were necessary to meet the objectives of this survey. It was not only to identify the CE body of practice and CE profiles worldwide but also to use the identified the body of practice to understand the body of knowledge required by CEs to successfully develop such activities. It is expected that in the near future this set of knowledge would help to develop a scope of academic subjects necessary for graduating students to understand to optimally practice such activities.

The structure of the survey allows a more detailed analysis of the data obtained. It is possible, according to the answers and number of responses, to have the profile not only of each respondent, but also the CE model practiced by the country, and the health unit he/she is working at.

No doubt that a higher number of responses from clinical engineers and other countries would make the information more accurate. However, it is already possible to devise a core of activities practiced by CEs all over the world. Regarding the needed knowledge for better developing their work, the results showed that though its importance varies according to the CE model practiced in the country/region, there is also a set of knowledge that is commonly needed worldwide.

There is a need to periodically update the information obtained in this survey due to the dynamic characteristic of the CE profession and the changing dependence of healthcare services on technology. For almost every new technology and procedure to be used in the health area there is an anticipated and required a new set of knowledge for the practicing clinical engineers throughout the technology life cycle stages from innovation to disposal and replacement.

CONCLUSION

We hypothesized that a common body of knowledge and body of practice for CE would emerge from the analysis of a worldwide survey.

Despite some differences between regions, some patterns of perceived relevance of different fields of knowledge and activity responsibilities within the areas are visible.

This suggests that CE does have something in common around the world but more responses are necessary to define a solid worldwide Body of Knowledge and Body of Practice for the Profession.

ACKNOWLEDGEMENTS

The authors wish to thank Eng. Frank Painter for authorizing the adaptation and use of an earlier version of the survey he developed.

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Integration of the trans-operative information with the patient's electronic record

By E. K. Souza[1], A. M. Marciano[2]

[1]Moinhos de Vento Hospital/ Clinical Engineering, Porto Alegre, Brazil

[2]Moinhos de Vento Hospital/ Clinical and Hospital Engineering, Porto Alegre, Brazil

ABSTRACT

This article presents an integration project between the anesthetic station used in the step of trans-operative (life signals multiparameter monitor, anesthesia device and controlled-target infusion pump) and the system of hospital information. The main goal of this project is to automatically capture the vital signals from the medical equipment and the records trans-operatives and provide an anesthesia record to be stored in the patient's electronic medical record. The integration mode is through a gateway that executes the conversion of the machine- specific language into data/information of the HL7 standard. This interaction will allow integrating data and information from multiparametric monitors, anesthesia devices, Controlled-target infusion pumps, and the intra-operative anesthesiologist inputs.

Keywords – *Medical Equipment, Anesthesia Station, Step of the trans-operative, Patient Data Integration, Electronic Records.*

INTRODUCTION

The patient's record is a mandatory document in Health Assistance Establishment and is considered an extremely important tool that requires a mechanism of follow up of the data inserted in it. The electronic medical record can be quoted as one of the mechanisms that present many advantages to the institution such as paper use reduction, digital certification, more reliability and safety for the data inserted in the records and, to the information derived from it.[1]

It has been claimed that a combination of Information Technology (IT) devices such as computers, communication networks, medical information, and online electronic data can improve the quality and decisions concerning health care. Therefore, the automation of the patient's records (even incomplete) contributes significantly to the quality improvement of the treatment beyond the effective control of costs involved.[2] A medical record system is represented by a series of components that form mechanisms so the records can be created, used, stored, and accessed as part of a hospital information system (HIS).[3]

In the surgical environment, there are examples of software development that consists of the data integration of monitoring parameters during anesthesia and a group of rules configured by the anesthesiologist. Alerts generated by the software provide important information about the patient's condition and eventual risk situations which wouldn't be highlighted if only the individual alarms of the parameters coming from the monitors were considered.[4]

This project presents an integration proposition between the anesthesia station equipment used in the trans-operative stage (multiparametric monitors, anesthesia devices, controlled-target infusion pumps) and the patient's medical electronic records (PEMR). The goal is to automatically capture the vital signals from the medical equipment and the records of the trans-operative data to create anesthesia file that integrate the PEMR with the HIS. The specific goals of this project are: (a) increase the safety and reliability of data and information from the trans-operative stage; (b) qualify this data and information via automatic inputs with no further manipulation; (c) improve the medical document and protocol pattern; (d) diminish the probability of failures and increase clarity; (e) facilitate the data research and information for studies, benefiting doctors, hospitals, and patients.

METHODS

Described below are the development phases of the project, the integration alternatives, the integration method option used, and the information that will be integrated into the implementation stage.

A. Project Development

The stages of development flow-gram of the project are described below in Figure 1.

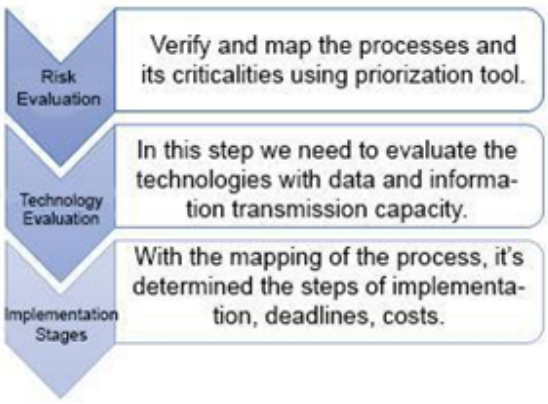

FIGURE 1. Project development flow-gram.

As demonstrated in Figure 1, risk evaluations were executed as well as the vulnerability/fragility of the anesthetic procedure related to the absence of automated records and data integration and information from the medical technology used in this stage of the surgical process. Next, we surveyed the hospital's equipment that can already transmit data for then plan and the sub-stages of the implementation. The next stage consisted of the processes/operations/activities detailing the peculiarities that determine which data and information would be registered and integrated, the technologies available in the market for this type of record integration as well as the costs.

B. Architecture/Topology of the Integration System

The definition of interoperability, according to the Institute of Electric and Electronic Engineers (IEEE) deals with the capacity of two or more systems to exchange information and being able to use the information exchanged.[5] The communication Health Level 7 (HL7) is a communication structure with determined standards to the exchange execution, integration and sharing of communication information between devices or clinical data system devices.[6]

The architectures or topologies of communication can be divided into two suggested formats, "without Gateway" and "with Gateway." In the topology format without gateway, the data are transmitted from equipment in HL7 and are processed before storage in HIS. The format with Gateway requires an intermediary device that physically separates the HIS and the biomedical equipment. This device performs the machine-specific language conversion of HL7 standard to be consequently processed and stored. Concerning the integration method of monitoring data and trans-operative stage information, the topologies and/or architectures are demonstrated in Figures 2 and 3.

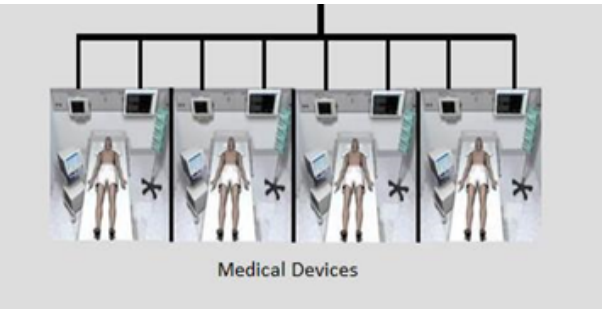

FIGURE 2. "Direct" topology without Gateway.

In the architecture model of Figure 2, the equipment provides the information directly in the HL7 language allowing the storage of clinical data in the HIS database. In Figure 3 below, it is demonstrated the topology using the intermediary device, named Gateway.

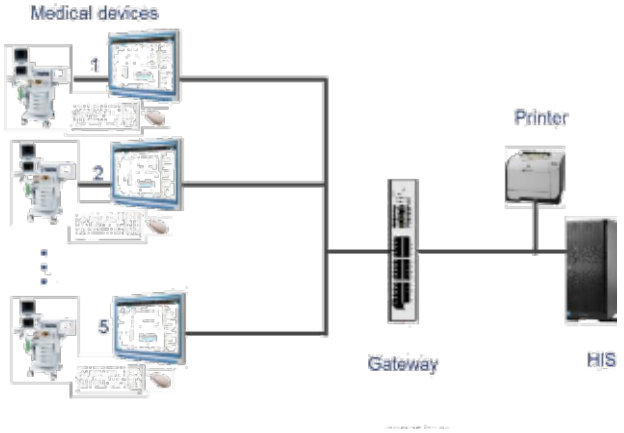

FIGURE 3. "Indirect" topology with Gateway.

In this type of topology, the information from the equipment needs a data converter named Gateway responsible for trans-coding the information from the equipment to clinical storage data in PEMR.

In this last model evaluated it is observed the need of more devices to integrate and intercommunicate data treatment and information storage appliance so the information generates an electronic anesthesia file with further storage in PEMR.

Considering the evaluated options of integration methods and equipment profiles installed in hospitals it was necessary to use the topology demonstrated in Figure 4.

RESULTS

The suggested method was applied in a private, non-profit hospital that has around 400 hospital beds and is located in the capital of Rio Grande do Sul (a Brazilian State). The hospital has around 4500 pieces of biomedical equipment.

Among the various areas that execute assistance health care treatment, using technologies, was defined the automatic capture of information from the trans-operative process from the equipment that was able to transmit data referring to the patients' monitoring and therapy, in 5 specific surgical rooms to store in PEMR and HIS. The topology to be used in this project is illustrated in Figure 4.

The data to be captured and information inserted in this integration are related in Table 1.

TABLE 1. Integration Parameters

Origin	Information
Multi - parameter Monitor	Vital Signals (ECG, SpO2, PNI, PI, CO2)
Anesthesia Equipment	Ventilator Data and Anaesthetic Gases (Vmin, Aereal vias pressure, frequency, PEEP, ventilator mode)
Controlled Target Infusion Pumps Drugs	Volume and administered concentrations
Anaesthesiologist Input	Events and information trans-operative elapsed

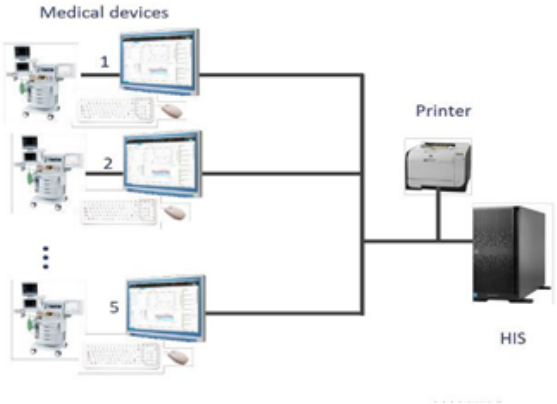

FIGURE 4. Topology used in the project (without Gateway).

In the architecture of Figure 4, the data of the anesthesia station provided by the equipment (multiparametric monitors, anesthesia devices, Controlled target Infusion pumps) and the information and events manual input in the trans-operative (executed by the anesthesiologist) are integrated and converted in HL7 by an All in One Computer (AOC) attached to the anesthesia activities medical-assistance device, providing the institution the information to improve its procedures.

As described in Table 1, this integration allows to automatically register data from the patient's vital signals in surgery, ventilator mechanics, anesthetic gases, drugs

infused, as well as the events and information trans-operatively executed and informed by the anesthesiologist.

It was also possible to identify which types and quantities of equipment are integrated with further stages so the solution can be implemented in all surgical rooms in the hospital, and thus allow the estimation of the financial resources needed to invest in future implementation to include budget planning in the institution's posterior year.

DISCUSSION

This project is a consequence of the maturing associated with the continuous improvement of the storage processes of the patient information from the service promoted by a large hospital in the south region of Brazil.

It's worth pointing out that the success of this project is directly tied to the active participation of the Medical, Technology Information, Clinical Engineering teams beyond investing in needed hospital equipment that can export data, besides in technology information infrastructure including processing and storage servers, cabling, enabled network points, etc.

Attention is needed concerning issues including concept alignment with the board of directors and scenario evaluation referring to opening the service suggested (because this project will change the *modus operandi*). Another important factor is in the previous capacity of all the teams involved.

The data safety has worried various sectors in many areas in the world, therefore, it is recommended that the product selection and technologies have the recognition of the National Health Surveillance Agency (ANVISA) or similar group in the application country and are in compliance with the Information Safety Rules.

The continuity of application of this integration, the way the data and information are transferred, stored and further accessed, and the safety protocols, are susceptible to further analysis, developments, adjustments, and validations.

CONCLUSION

The health organizations using electronic systems tend to have more effective control over data and patients' clinical information. This more efficient way of information collection can provide safety, transparency, and better service to the patient, allowing the audit of activities such as medical-assistance, providing the institution data to improve its procedures.

In more advanced centers and some Brazilian hospitals this form of more efficient collection, storage, and information integration begins to develop, mainly in the application of intense therapy unities.[7]

The clinical engineering teams with their multidisciplinary knowledge can contribute to the medical teams, assistance, and information technology and become increasingly applied to the integrated possible technologies.

The expectation is that the project will automatically capture the vital signals from the medical equipment and the records from the trans-operative and to provide an anesthesia file to be stored in the PEMR and in HIS, which can effectively contribute to the safety and reliability of data and information from the trans-operative stage. The project will also qualify the data and information via the automatic inputs and with no further manipulation.

This will contribute to improving the standardization of documents and medical protocols, decrease failures, and provide more clarity in adverse events via the ease of data search and information for studies which benefits doctors, assistants, hospitals, and patients.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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Distribution and utilization of Radiotherapy Units in Greece

By A. Dermitzakis[1], S. Domente[2], N. Pallikarakis[1]

[1] Institute of Biomedical Technology, Greece

[2] Regional Office for Europe, World Health Organisation

ABSTRACT

Biomedical engineering is playing a leading role in the development of medical technology which is one of the pillars of modern medicine, or as differently expressed at the European Economic and Social Committee (EESC) opinion paper: "Biomedical Engineering is not simply a subset of modern medicine. Modern medicine predominantly secures important advances through the use of the products of biomedical engineering."[1] Health technology, according to the World Health Organization (WHO), refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of life. Therefore, medical devices (MDs) belong to health technologies, and radiotherapy (RT) is an important subgroup.

RT refers to high-tech MDs that are of high capital value both in terms of initial investment and operation, requiring specially trained personnel for its use and needs regular quality control, preventive maintenance and management procedures, to function properly and safely. Clinical engineering plays a major role in facing of the aforementioned challenges.

The present paper provides an overview of the results of an assessment report under the WHO action on Strengthening Capacity for Universal Coverage Greece/Phase 2 (SCUC2)[2] aiming to:

- Assess the sufficiency and equity in the distribution of RT and its use in Greece
- Identify eventual inequalities in terms of geographical coverage, specific needs and lack of RT
- Assess the current status of staffing in RT units
- Estimate the costs for the use of high-value capital medical equipment (HVCME)

Since a country-wide medical equipment inventory for Greece does not exist, various sources were used to obtain a clear picture of the installed units in public Greek hospitals, and private clinics.

As a result, it came out that, in terms of the number of units per million population the number of RT units rose by 23% from 4.3 in 2009 to 5.3 in 2017. In terms of the number of acts, a general increasing trend is noticed, resulting in a total cost increase of 25% from 2013 to 2016.

The analysis revealed that in Greece, there are quite pronounced inequalities in terms of availability of RT technologies in different regions. Long term strategic planning is needed based on evidence, such as updated inventory of MDs, acts performed, associated costs etc., which are unfortunately lacking in Greece. Additionally, the role of clinical engineers in effective management and safe use of this technology should be widely recognized and regulated.

Keywords – *Radiotherapy Units, Inventory, Clinical Engineering, Distribution, Greece.*

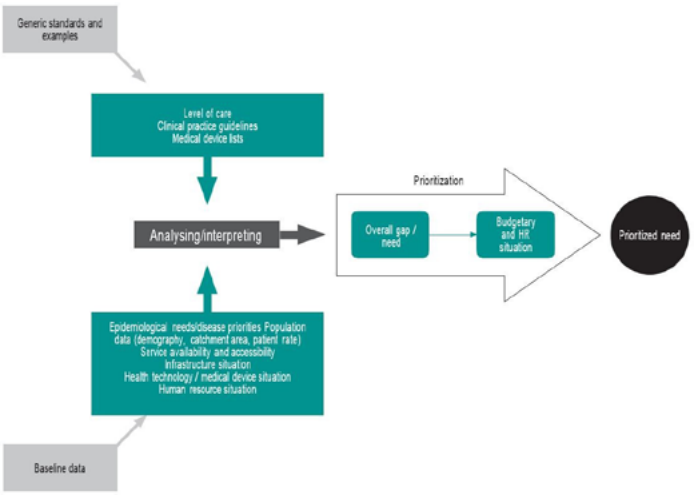
INTRODUCTION

Advances in biomedical research are leading to a storm of innovation and the development of new diagnostic and therapeutic devices has led to a radical change in current healthcare delivery. Modern medicine is strongly dependent on technology.

WHO has published a general approach for performing a needs assessment based on existing and available equipment in a region or country, comparing it with what should be available, considering particular demands and needs, and taking account of epidemiological data, recognized standards, and Clinical Practice Guidelines. By considering this alongside with possible financial restrictions and the human resources available, the actual technological gap can be identified.

The whole approach is depicted in the general needs assessment diagram shown in Figure1.

FIGURE 1. WHO needs assessment diagram.



Source: WHO, 2011

It is important to note that reliable baseline data on the existing situation and evidence-based assessment of needs are prerequisites for effective use of such a model. In addition to the international scientific and technical literature, the standards and best practices in use and the current trends on these technologies, the general information sources for this report are data available from international organizations such as WHO; Organisation for Economic Co-operation and Development (OECD), European Union (EU), National Institute for Health and Care Excellence (NICE), ECRI Institute (ECRI), and other reliable web sources.

In Greece, there is no centralized national inventory for installed HVCME, so the relevant information and data collected and used in this report are based on cross-referenced sources which creates several problems associated with data integrity, reliability, and (in some cases) compatibility.

There are also no available data related to the actual use of these technologies, except for indirect information on those procedures that are reimbursed by the National Organization for Healthcare Provision (EOPYY). However, these data do not present the whole picture of actual use and the associated expenditures since the numbers of diagnostic or treatment procedures not reimbursed by EOPYY are not known. Furthermore, the rebate and claw-back procedures applied in Greece due to the economic crisis, are resulting to partial cost estimation.

Finally, several interviews/discussions with medical specialists in the fields of radiology, RT and nuclear medicine; medical physicists; biomedical engineers; technologists and other specialists provided valuable input.

Radiotherapy planning and acts, require the collaboration of mainly medical doctors and medical physicists, which both have a recognized, distinguished, and established role in the field. Although RT unit's state and quality of maintenance, play a crucial rule for the overall effectiveness, safety and quality of the provided health service, the intervention of clinical engineers which is of utmost importance to achieve these goals, is not yet regulated.

The present assessment report aims to assess the sufficiency and equity in the distribution of RT and its use in Greece, to identify eventual inequalities in terms of geographical coverage, specific needs and lack of RT, estimate the associated costs of use and assess the current status of staffing in RT units.

MATERIALS AND METHOD

In the present assessment report, due to the lack of a concrete set of reliable data, a great number of different sources had to be used. Since there is no centralized national inventory for installed HVCME in Greece, the relevant

information and data collected and used in this report are based on cross-referenced sources from the Greek Atomic Energy Commission (EEAE), National Evaluation Center of Quality and Technology in Health (EKAPTY), Hellenic Association of Medical Physicists (HAMP), Federation of Technologists Radiologists of Greece (OTAE) and the inventory for medical devices (MDs) performed in 2015 by the Biomedical Technology Unit of the University of Patras under an ESPA [in english NSRF (National Strategic Reference Framework)] project. This creates some problems associated with data integrity, reliability, and (in some cases) compatibility.

The data available from international organizations (e.g., OECD, WHO) rely also on sources providing the information (e.g., EKAPTY, EEAE, professional societies) and therefore also present discrepancies in the numbers of equipment installed in Greece. These various sources were not set up to provide a continuously updated and reliable MDs inventory, but for other more specific reasons. For instance, the EEAE database (considered as the most reliable) focuses on licensing and radiation safety issues and does not gather information on the year of manufacture or of entry into service. As a result, the database does not reflect the actual situation of the installed base (i.e., number of units actually in use) of these technologies at any moment.

Additionally, there are no available data related to the actual use of these technologies except for indirect information on those procedures that are reimbursed by EOPYY. However, these data do not provide the whole picture of actual use and the associated expenditures since the numbers of diagnostic or treatment procedures not reimbursed by EOPYY are not known. Furthermore, the rebate and claw-back procedures applied mean that EOPYY's data are also partial.

Taking into account the various sources of information, this analysis focuses on the existing RT installed technology as of November 2017. Existing online information available at the EEAE website was cross-checked against that obtained from the other sources mentioned previously, duplicate entries were deleted and any new data identified were added.

Data are organized and presented per administrative region in which each unit is installed. The administrative regions and their populations are shown in Table 1. All data are based on the 2011 census.

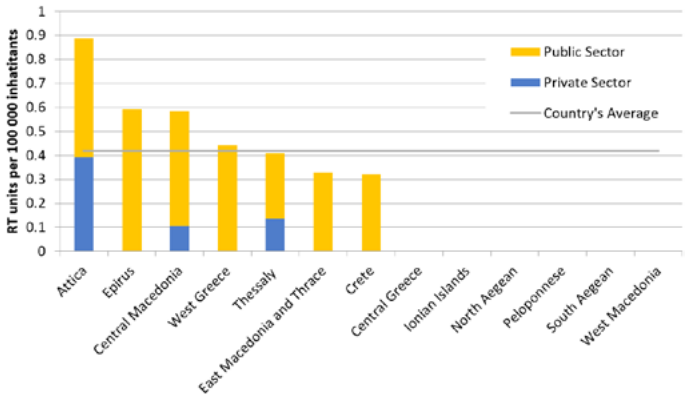
TABLE 1. Populations of Greek Administrative Regions, 2011 Census

Regions	Population
Attica	3.833
Central Greece	547
Central Macedonia	1.882
Crete	623
East Macedonia and Thrace	608
Epirus	336
Ionian Islands	207
North Aegean	199
Peloponnese	577
South Aegean	306
Thessaly	732
West Greece	679
West Macedonia	283

RESULTS

The distribution of RT units is very sparse in comparison with other modalities and only a few regional sectors have these facilities. The distribution of RT units in the different administrative regions is shown in Figure 2. Five of the 13 regions have no RT units – Central Greece, North Aegean, Peloponnese, South Aegean, West Macedonia and Ionian Islands. Of the 7 regions that have RT units available, only 3 have units in the private sector. This is expected since RT facilities are very expensive, need both dedicated infrastructures and specialized human resources, and should be linked to cancer diagnosis and treatment facilities. Conversely, RT units in public hospitals are

FIGURE 2. Radiotherapy units: distribution per 100 000 inhabitants in each administrative region, 2017.



available in all the other 7 regions. Athens (in the region of Attica) has the greatest number of RT units.

With a total of 57 RT units available, resulting in a ratio of 0.53 units per 100 000 inhabitants, Greece meets EU recommendations.[3] Of these 57 units, 39 are in the public sector and 18 in the private. The exact number and technologies installed in each region are shown in Table 2. It is important to point out that technologies other than LINAC (Linear Accelerator) and Co-60 are available only in Athens.

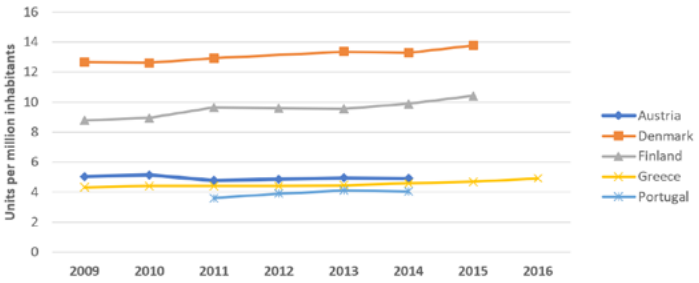
Source for Fig.2 and Table 2: data from EEAE

TABLE 2. Radiotherapy units: absolute number and number of units per 100 000 inhabitants in each health region, 2017

Health region	Total radiotherapy units		Private sector		Public sector	
	Absolute no.	Per 100K inhabitants	Absolute no.	Per 100K inhabitants	Absolute no.	Per 100K inhabitants
Attica (Athens)	34	0.89	15	0.39	19	0.50
Cyberknife	1	0.03	1	0.03		0.00
LINAC	22	0.57	11	0.29	11	0.29
Co-60	8	0.21			8	0.21
Tomotherapy	2	0.05	2	0.05		
γ knife	1	0.03	1	0.03		
Central Macedonia (Thessaloniki)	11	0.58	2	0.11	9	0.48
LINAC	9	0.48	2	0.11	7	0.37
Co-60	2	0.11			2	0.11
Crete (Heraklion)	2	0.32		0.00	2	0.32
LINAC	2	0.32		0.00	2	0.32
East Macedonia and Thrace (Alexandropolis)	2	0.33		0.00	2	0.33
LINAC	1	0.16		0.00	1	0.16
Co-60	1	0.16		0.00	1	0.16
Epirus (Ioannina)	2	0.59		0.00	2	0.59
LINAC	2	0.59		0.00	2	0.59
Thessaly (Larissa)	3	0.41	1	0.14	2	0.27
LINAC	3	0.41	1	0.14	2	0.27
West Greece (Patras)	3	0.44		0.00	3	0.44
LINAC	3	0.44		0.00	3	0.44
Total	57	0.53	18	0.17	39	0.36

A comparison between Greece and other EU countries of similar population is shown in Figure 3. As can be seen, Northern EU countries, such as Finland and Denmark, have twice as high a ratio of units per 100 000 inhabitants. While Portugal and Austria have similar ratios to Greece.

FIGURE 3. Evolution of the number of radiotherapy units per million inhabitants: comparison with 4 EU countries, 2009–2016.



Source: data from OECD (other EU countries) and EEAE (Greece)

Concerning use and cost, the evolution of the number of reimbursed RT acts and the associated reimbursement costs from 2013 to 2016 are presented in Table 3, based on data provided by EOPYY.

TABLE 3. Radiotherapy acts: analytical data, evolution and comparison of number of acts, installed units and costs reimbursed by EOPYY, 2013–2016.

Year	Number of reimbursed RT acts per year					Nº of units
	Public		Private		Total	
2013	232 574	64%	132 986	36%	365 560	49
2014	248 409	61%	160 617	39%	409 026	50
2015	245 393	58%	174 443	42%	419 836	51
2016	233 892	57%	176 549	43%	410 441	53

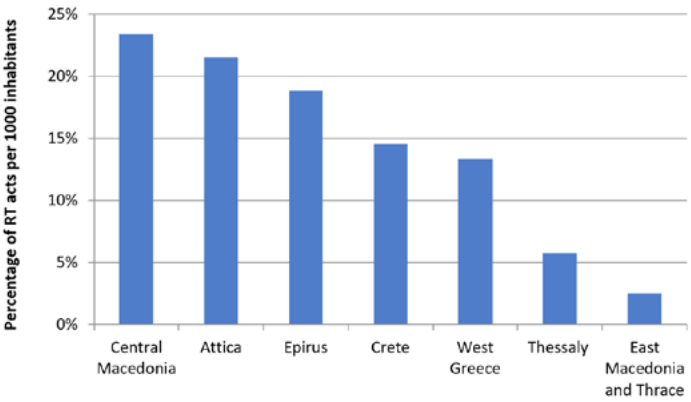
Year	Total EOPYY expenditure per year (€)				
	Public		Private		Total
2013	18 564 495	50%	18 630 985	50%	37 195 480
2014	19 373 735	47%	21 625 454	53%	40 999 189
2015	19 416 459	44%	24 896 716	56%	44 313 175
2016	18 616 010	40%	27 935 467	60%	46 551 477

RT = radiotherapy; EOPYY = National Organization for Healthcare Provision
Source: data from EOPYY

Despite a few fluctuations, the number of RT acts remains more or less steady between 2013 and 2016. The market share also appears to be almost evenly distributed between the public and the private sector, with a 57/43 ratio.

The relative distribution of RT acts per 1000 inhabitants per administrative region in 2016 is shown in Figure 4. This graph shows only the regions where RT units are available.

FIGURE 4. Relative distribution of radiotherapy acts per 1000 inhabitants in each administrative region, 2016.

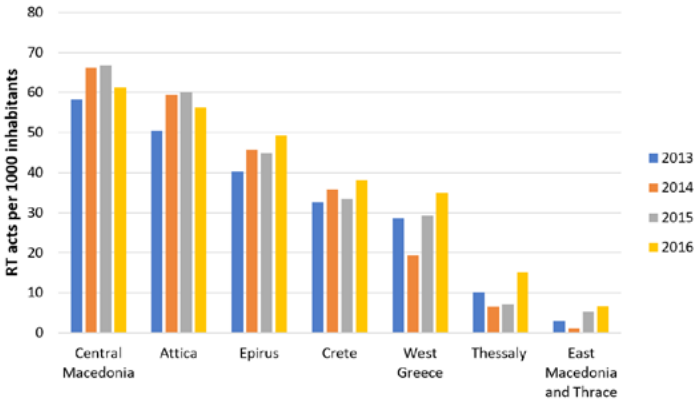


Note: regions without radiotherapy facilities are not shown. Source: data from EOPYY

Central Macedonia and Attica have the highest percentages of acts because they compensate for the lack of RT facilities in surrounding regions. Some technologies (e.g., γ-knife, cyberknife, tomotherapy) are available only in Athens. The time evolution of the number of RT acts per 1000 inhabitants per region between 2013 and 2016 is shown in Figure 5.

The number of acts shows an increasing trend in all regions where RT units are available, except for Attica (Athens) and Central Macedonia (Thessaloniki). These 2 regions show a steady increase from 2013 to 2015 but a slight drop in the number of acts during 2016. This may indicate that fewer patients are moving to these cities from other regions.

FIGURE 5. Time evolution of number of radiotherapy acts per 1000 inhabitants in each administrative region, 2013–2016.



Note: regions without RT facilities are not shown. Source: data from EOPYY

DISCUSSION

In both private and public health sectors, all RT departments in Greece are licensed according to the national law on radiation protection.[4] In addition, the EEAE closely supervises the terms of radiation protection and compliance with quality and safety regulations for RT treatments. A common practice for the lifetime of RT treatment machines (8–15 years) does not appear to have changed over the last decade. However, in Greece until 2016, the vast majority of RT equipment (mainly LINACs and Co-60 units) in the public sector was more than 15 years old. In 2017, this situation changed radically as a result of the Stavros Niarchos Foundation donating 10 new LINACs to replace old equipment in 7 public hospitals.

European directive guidance on the important issues of accessibility and availability of RT equipment[5] is based on the corresponding European Society for Radiotherapy & Oncology (ESTRO) and European Federation of Organizations for Medical Physics (EFOMP) guidelines. These guidelines, recommend a ratio of at least one RT equipment available for every 200 000 to 250 000 inhabitants. Given the population of 11.4 million, Greece should have at least 45 to 50 RT machines and therefore it can be concluded that it meets the guidelines on the number of units.

Staff levels in both private and public health sectors fall far below European standards and guidelines. The Hellenic Association of Medical Physicists (HAMP) reported that the New European Directive 2013/59/EURATOM on basic safety standards for protection against the dangers arising from exposure to ionizing radiation, includes several articles related to the medical physics profession and competency requirements (articles 14 and 18). It also details the tasks required of experts in medical exposures and radiation protection that are pertinent to the roles and responsibilities of the medical physicist – namely the medical physics expert and the radiation protection expert (RPE)[6].

On the contrary, no regulation and guidelines are existing concerning the role of clinical engineers inside the RT departments. It is well known that maintenance is assigned to private companies under maintenance contracts. Although maintenance is crucial for the quality of provided health service, unfortunately, no data are available on the quality of repair or preventive maintenance acts, safety checks etc. As for the case of medical physicists, which have a clearly stated role with well-defined rules and guidelines, the same should apply for clinical engineers, which should be responsible to closely inspect and supervise the maintenance procedure and the safety status of the RT units.

As reported by HAMP, under-staffing is one reason why RT, as the primary treatment for more than 60% of cancer patients in Europe and the United States, is used to only 30% of cancer patients in Greece.7 As a result, health system in Greece is forced to pay for less effective and more expensive treatments such as surgery and extensive chemotherapy.

A structural problem should also be mentioned. The fact that most centers have only one or 2 RT units results in high overhead costs for the accompanying equipment and eventually staff. At the same time, the widespread of equipment critically affects a patient's treatment. Currently, 28 LINACs are installed in 15 public-sector RT departments in 7 large Greek cities. Of these, 4 have only one unit, 10 have two units and only one has 3 units. In cities with other public RT departments, single-unit RT departments are ineffective in both organization and service provided. Reorganization into bigger RT centers could produce serious resource savings and improvements in the treatment provided.

Whether used for diagnosis or therapy, a healthcare facility should ensure that the equipment is performing as intended by the manufacturer. Uncontrolled use of technology in medicine can result in increased costs for the delivery of healthcare services. Hence, it has become evident that there is a need to develop proper infrastructure for evaluating, supporting and managing biomedical technology. Greece lacks reliable information related to MDs, including the RT technologies addressed in this assessment. Data on the purchase price, annual maintenance costs, downtime, and actual use of devices are lacking. Evidence-based decisions are impossible without adequate data and information and it is impossible to calculate the median age of the installed bases, their value, annual service costs and annual use; or to estimate potential underuse of the machines or calculate incremental costs of corrective actions.

During the last 3 decades, computerized maintenance management systems (CMMSs) for medical equipment have been used worldwide, providing all necessary data for cost-effective management and evidence-based decisions. Such systems these have been available since the late 1980s but installed in just a few Greek hospitals till today. CMMSs have multiple advantages, providing a complete and updated inventory at any time, with at least the following essential information for each machine – make and model, value, annual maintenance costs, weekly operating hours and number of uses. Such a system would have made the data collected within this assessment report available instantly to the Ministry of Health, avoiding a great deal of effort and enabling verification. Additionally, such systems are essential for vigilance purposes, evidence-based decisions on replacement, and control of service providers (i.e., response time, cost, respect of service contract rules) amongst many others, which are under the responsibility of the clinical engineering departments.

Aggregated data on maintenance costs of RT units in the public sector are not available. Most hospitals have maintenance contracts with equipment providers but these are negotiated on a case-by-case basis and the actual costs are not known. As a general rough estimate, the assumption of an annual cost of 8–10% of the initial equipment purchase price could be used. Maintenance and repair issues are becoming more critical as the equipment ages. After the initial few years period during which maintenance is usually well-defined in the procurement agreement, in many cases price negotiations are under the control of manufacturers.

Additionally, rapid technological developments lead to the high-paced introduction of new or improved devices and require lifelong learning and continuous training for all healthcare professionals. Therefore, necessary means and facilitating conditions should be provided to guarantee the level of knowledge and skills of staff involved. Professional associations should play an important role in such procedures, and assessment should become a priority for all.

CONCLUSIONS

Lack of a continuously updated inventory means that there are no centrally available data concerning medical equipment information on maintenance, age and actual use of devices. The availability of such data is necessary for correct decisions on technology procurement, management, and replacement. This information is generally needed to estimate potential underuse, identify unjustifiably high management costs or calculate incremental costs of corrective actions. Evidence-based decisions are impossible without adequate data and information.

Personnel issues are considered to be a problem in RT departments and there is a discrepancy between the actual number of staff employed (especially non-medical) and the number recommended by (already approved) EU guidelines. Staffing of RT departments should be regulated in line with best practices and guidelines, and in accordance with EU regulations and directives. The application of these regulations should become a priority. Adequate staffing could allow the available infrastructure to be fully exploited, resulting in economy of resources and better patient treatment, the presence of clinical engineers should be regulated. Continuing professional development should also be organized in collaboration with professional societies to assist personnel in keeping pace with recent technological developments.

Improvement of RT investment planning is a critical factor for ensuring that healthcare systems are more cost-effective and able to respond to patient needs in a

most efficient way. Therefore, RT should be installed and used according to well-defined criteria, needs assessment analysis and priority settings. Greece should develop its Health Technology Assessment (HTA) capacity, as suggested by a 2016 WHO mission on HTA in Greece[7].

The absence of biomedical/clinical engineering departments in most Greek hospitals, is a great obstacle to effective and safe management of medical technology, resulting in incomplete records and no quality and cost control. Maintenance of RT and the relevant costs should be followed using modern computerized systems in all public-sector hospitals.

ACKNOWLEDGEMENT

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