Global Clinical Engineering Journal

Vol.6 Issue 1

Publisher International Medical Sciences Group, LLC

GlobalCE

open access

ISSN: 2578-2762

www.GlobalCE.org

Editor's Corner

365 DAYS YEAR END REPORT

As the year comes to its end and this Journal publishes its volume number six, the opportunity presents itself for the Global Clinical Engineering Journal's Editor-in-Chief to look back. Measure if, and how far, we progressed and reflect on the contributions that this Journal has made. We know that healthcare services are a local issue, and that technology on which these services are dependent is a global one. This was especially evident in the case of healthcare, as we dearly learned from the Pandemic era. Therefore, an international journal that focuses on the cross between patient care outcomes and the lifecycle of the technological tools, particularly those used at the point-of-care and the associated management of the technology is critically important.

Healthcare technology is the result of an idea, an innovation or application of an improvement, that has been sufficiently funded to move on to the prototyping, manufacturing, clinical trials, regulatory compliance, and on to the commercialization and management of its deployment at the conventional point-of-care or at home. In short, the full spectrum of healthcare technology solutions regardless of the location of deployment and use.

Our Journal is still the only international periodical dedicated to sharing and expanding clinical engineering applied knowledge, that is accessible on-line, Diamond open access (CC BY 4.0) and free to both authors and readers. It is conducting a double-blind review of submissions received, check for plagiarism, managed by an international Editorial Board of experts having clinical engineering, academia, research, regulatory, industry, medicine, surgical disciplines, and World Health Organization expertise. Our Journal is also unique as it is published in both English and Chinese languages and is advertisement-free. The double-blind review is fed by a growing reviewers' community (270) with wide range of experiences representing almost 60 countries and are committed to voluntarily serving the field and advancing the Journal's mission. Thus, ensuring that the Journal's platform promotes up-to-date quality engineering information on the relationship between technological tools, its development and management, and patient experiences.

I encourage you to find more information about the Journal by visiting the website www.GlobalCE.org and at the Global Clinical Engineering Alliance website under the 2023 State of the Alliance State of the Alliance report. When you visit the website, you will find rich and interesting content that includes: Editor's Corner, Engineering Report, Book Review, and manuscripts ranging in subjects from Molecular Sieve Oxygen Generation and Procurement of Medical Devices in International Context to Clinical Engineering Status in Post COVID-19 and Analysis of Dental Unit Failure as well as COVID019 Experience of Nigerian Radiotherapy Engineer. In addition to the six volumes and issues that archives engineering and scientific manuscripts from over 150 authors, the Journal is also unique in its ability to organize and publish the Proceedings of the last three International Clinical Engineering & Health Technology Management (ICEHTMC) Congresses, a major accomplishment where the 5th ICEHTMC Congress proceeding just published this month https://doi.org/10.31354/globalce.v5iSI5.

This year, the Journal achieved another milestone, that of the recognition received by being indexed by Scopus. The Comprehensive, multidisciplinary, trusted abstract and citation database Using Scopus metrics, where a journal can demonstrate the influence of its scholarly output.

There are times, like the yearend, that the Editor-in-Chief must ring the alarm to create a needed inflection in Clinical Engineering practitioners' behavior. Practitioners use variety of excuses, from "I am too busy" to "No one taught me how to write a paper" and on to "No hablo Ingles" to avoid the slight stress of added work associated with authoring a manuscript. This is the golden era to be in the Clinical Engineering field, however, without publishing your work you may fall short of developing your career and allowing the discipline to stay static or even

shrink. We all must advocate and share evidence for our field criticality in building access to safe and quality care experiences. You can trigger this inflection by submitting your manuscript now and encouraging your colleagues to follow the very same.

Our field is going through exciting evolution and our year-end report is full of achievements and growing readership. We encourage you to contact any member of the Editorial Board or myself for specific information relating to publishing your research or best practices. Here are some general steps you can take:

1. **Visit the Journal's Website:** Where you can find information about the editorial board, submission guidelines, how to write a scientific paper, and archived issues of the Journal.
2. **Contact the Editorial Office:** Look for contact information for the journal's manager on the website. You can send an email or make a phone call to inquire about the any other information you may be seeking.
3. **Write a Paper:** Start now drafting an idea and reading how to craft a full manuscript at - https://www.globalce.org/index.php/GlobalCE/article/view/102
4. **Professional Associations:** The journal is associated with a professional organization, Global Clinical Engineering Alliance, you might find relevant information through that organization's website or publications.

Remember that the Journal is only a platform to help build the C.E. discipline, its networking, sharing of quality information, and your professional future. You, as participating authors and readers, will hopefully enjoy reading in next year-end Editor's Corner of the many more achievements we will report together.

Have a wonderful and productive 2024!

Dr. Yadin David

CONTENTS

Received May 5, 2023, accepted October 3, 2023, date of publication November 28, 2023

An Analysis of Adverse Event Reports in FDA's MAUDE Database

By Spilios Zisimopoulos, Nicolas Pallikarakis

Institute of Biomedical Technology (INBIT), Greece

ABSTRACT

Background and Objectives: Medical devices (MDs) are pivotal in the modern healthcare environment. Adverse events are an expected part of an MD's lifecycle. Various vigilance systems have been established worldwide to prevent such events' recurrence. The Manufacturer and User facility Device Experience (MAUDE) database of the US Food and Drug Administration (FDA) is a publicly accessible database that contains data on medical device reports (MDRs) submitted to FDA since 1991. This study aims to examine the evolution of MD adverse event reports and analyze several characteristic parameters as they evolved during the last three decades.

Material and Methods: An analysis of MAUDE data was performed to examine the outcomes and device characteristics of adverse event reports from 1991 up to 11/2022. These outcomes included the event type, remedial action, report source, reporter occupation and device evaluation by manufacturer. Specific MD groups were analyzed separately to examine their effect on the event outcomes. Segregated files of the database that contain different types of information on adverse event reports were combined to investigate the various aspects of these reports.

Results: Event outcomes are presented as annual histograms. An overall of about 15 million reports have been submitted to MAUDE during the 30 years examined with more than 2.5 million of them during the first 10 months of 2022. This number is growing at an increasing rate. Most of the events (63.5%) have resulted in simple device malfunctions without serious implications to the patient. Depending on the device type, however, the health risks may be higher (98.4% injuries from specific dental implants and 3.2% deaths from implantable defibrillators). About 20% of the reports have led to recalls or corrective actions. Most of the reports (96%) are submitted by manufacturers, and over 70% of the devices returned to them are evaluated, following the requirements of FDA 21 CFR, 803. Finally, the average device age was found to be 5.4 years, with an increasing tendency observed over the years, while 43% of the events that occur are associated with devices during their first year of operation.

Conclusion: A medical device adverse event reporting system is a critical component of safety in the use of medical technology in modern healthcare. The information available in MAUDE and its use continues to grow at an accelerated rate and allows critical improvements of MDs, especially in terms of risk prevention, as it gives perception about their safety issues. FDA has taken various steps to encourage and facilitate adverse event reporting and make the data available to the public.

Keywords – *MAUDE, FDA, Adverse Events Reports, Medical Devices, Vigilance.*

INTRODUCTION

In today's world, medical devices (MDs) have become a fundamental component of modern healthcare systems. MDs range from simple face masks and syringes to complex implantable devices and medical imaging systems and are used to diagnose, treat, and manage various medical conditions. However, like any other medical procedure, MDs are not without risks. Adverse events can occur due to various factors like device malfunction or misuse, resulting in serious patient harm. To prevent and mitigate these risks, it is essential to have a robust MD vigilance system involving Health Competent Authorities[1] and MD manufacturers that investigate and eventually perform necessary remedial actions following adverse events with MDs. In most developed countries MD vigilance systems have been implemented for more than 30 years, aiming to reduce the likelihood of similar adverse events happening again in another place and time. The cornerstone of the MD vigilance systems is adverse event reporting.

A medical device adverse event reporting system is a mechanism that enables healthcare facilities, patients, and manufacturers to report incidents associated with MDs. These systems provide standardized processes for reporting such events and allow the collecting and analysis of information related to MD safety. Such a system is of the utmost importance, as it is critical in ensuring patient safety and improving healthcare quality.

One of the primary benefits of an MD adverse event reporting system is that it enables healthcare providers and manufacturers to identify and address safety concerns related to medical devices. The report of adverse events by healthcare facilities helps manufacturers gain insight into the performance and safety of their devices. The information provided can then be used to identify design flaws, manufacturing defects, software problems, or other issues that may contribute to adverse events and take appropriate action to address these issues, such as modifying the device design or implementing new quality control processes. On the other hand, when information about the risks associated with specific devices is publically available, healthcare providers can investigate whether an event they faced has also been manifested in a different facility, and, in that case, follow the instructions that the manufacturer has proposed.

A medical device adverse event reporting system also enables better communication between healthcare providers, regulatory agencies, and competent authorities. When adverse events are reported, the authorities can use this information to take appropriate action when necessary. For example, if a particular device is associated with a high rate of adverse events, regulatory agencies may require additional testing or labeling changes from the manufacturer to improve safety.

Finally, a medical device adverse event reporting system can promote transparency and accountability in the healthcare industry.[(a)] By publicly making information about adverse events, the system can help hold manufacturers, distributors, and healthcare providers accountable for their actions. This can help with the trust-building process between patients and healthcare providers and ensure that the healthcare industry is held to the highest safety and quality standards.

The aim of this study is to examine the evolution of medical device adverse event reports, available at the Manufacturer and User facility Device Experience (MAUDE) database of the US Food and Drug Administration (FDA) and analyze several characteristic parameters of these reports as they evolved during the last three decades.

Adverse events reporting systems

There are several MDs adverse event reporting systems worldwide, aiming to address safety issues that arise from the use of medical devices. The reports can be generally made by manufacturers, healthcare professionals and volunteers.

FDA's MAUDE database, designed to collect reports of adverse events associated with MDs is the most well known, it is available to the public and can be accessed online, allowing the analysis of the available data.[2] MAUDE contains the reports submitted through the Medical Device Reporting (MDR) system, which are used by manufacturers,

[a] The Competent Authorities for Medical Devices (CAMD) facilitate implementing and enforcing the Regulations on medical devices and on In Vitro Diagnostic medical devices in the EU. https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/overview_en#competent-authorities-for-medical-devices---camd

importers and users of MDs. The MDR system is a mandatory reporting system, and manufacturers must report any adverse event that involves their device.[3]

The European Databank on Medical Devices (EUDAMED) is maintained by the European Union (EU) and is designed to provide a living picture of the lifecycle of MDs, including modules related to device registration, notified bodied and certificates among others. The database has been established in the 2000s according to the MDs Directives: 90/385/EEC for the Active Implantable Medical Devices (AIMD), 93/42/EEC (MD) for the Medical Devices and 98/79/EC for the In Vitro Diagnostics. The EU vigilance system is based on the MEDDEV 2.12/1 rev.8 series of guidelines of 2012[(b)] on Post-Market surveillance and Vigilance System adopted in 2019.[(c)] The EU's new 2017/745 and 2017/746 MDRs, reshaped the structure and use of EUDAMED to improve the safety and performance requirements of medical devices bearing a CE Mark.[4] However, access to EUDAMED is restricted only to Competent Authorities and partially to Notified Bodies for devices that are involved, and the information on MDs related incident reports is not yet available to other parties, despite the explicit reference in the regulations.

Various other adverse event reporting systems are being used at the national level. Some well known examples are the Australian Therapeutic Goods Administration (TGA) Adverse Event Reporting System,[5] Health Canada's Medical Device Adverse Event Reporting (MDAERS)[6] UK's Medicines and Healthcare products Regulatory Agency (MHRA)[7] and Germany's Federal Institute for Drugs and Medical Devices (BfArM).[8] These systems are used to report or access adverse events associated with MDs and are open to healthcare professionals, patients and manufacturers, while they can also be accessed online. Many other countries have also similar systems in place, and many manufacturers have their own reporting systems for post-market surveillance purposes.

Relevant work using MAUDE

A search was performed in the PubMed database on papers published from 2000 to date, with the term *"MAUDE database"* included in the title or abstract of the paper (MAUDE database [Title/Abstract]). This was done to include only papers whose content was focused on the analysis of MAUDE's data, and the search yielded 303 results. Next, another query was performed, adding the terms "*MAUDE*" and "*FDA*" in the title or abstract of the journal papers (MAUDE database [Title/Abstract] OR (MAUDE[Title/Abstract] AND FDA [Title/Abstract])). The latter broader search was performed to find articles that may have been eluded from the initial query, while keeping their content mainly based on data from MAUDE and excluding ones with simple references and various irrelevant synonyms. The final search yielded 308 results up to 2022 (Figure 1), with 31 additional articles been published during the first quarter of 2023. Most of these studies analyze adverse events for specific medical device groups.[9] Recent years examples involve MDs like Injectable Fillers, Deep Brain Stimulators, middle ear prostheses, ossicular prostheses and catheters.[10–14] During the last years, a couple of studies analyzed MAUDE data taking into consideration the full spectrum of medical device groups.[15–17] However, they were focused on limited aspects of the available data, like reporting source and reporter occupation, and they were published before the boom of reports submitted to MAUDE after 2019 (Figure 2).

The number of studies mining the information used from MAUDE are constantly increasing during the last ten years and provide very valuable insights on safety issues concerning MDs. This trend was reported in a study by P. Malataras and N. Pallikarakis, regarding the use of

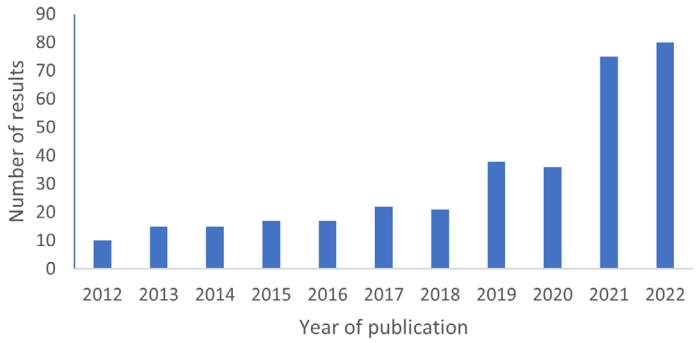

FIGURE 1. PubMed articles with relevant MAUDE terms in title/abstract.

[b] https://ec.europa.eu/docsroom/documents/32305
[c] ttps://ec.europa.eu/docsroom/documents/32305

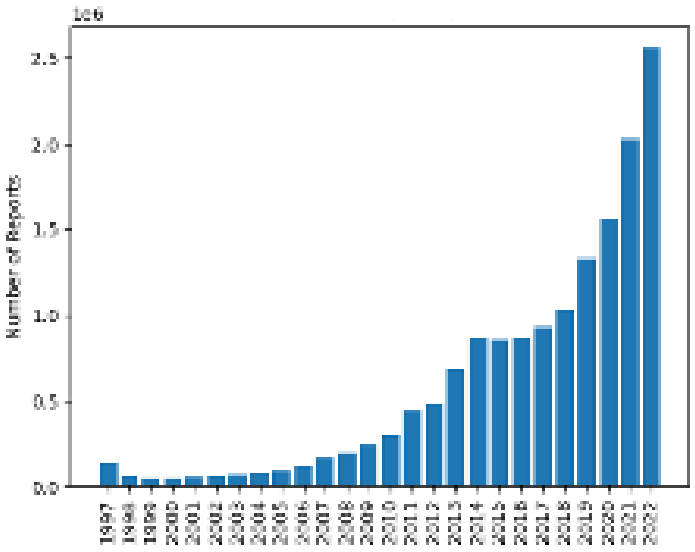

FIGURE 2. Annual MAUDE adverse event reports. Data until 4/11/2022

MAUDE's data in research between the years 2005 and 2014,[9] where a linear increase of papers published each year was showcased. To add into that, a sharp increase of publications has been observed in the last couple of years, highlighting the developing interest in utilizing FDA's MAUDE data as shown in Figure 2.

MATERIALS & METHODS

The MAUDE database was used for the analysis performed in this study. Of all the afore-mentioned adverse event report databases, MAUDE is the best structured and most complete, with data ranging from 1991 to date. Furthermore, it can be easily accessed and has been used in other studies in the past. Data processing and analysis was performed using the Jupyter Notebook web application, along with the Python Data Analysis (pandas) and Numerical Python (NumPy) Libraries.

Data acquisition and pre-processing

All data used in this study are publicly available on FDA's MAUDE page.[2] Data available in MAUDE span from 1991 up to 2022 (user facility reports since 1991, distributor and voluntary reports since 1993 and manufacturer reports since 1996). For the remainder of this work, data referring to the year 1997 will consist of events reported between 1991 up to 1997, according to MAUDE's "*foidevthru1997*" file. Data regarding 2022 contains reports that were available on MAUDE until 4/11/2022, due to the time of research. For the remainder of the work, data up to 4/11/2022 will be referred to as data for the year 2022. Device information associated with an event was taken from the available "*foidevxxxx*" and "*devicexxxx*" files, were xxxx annotates the year. Information about the adverse event was found in the files named "mdrfoithru2021", which contains data from inception up to 2021 and "*mdrfoi*", which contains data of the present year (i.e., 2022). The device and mdrfoi files were joined together using the "*MDR_REPORT_KEY*" field as primary key.

Data pre-processing

A total mdrfoi dataframe was created by merging the "mdrfoithru2021" and "mdrfoi" files. After data cleaning by deleting rows with wrong field format, wrong delimiter, unreadable characters, duplicate key values etc. 15,387,348 lines of data remained. The same process was carried out for all "devicexxxx" files, and a total device dataframe was created containing 15,386,069 lines of data. After merging these mdrfoi and device dataframes, using the MDR report key value as primary key, a final dataframe with 15,343,314 lines of data was created, upon which the analysis of adverse event reports was carried out.

Event Outcomes

All adverse event reports available on MAUDE were analyzed under the scope of various event outcomes. Using the various outcome codes presented below as queries, the data are organized and presented as histograms of number of reports for each year until 2022. Outcomes included whether the device was evaluated by the manufacturer, event type, remedial action, problem code, and device age (year of report minus year of manufacture).

Event Type

The Event Type (H1 field on the 3500A form) is used to describe the impact of adverse events. It is only considered relevant by the FDA when the reporter of the event is a manufacturer and makes use of the following codes: D = Death, {IN, IL, IJ} = Injury, M = Malfunction, O = Other, {Blank}= No answer provided. Only one code may be used for each event. A malfunction refers to an adverse event

where the device demonstrated an unexpected behavior, without any further implications to the patient or the user. One should keep in mind that the submission of an MDR itself is not evidence that the device caused or contributed to the adverse outcome or event. Moreover, the Event Type field is not available on the form for voluntary reporting of adverse events.

Remedial Actions

A Remedial Action (H7 field on the 3500A form) corresponds to any actions outside the scope of routine maintenance of a device, when necessary to prevent an adverse event from recurring that could pose safety issues. The following codes and their interpretations are being used by the MAUDE database at this point: RC = Recall, RP = Repair, RL = Replace, RB = Relabeling, OT = Other, NO = Notification, IN = Inspection, PM = Patient Monitoring, MA = Modification/Adjustment, {Blank}= Invalid Data/ NaN. According to 21 CFR Part 7, recall means a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure.[d] A recall can be initiated by the manufacturer, the FDA, or both, and may be required when a device poses a significant risk of harm to patients or users. Replacement, on the other hand, is the process of providing a new, corrected or modified device to replace a defective or unsafe device that has already been distributed to patients or healthcare facilities. A replacement may be initiated by the manufacturer as a proactive measure to address a safety issue or may be required by the FDA as part of a recall. In some cases, the manufacturer may offer a replacement device to patients as a voluntary corrective action, even if the device has not been recalled by the FDA.

Apart from the removal of the unsafe device from the market and the notification, healthcare providers and patients may be requested to return the device for corrective action to address the safety issue. Correction means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location. As a result, an adverse event report may be associated with one or more remedial action codes, for example RC, RP.

Report Source

The Reporting Source refers to the official submitter of the report to FDA. The available codes are P= Voluntary report, U = User Facility report, D = Distributor report and M = Manufacturer report. The initial reporter of the event can be any person. For example, an affected patient may choose to submit the report himself (using the 3500 form), which will then be classified as voluntary report, or send it to the manufacturer who is obligated to submit it (using the 3500A form). In the latter case, the code M will be used. Track is also kept of the initial reporter.

Initial Reporter Occupation

Regardless of the formal submitter of an event to FDA (i.e., a user or a manufacturer), the occupation of the initial reporter is recorded separately (E3 field on the 3500A form). The classification codes for the initial reporter occupation consist of three digits and can be found on the MAUDE database site.[e] The available occupations range from physician and patient to biomedical engineer or attorney.

Device Evaluated by Manufacturer

According to CFR 21, 803, §50, manufacturers are responsible for conducting an investigation of each event and evaluating the cause of the event. In case the device was returned to them and information in a report is not complete, they must provide an explanation on why, as well as the steps taken to obtain it. To this end, the *"Device Evaluated By Manufacturer"* (H3 field on the 3500A form) is being used. The acceptable values are: Y = Yes, N = No, R = Device not returned to manufacturer and {BLANK}= No answer provided. These values are mutually exclusive.

Device Age

The associated device age for the adverse events was calculated by subtracting the year of the device manufacture date (H4 field on the 3500A form), as filled in by

[d] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-7

[e] https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/about-manufacturer-and-user-facility-device-experience-maude

the manufacturer of the device, from the year in which the report was submitted to the FDA.

Device Groups

Event outcomes such as Event Type and Remedial Action were analyzed separately for various device groups. This was done to investigate the differences an adverse event may have regarding the involved device. The MD groups chosen were ones with a notable percentage of each year's total reports and are presented in Table 1.

RESULTS

Number of Reports

The histogram of the annual number of submitted reports to FDA from 1997 to 2022 is presented in Figure 1. About 15 million reports have been submitted to MAUDE until the end of 2022 and over 2.5 million of them occurred during the last year. A big increase in the number of reports can be observed over the last few years.

TABLE 1. Medical Device Groups with Frequently Presented Adverse Events

FDA Group Code	Group Name
CFR	HEXOKINASE, GLUCOSE
LFR	GLUCOSE DEHYDROGENASE, GLUCOSE
NBW	SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER
MDS	SENSOR, GLUCOSE, INVASIVE
OYC	PUMP, INFUSION, INSULIN, TO BE USED WITH INVASIVE GLUCOSE SENSOR
PQF	SENSOR, GLUCOSE, INVASIVE, NON-ADJUNCTIVE
LWS	IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (NON-CRT)
DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM
FRN	PUMP, INFUSION
KWA	PROSTHESIS, HIP, SEMI-CONSTRAINED (METAL UNCEMENTED ACETABULAR COMPONENT)

Event Types

Table 2 presents the distribution of event types for 6 different examples of prominent MD groups, as well as all the average values for all available FDA Device groups that exist in MAUDE. From the grand total of the reports in Table 2, we can see that most of the events result in simple device malfunction, without further implications to the patient (63.5%). About 1% of the total reported events is associated with patient death.

TABLE 2. Event Type Distribution for Various MD Groups

	Event type			
	Malfunction	**Injury**	**Death**	**Other - n/a**
Glucose monitors ['MDS', 'OYC', 'PQF']	89.1	10.7	0.2	≈ 0.0
Glucose test ['CFR', 'LFR', 'NBW']	90.2	9.0	≈ 0.0	0.8
Pump, Infusion	98.3	1.4	≈ 0.1	≈ 0.2
Implantable Cardioverter Defibrillator (Non-CRT)	36.3	60.0	3.2	≈ 0.5
Prosthesis, Hip, Semi-Constrained (Metal Uncemented Acetabular Component)	2.7	95.0	0.3	≈ 0.0
Implant, Endosseous, Root-Form	1.6	98.4	≈ 0.0	≈ 0.0
Average for all Device Groups	**63.5**	**34.3**	**1.2**	**1.0**

The average numbers derived from all the available device types can vary significantly across different device groups. As observed in the trend (Figure 3), there is a steady decline in the ratio of adverse events that result in deaths, from 2.5% up until 1997 to 0.3% in 2022 (R^2 = 0.66). Similarly, events with outcome categorized as "Other" or without applicable information (n/a) decreased from 7.5% in 1997 to almost 0% in 2022 (R^2 = 0.85), showing the increased completeness of the information provided to the FDA over the years. Subsequently, more incidents are manifested as device malfunctions, with 73% reported

as such in 2022, compared to only 40% up to 1997 (R^2 = 38%). Although injury reports dropped from 49.2% in the period 1991 - 1997 to 26.6% in 2022, their fluctuations seem to be independent of the time ($R^2 \approx 0$).

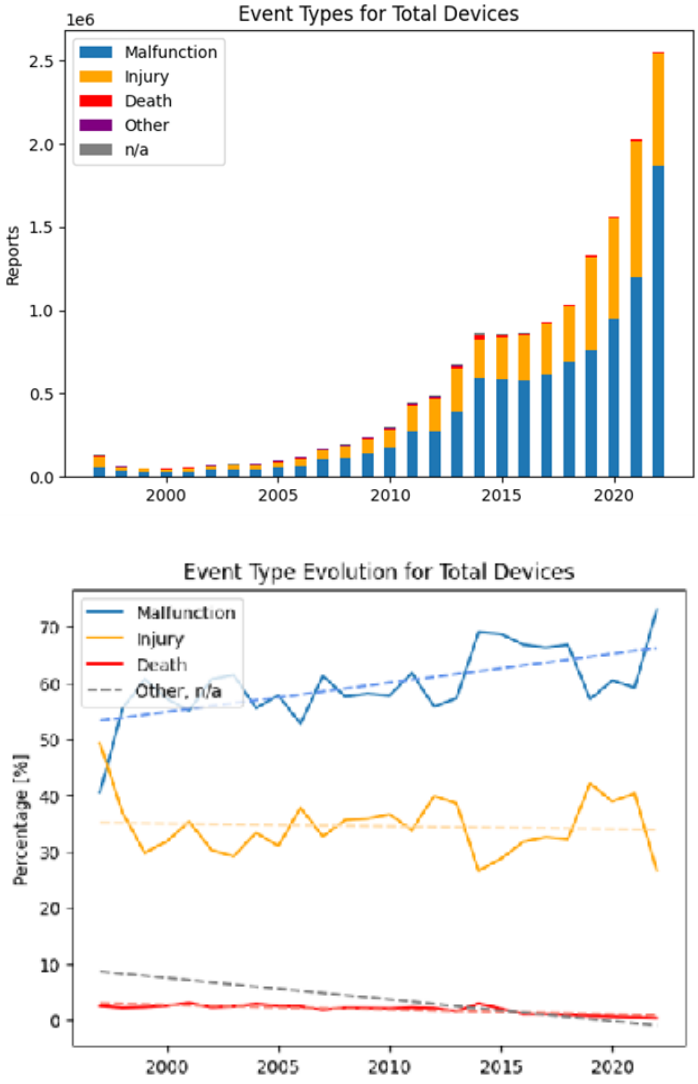

FIGURE 3. Adverse Event Types. Number of reports(top) and percentage evolution(bottom).

According to Table 2, more than 90% of events related to glucose test groups have been about device malfunctions, with the rest (about 10%) being associated with injuries. In contrast, about 95% of the reported incidents of Metal Uncemented Acetabular Component hip prostheses (KWA) resulted in patient injury. Similarly with implantable defibrillators, the majority of dental implant event types were categorized as injuries (98.4%). Implantable defibrillators adverse events have the highest probability of death (3.2%) compared to the rest of the examined device groups, due to their crucial role in physiological heart function. Finally, most of the reports regarding infusion pumps (over 98%) were about simple device malfunctions.

Figure 4 shows that most reports have no remedial action connected with them (80%). Nevertheless, for the remaining 20%, where information is available, the most common action happens to be a recall, which is associated with three-quarters of adverse events (Table 3). Repair of the affected devices was a common action during 2011, 2013 and 2014 and may depend on the types of affected devices. Actions categorized as "Other" were more common until the mid '10s, while being the most common remedial action during the older years. Recently, the "Other" category stopped being used so frequently (7% of total reports).

Remedial Actions

Different MD groups are associated with different remedial actions (Table 3). For example, reports involving continuous glucose monitoring devices and infusion pumps resulted in a recall action by the manufacturer or FDA 9 out of 10 times. On the other hand, dental implants resulted in almost no recalls, and the main action taken by the manufacturers was either an inspection (69.7%) or replacement of the implant (26.0%). Finally, about 1 out of 10 reports about glucose test device groups led to a recall, as devices like test strips are not so crucial to patient safety compared to previously referred devices. Replacement (38.0%), Notification (28.6%) and Other (23.3%) were the most frequent remedial actions for dealing with issues such as incorrect measurements.

Report Source

The majority of the total reports (96%) were filed by the device manufacturers, as shown in Figure 5. This concerns the stricter requirements about adverse event reporting imposed on manufacturers. In the last 4 years there has been an increase in distributor reports. During these years, dental implants and implantable defibrillators were the main types of devices reported.

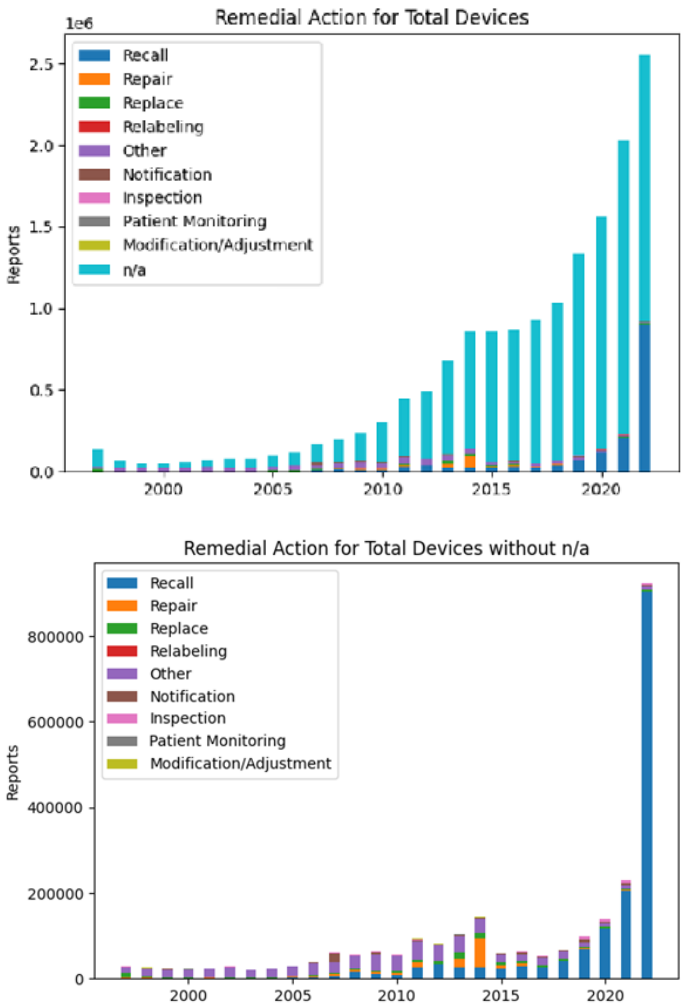

FIGURE 4. Adverse event remedial actions.

Initial Reporter Occupation

Figure 6 presents the occupation of the initial adverse event reporter. The initial reporter may be different than the one that submits the final report to FDA, like in the case when a user of a medical device notifies an event to its manufacturer, who is then obligated to file an official report to the FDA. Physicians and other health care professionals have a constant rate of reporting adverse events. In the years 2012 and 2013, a considerable number of events were reported by attorneys. This was the period of lawsuits filed against metal-on-metal hip prosthetics manufacturers.[18,19]

Between 2013 and 2018 about 15% of reports (peaking at 21% in 2016) were made by the patients themselves. During this period, insulin pumps and glucose sensor events were predominant, so it makes sense that home users initially made a lot of the reports. An increase in the percentage of reports initially submitted by dentists can be observed after 2019. Deeper analysis showed that many of the events were caused by dental implants (peaking at 24% of the total reports in 2021) during the last 4 years. Finally, more events have been reported in the previous five years, especially in 2022 (35%), by other non-healthcare professionals than in the past.

TABLE 3. Adverse Event Remedial Action Distribution for Various MD Groupss

	Remedial Action (%)								
	Recall	**Repair**	**Replace**	**Relabeling**	**Other**	**Notification**	**Inspection**	**Patient Monitoring**	**Modification/ Adjustment**
Glucose monitoring ['MDS', 'OYC', 'PQF']	93.58	0.01	4.27	0.01	0.12	1.99	0.01	0.01	≈ 0.0
Glucose test ['CFR', 'LFR', 'NBW']	9.55	0.10	38.03	0.02	23.27	28.60	0.02	≈ 0.0	0.40
Pump, Infusion	89.86	9.53	0.05	≈ 0.0	0.42	0.10	0.02	≈ 0.0	0.03
Implant, Endosseous, Root-Form	0.36	0.03	26.04	0.02	3.76	0.06	69.66	0.06	0.01
Average for all Device Groups	**74.0**	**7.0**	**5.5**	**≈0.1**	**7.0**	**3.6**	**2.1**	**0.2**	**0.5**

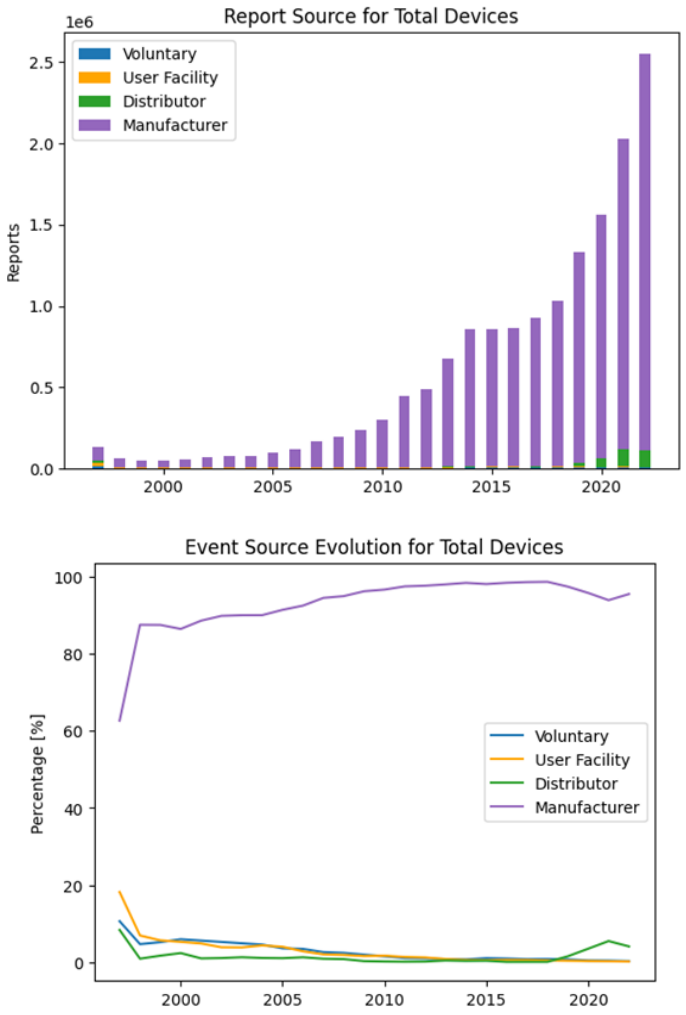

FIGURE 5. Adverse events report source.

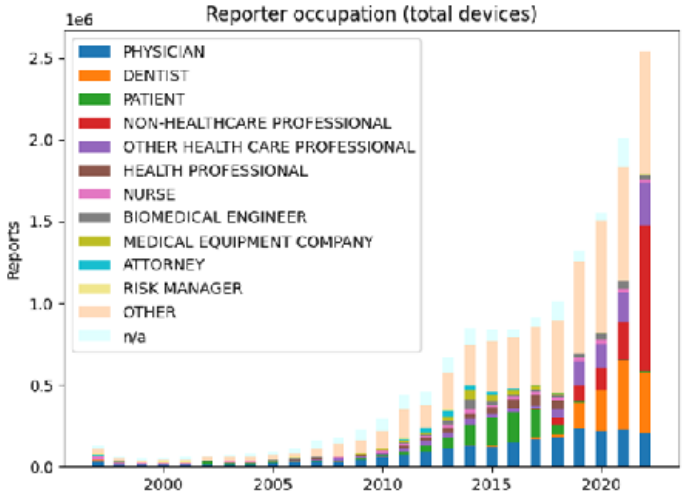

FIGURE 6. Adverse event initial reporter occupation.

Device Evaluated by Manufacturer

Figure 7 shows the status of reports as far as the device evaluation by the manufacturer is concerned. More than half of the devices reported (52.3%) are sent to the manufacturer, and most of them are evaluated (70.8% of sent devices). 2022 was an exception, with 55% of the devices sent to the manufacturer not being evaluated.

Device Age

The mean age of the devices involved in all adverse events of the MAUDE database is 5.4 years. However,

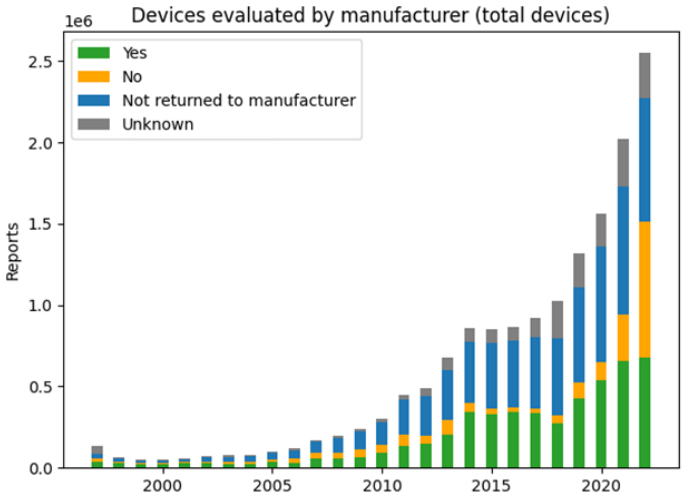

FIGURE 7. Device evaluation by manufacturers.

this result is strongly influenced by the impact of the last couple of years' reports, as shown in Figure 8. Up until 2019, the average device age was 2.8 years. The seeming rise in the device's age might be related to the reported devices' types. Most of the events (43%) are associated with devices during their first year of operation.

DISCUSSION

There has been an obvious increase in the number of reports over the last years (see Figure 1), which can be attributed to several factors. One reason is the increased awareness and reporting of adverse events by healthcare professionals and patients due to improved access to information and reporting systems. Another reason is the growing number and complexity of MDs, which increases

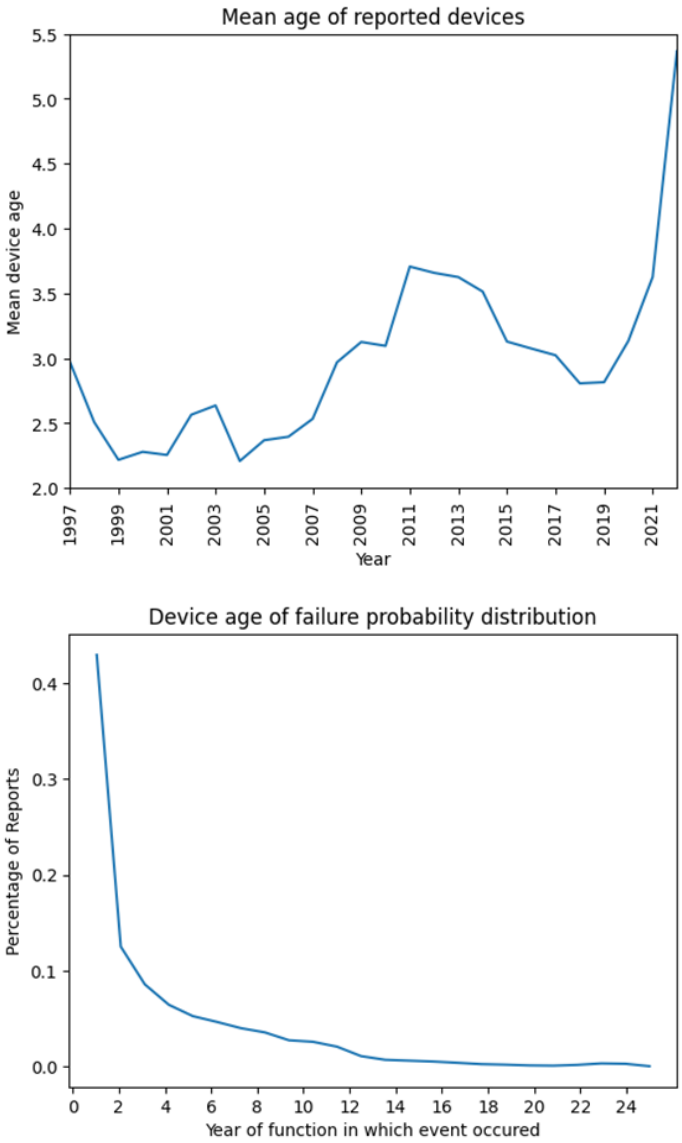

FIGURE 8. Device age distribution. Annual mean age of reported devices (top) and Total device age histogram (bottom).

the likelihood of adverse events. In addition, the FDA has expanded the types of adverse events that must be reported by manufacturers and healthcare facilities, which has led to an increase in the number of reports submitted to MAUDE. Other changes included updated reporting requirements for specific devices and improved clarity on using the FDA Forms 3500/ 3500A for reporting. These requirements are outlined in the Code of Federal Regulations (CFR) Title 21, Part 803,(f) which establishes the mandatory medical device reporting criteria. This Rule was published in 2014 and implemented in 2015. Under its requirements, manufacturers and importers of MDs are required to report to the FDA any serious injuries or deaths associated with their devices within 30 calendar days of becoming aware of the incident. Additionally, manufacturers must report any malfunctions that could result in a serious injury or death within 5 workdays of becoming aware of the issue. Moreover, healthcare facilities, such as hospitals, nursing homes, and outpatient clinics, must report certain adverse events related to MDs to the FDA within 10 days. These events include incidents that result in serious injury or death or require intervention to prevent serious injury or death. Finally, in 2014, the FDA published a final rule on Electronic Medical Device Reporting (eMDR), effective from 2015, that requires manufacturers and importers to submit MDRs to the FDA in an electronic format that the FDA can process, review, and archive(20). Last but not least, in the previous two decades, there has been observed an increasing number of MDs that have received a 510(k) clearance compared to a premarket approval (PMA). Safety issues are raised as the clearance provision pathway does not require clinical trials and is less rigorous than the PMA process (21,22).

Considering the number of total reports in MAUDE and the death event type percentage of these reports presented in Table 2, it means that more than 180,000 adverse events are historically related to patient death. However, this number can be used only as an approximation due to the limitations of the database (i.e., multiple reports on the same incident, underreporting, incomplete information, etc.). Although the decrease in deaths and increase in malfunctions reported in Figure 3, although possible, does not explicitly indicate an increase in device safety, as it could also mean the intensified reporting of less severe adverse events compared to the past years.

Some intuition can be gained about the event types for each examined device group. Glucose testing devices, such as test strips, are associated mainly with a less

[f] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-803. Medical Device Reporting: Electronic Submission Requirements. A Rule by the Health and Human Services Department, and the Food and Drug Administration. Published 2014. Effective after 2015.

serious malfunction (see Table 2). An example of such a malfunction could be wrong glucose test results. Although not crucial as an adverse event itself, such a malfunction could pose more serious consequences for the patient in the long term. This may be why these devices have a very high rate of recalls (Table 3). In contrast to glucose testing devices, most of the reported incidents of hip prostheses (KWA) resulted in serious patient injury, with a probability of patients having to undergo revision surgery. Patient injury was almost universal (98.4%) for dental implant adverse events. A factor that may be of importance is the absence of implant dentistry from the recognized dental specialties of the American Dental Association.(g) Although the FDA monitors and regulates MDs, it does not act toward healthcare practice regulations. The fact that implantable defibrillators adverse events showcase the highest probability of death (3.2%) compared to the rest of the examined device groups is expected, due to their crucial role in physiological heart function. Finally, the fact that almost all the reports regarding infusion pumps were about simple device malfunctions, without further serious implications to the patients, may indicate an increased awareness regarding adverse event reporting of crucial devices. However, it should be noted that infusion pumps malfunctions have a high potential for patient injury and must be treated as near-miss adverse events. These events are incidents that can potentially cause harm to a patient but are caught or mitigated before any actual harm occurs. Examples of reported infusion pump problems that could lead to such incidents include lack of warning when inappropriate data is entered or failure to generate audible alarms for critical problems such as an occlusion in the tubing.23 and adverse events are often avoided due to luck or vigilant healthcare professionals.

Remedial action codes were found to be often omitted from the adverse event reports. It is unclear whether this is because the event resulted in no action to be taken by the manufacturer or the information was not correctly updated in the database. As a silver lining, the rate of existing remedial actions has risen in the last year. Moreover, the "Other" category is used less frequently, which may indicate that the report form became more user friendly and awareness toward adverse event reporting has risen.

The fact that the device manufacturers have filed 96% of the reports, while the trend is continuously rising (Figure 5), is related to the stricter requirements imposed on manufacturers by CFR 21, 803. This is also the reason behind the high device evaluation percentage by the manufacturers (Figure 7). Adding to this, many users from facilities or homecare prefer to file a report to the manufacturer, who then submits it to FDA. This is the reason why the initial reporter occupation is analyzed separately. Data for 1997 consists of all data available from 1991 to that year. According to MAUDE, user facility reports have been submitted since 1991, distributor and voluntary reports since 1993 and manufacturer reports since 1996. For this reason, the report rates by manufacturers are quite low until 1996, compared to the next years.

According to CFR 21, 803, §50, manufacturers are responsible for conducting an investigation on each event and evaluating the cause of the event. If the device was returned to them and information in a report is incomplete, they must explain why and the steps taken to obtain it. This is why most devices returned to the manufacturer by the user facility or the distributors are evaluated (70.8% on average). The last year was an exception, and the reason could be further investigated.

Regarding the MAUDE database, several issues were discovered. First, there are some instances of unintuitive or straight up incorrect information on the use or description of the files. As an example, the "*deviceproblemcodes*" file should contain the MDR report keys with the corresponding device problem code, while the "*foidevproblem*" file should contain a list of device problem codes with their matching code description, according to the site's description. However, the data contained in these files are interchanged. Additionally, "*mdrfoi*" file's description was not updated for the current year, at the time of this work. Though it contained data from 2023, it read "*MAUDE Base records received for 2022*". The mdrfoithruxxxx file also contains a vast amount of information of 5 GB, making it difficult for casual users to access it. Splitting it as is the case with device files would facilitate further database usage.

g https://ncrdscb.ada.org/recognized-dental-specialties

Other shortcomings of MAUDE derive from adverse event reporting system issues. A common problem for all vigilance systems worldwide is underreporting adverse events. Though events seem to be reported more frequently during the last years, it is still plausible that more adverse events occur than those finally reported to the FDA. The rate of medical device adverse events underreporting is difficult to determine, as the number of incidents is unknown accurately. Non-reporting can be attributed to many factors, such as fear of blame, lack of time, complexity of the reporting system, or even perceived ineffectiveness. Adding to this, in cases of human error, underreporting is expected to be even more prevalent.24,25

Other issues may be the symptoms of underutilizing the MDR system's potential. For example, although more than one remedial action code can be assigned to an adverse event, in practice reports in MAUDE, use a single code. As a result, when an event is marked with a corrective action (i.e. replacement of the device), the recall code is omitted and vice versa. Therefore, it becomes unclear whether the corrective action was part of a recall, or a voluntary preventive manufacturer action.

Finally, it is important to note that an increase in adverse event reports does not necessarily mean that the number of adverse events has increased, but rather that reporting systems have become more effective in capturing and documenting these events.

CONCLUSIONS

It is obvious that the FDA encourages reporting adverse events and MAUDE plays an essential role in identifying potential safety issues and facilitating corrective actions that protect public health. It also provides an essential source of data for review studies in this area, as demonstrated by the increasing number of related publications mentioned in the introduction.

In Europe, despite the explicit reference in the MD regulations on the availability of the vigilance data in the EUDAMED, this part of the database is still not accessible. This fact restricts the utilization of this critical data for advancing safety in medical technology in Europe and worldwide.

In conclusion, using an adverse event reporting system efficiently facilitates communication between regulatory agencies and healthcare providers and promotes transparency and accountability in the healthcare industry. Ensuring that MDs are safe and effective will improve patient outcomes, with clear benefits for the healthcare sector that remains a cornerstone of our society.

REFERENCES

1. Wiig S, Aase K, Bourrier M, Roise O.Transparency in Health Care: Disclosing Adverse Events to the Public | SpringerLink [Internet]. [cited 2023 May 5]. Available from: https://link.springer.com/chapter/10.1007/978-3-319-74098-0_8
2. FDA. About Manufacturer and User Facility Device Experience (MAUDE) [Internet]. FDA; 2023 [cited 2023 Apr 11]. Available from: https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/about-manufacturer-and-user-facility-device-experience-maude
3. FDA. 2023 Medical Device Reporting (MDR): How to Report Medical Device Problems. [cited 2023 Apr 11]. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems
4. EUDAMED database - EUDAMED [Internet]. [cited 2023 Apr 11]. Available from: https://ec.europa.eu/tools/eudamed/#/screen/home
5. Government of Australia Department of Health and Aged Care. Therapeutic Goods Administration (TGA). Safety monitoring: Medical devices [Internet]. 2022 [cited 2023 Apr 11]. Available from: https://www.tga.gov.au/safety/safety/safety-monitoring-medical-devices
6. Government of Canada - Health Canada. Find recalls, advisories and safety alerts – Canada.ca [Internet]. 2021 [cited 2023 Apr 11]. Available from: https://recalls-rappels.canada.ca/en
7. MHRA.GOV.UK. 2023 [cited 2023 Apr 11]. Alerts, recalls and safety information: drugs and medical devices. Available from: https://www.gov.uk/drug-device-alerts
8. Federal Institute for Drug and Medical Devices. Field corrective actions [Internet]. [cited 2023 Apr 11]. Available from: https://www.bfarm.de/EN/Medical-devices/

Tasks/Risk-assessment-and-research/Field-corrective-actions/_node.html

9. Malataras P, Pallikarakis N. Spin-off use of adverse events data: why and how. The case of FDA's MAUDE. Global CE J. 2018;1(1):9–23.
10. Rayess HM, Svider PF, Hanba C, Patel VS, DeJoseph LM, Carron M, et al. A Cross-sectional Analysis of Adverse Events and Litigation for Injectable Fillers. JAMA Facial Plast Surg. 2018 May 1;20(3):207–14.
11. Rahimpour S, Kiyani M, Hodges SE, Turner DA. Deep brain stimulation and electromagnetic interference. Clin Neurol Neurosurg. 2021 Apr;203:106577.
12. Carey J, Gabbireddy S, Mammen L, Rosamilia G, Patel V, Foyt D, et al. FDA MAUDE database analysis of titanium middle ear prosthesis. J Otol. 2022 Jan;17(1):18–24.
13. Tong JY, Pasick LJ, Benito DA, Monfared A, Sataloff RT. Adverse Events Associated With Ossicular Prostheses: Utility of a Federal Database. Otol Neurotol. 2022 Feb 1;43(2):e229–34.
14. Alhusain R, Dayco J, Awadelkarim A, Almas T, Halboni A, Ahmed AK, et al. Turnpike Catheter failure, causes and mechanisms: Insights from the MAUDE database. Ann Med Surg (Lond). 2022 Jun;78:103923.
15. Ensign LG, Cohen KB. A Primer to the Structure, Content and Linkage of the FDA's Manufacturer and User Facility Device Experience (MAUDE) Files. EGEMS (Wash DC). 5(1):12.
16. Kavanagh KT, Brown RE, Kraman SS, Calderon LE, Kavanagh SP. Reporter's occupation and source of adverse device event reports contained in the FDA's MAUDE database. Patient Relat Outcome Meas. 2019 Jul 2;10:205–8.
17. Connor MJ, Tringale K, Moiseenko V, Marshall DC, Moore K, Cervino L, et al. Medical Device Recalls in Radiation Oncology: Analysis of U.S. Food and Drug Administration Data, 2002–2015. Int J Radiat Oncol Biol Phys. 2017 Jun 1;98(2):438–46.
18. Bitar C, Krupic F, Felländer-Tsai L, Crnalic S, Wretenberg P. Living with a recalled implant: a qualitative study of patients' experiences with ASR hip resurfacing arthroplasty. Patient Safety in Surgery. 2021 Jan 6;15(1):2.
19. Drugwatch. Drugwatch.com. [cited 2023 Apr 25]. Hip Replacement Recall | Causes and FDA Information. Available from: https://www.drugwatch.com/hip-replacement/recalls/
20. FDA. Federal Register. 2014 [cited 2023 May 3]. Medical Device Reporting: Electronic Submission Requirements. Available from: https://www.federalregister.gov/documents/2014/02/14/2014-03279/medical-device-reporting-electronic-submission-requirements
21. Zuckerman DM, Brown P, Nissen SE. Medical Device Recalls and the FDA Approval Process. Archives of Internal Medicine. 2011 Jun 13;171(11):1006–11.
22. Dubin JR, Simon SD, Norrell K, Perera J, Gowen J, Cil A. Risk of Recall Among Medical Devices Undergoing US Food and Drug Administration 510(k) Clearance and Premarket Approval, 2008-2017. JAMA Netw Open. 2021 May 3;4(5):e217274.
23. FDA [Internet]. FDA; 2023 [cited 2023 Oct 5]. Examples of Reported Infusion Pump Problems. Available from: https://www.fda.gov/medical-devices/infusion-pumps/examples-reported-infusion-pump-problems
24. Craig A, O'Meley P, Carter P. The Need for Greater Reporting of Medical Device Incidents. EMJ. 2019 Oct 1;3(1):56–63.
25. 2Knisely BM, Levine C, Kharod KC, Vaughn-Cooke M. An Analysis of FDA Adverse Event Reporting Data for Trends in Medical Device Use Error. Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care. 2020 Sep 1;9(1):130–4.

Received October 10, 2023, accepted November 21, 2023, date of publication December 1, 2023

Sustainable Procurement of Medical Devices in an International Context - Part 2

Needs Assessment

By Valerio Di Virgilio[1], Alexia Bouchard Saindon[2], Francisco Becerra Posada[2]

[1] Università degli studi La Sapienza, Roma

[2] United Nations Office for Project Services (UNOPS)

ABSTRACT

Background and Objectives: This article describes how sustainable procurement of medical devices (MDs) can be implemented in operational projects in developing countries. It also further details how sustainability principles and the needs assessment can be applied by the biomedical/clinical engineer lead (BCEL) responsible for the technical and quality aspects of the procurement process of MDs. It also emphasizes the importance of the BCEL considering the country's or region's specific healthcare context when working on MD procurement projects in developing countries.

Material and Methods: Based on the author's experience of more than 20 years in procurement projects and implementation of MDs in developing countries, the role of the BCEL will be analyzed from a theoretical point of view with the description of the first pillar of a sustainable purchase, the needs assessment, to how it can be operationally applied through the analysis of relevant literature, case studies and lessons learned from past projects.

Results: The BCEL has a key role in the sustainable procurement of MDs as an integrator able to understand clinical needs and translate them into requirements while being aware of the sustainability and safety risks linked to technology implemented in the fragile environment of a developing country with limited resources.

This context also creates additional challenges that can be managed if the BCEL is conscious of the country's health expenditure, geopolitical, healthcare, model of care, regulatory, infrastructure, and logistical conditions in which the MDs will be installed. Many equipment may remain unused if the technology implementation is not in line with the needs of the beneficiaries. Therefore, a thorough needs assessment performed by the BCEL to obtain the detailed list of MDs, their technological level and estimated budget is of utmost importance to increase the project's sustainability and mitigate the risk of unused MDs.

Conclusion: Besides traditional disciplines in biomedical and clinical engineering, the BCEL shall also learn at least basic principles in public health, healthcare planning, project management, health infrastructure, and development aid to facilitate the dialogue with stakeholders based on knowledge, flexibility, and capacity to anticipate and solve practical issues on the ground. To this extent, it is advisable for a BCEL new to the environment of developing countries to have progressive exposure to more complex projects and to extensively use the peer review mechanism to assure sustainability and quality during project implementation. A theoretical background based on sustainable procurement principles, analysis of the local and national health context and regulations, and knowledge of lessons learned from past projects should guide the BCEL's approach to performing the needs assessment while implementing a new project.

Keywords – *Medical device procurement, sustainable procurement, needs assessment, health services in developing countries, quality assurance, sustainability, Biomedical/Clinical Engineer role, international health procurement.*

INTRODUCTION

In a previous article,[1] the concept of sustainable procurement of MDs has been discussed, and its importance regarding health services of developing countries emphasized. Public investments in MDs aim to improve health services and, thus the population's health. This creates a virtuous circle where a healthier population improves the economy, which translates into a better investment return. In this framework, the sustainability aspect in MD procurement projects has been defined as the critical factor that transforms financial resources into results: improved population health and wealth. This is particularly important in low-income countries (LIC) where healthcare financial resources are often scarce, and deciding where to invest them is paramount. An unsuccessful project, where for example, funds are spent to purchase equipment that is not needed or not efficiently used, can disrupt the virtuous circle by creating a major financial debt, which brings more poverty and, thus the population to a more fragile status.[1] The sustainability of MD purchasing projects is therefore intimately linked to their resulting impact on the population as well as the economy of the country. Therefore, the appropriate and efficient use of the purchased devices should be at the center of the efforts of the BCEL.

The concept of the three essential pillars to achieve sustainable procurement of MDs has been proposed as central to preventing the risk of purchasing equipment that will not be properly and efficiently used. This concept outlines the importance of concentrating the technical effort in assessing (1) the needs, (2) the local conditions, and (3) the conditions for the lifelong use of the MD. Consequently, technical decisions along the project should be strictly coherent with the results of these three assessments and the resulting planned project impact and objectives to guarantee the sustainable use of the purchased devices.

The objective of this article is to detail further how the first pillar for sustainability, the needs assessment, can be implemented in procurement projects within the environment of developing countries. The context of LIC creates additional challenges regarding MD procurement such as limited clinical, technical, and financial resources which need to be considered, especially during the introduction of complex MDs. The BCEL has a key role in facing these challenges and ensuring the project's sustainability. The responsibility and recommended actions that the BCEL can take in these circumstances are discussed and analyzed using examples from implemented projects.

DEFINITION AND CONTEXT OF SUSTAINABLE PROCUREMENT OF MDS

The concept of the three pillars to achieve sustainable procurement of MDs[1] is an addition to the social, economic, and environmental considerations that are widely included in the policies of the four UN agencies mainly responsible for MD purchase: WHO,[2] UNICEF,[3] UNDP.[4] and UNOPS.[5] The sustainability concept of a purchase shall be primarily linked to the use of the MD and only secondarily to its social, economic, and environmental impact. In fact, if the purchased MDs are unfit for purpose or wrongly installed and unused, they shall not be considered sustainable even if they are compliant to certain social, economic and/or environmental sustainability standards. A low environmental impact is unacceptable if the MD is not fit-for-purpose and brings no benefits (EG1 and Figure 1).

FIGURE 1. PubMed articles with relevant MAUDE terms in title/abstract.

EG1 *The purchase of a medical refrigerator meeting certain sustainability criteria such as durable material composition without ozone contaminants, high energy efficiency, reduced and recyclable packaging, ISO 13485 certification, and purchased at the best price available on the international market, faces risks to be unsustainable if the needs assessment was not correctly carried out. The refrigerator is not really needed or is too large for the needs of the beneficiary unit creating a problem of space and utilization that is solved with its early disposal.*

The context in developing countries creates additional challenges in the procurement of MDs. According to WHO: "in the Sub-Saharan Africa region, a large proportion (up to 70%) of equipment lies idle due to mismanagement of the technology, acquisition process, lack of user-training and lack of effective technical support."[6] Another study reported an average of 38.3% of out-of-service medical devices (MD) in developing countries due to a lack of training, health technology management, and infrastructure.[7]

EG2 *In an important procurement process managed by the Honduras Social Security Institute in 2011 and revised in 2014, it was found that about 20% of the purchased goods had not been used within 3 years from their installation while an additional 10% was seldom used.*

Developing countries conditions

The main conditions that a BCEL shall consider during the assessment of a new project in a developing country are:

1. Health expenditure conditions;
2. Geopolitical conditions;
3. Pre-existing healthcare conditions;
4. Model of care;
5. Infrastructure and logistical conditions;
6. Regulatory conditions.

Health expenditure conditions: the per-capita health expenditure (Figures 2 and 3) linked to the availability of human and material resources gives an overview of the economic conditions of each developing country. Low health expenditure is associated with few or limited trained medical and technical resources that might impact the technological level of the MDs to be purchased. It can also limit the availability of consumables and spare parts on the local market and cause a lack of tools and knowledge to repair the MDs. A BCEL shall, therefore, consider that even when a budget is available for the purchase of MDs, funds for their consumables or maintenance might not be available in the long run and might compromise their efficient use.

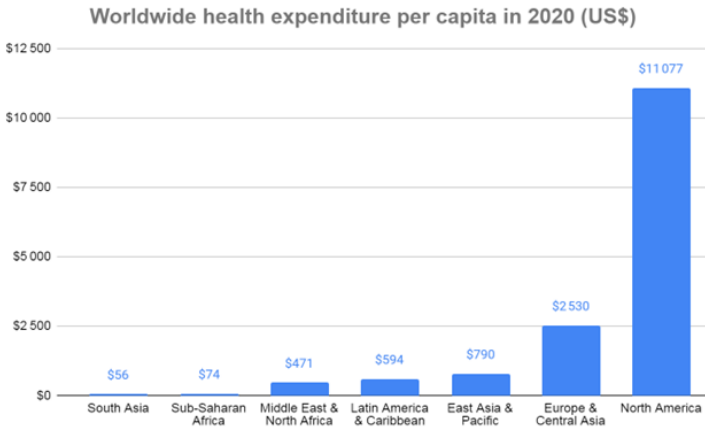

FIGURE 2. Worldwide health expenditure per-capita (US$).[8]

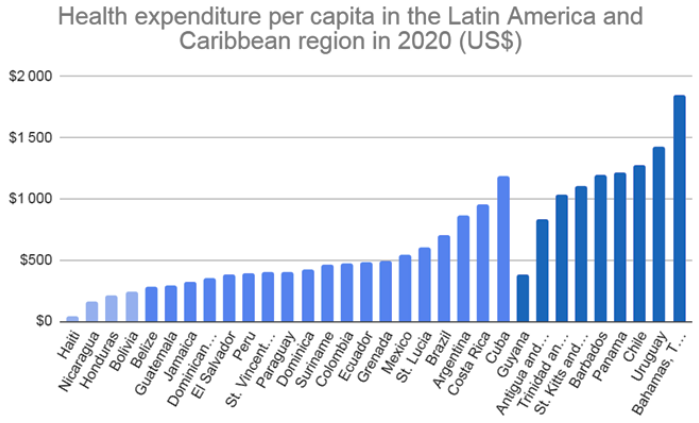

FIGURE 3. Health expenditure per-capita (US$) in Latin America and the Caribbean region.[8]

The huge gaps in per-capita health expenditure between the different regions of the world also hide important gaps inside a particular region. For example, in the Latin America and Caribbean region, the health expenditure has a mean value of 594 USD. Still, when countries of this region are taken individually, there is a great variance between the Bahamas which has an expenditure similar to Europe &

Central Asia, and Haiti, which has an expenditure similar to the poorest countries of Africa and South Asia, (Figure 2).

While per-capita and public health expenditure can estimate a country's effort to manage healthcare and improve universal health coverage, life expectancy is to be considered as a parameter that can roughly summarize the results of this effort, not considering other factors like lifestyle, socioeconomic, and genetics. It can be observed that the higher the health expenditure per-capita the higher the life expectancy of the country (Figure 4) with some interesting exceptions like the US where the health expenditure is mainly out of pocket, leading to less efficient use of the expenditures and the countries where per-capita annual expenditures go below $400. Over time, as countries invest more money in healthcare, the life expectancy of their population increases (Figure 5): *"on average, a 10% increase in health spending per-capita is associated with a gain of 3.5 months of life expectancy."*[9]

Geopolitical conditions: tense geopolitical conditions in countries affected by war zones, territories controlled

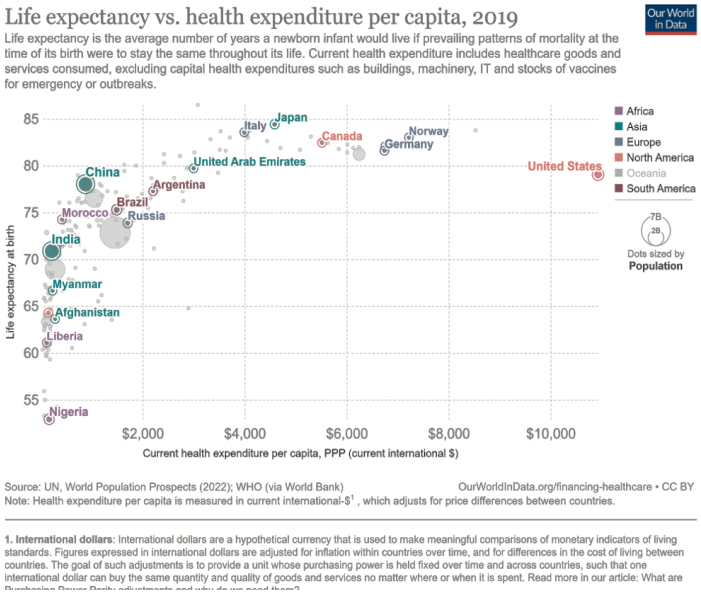

FIGURE 4. Life expectancy versus health expenditure per-capita in 2019.[10]

by rebel or criminal groups, and high criminality zones might complicate the delivery of equipment or the travel of technicians to perform the installation or the repair of MDs. In those cases, the delivery of the equipment or the maintenance technicians' access may require a police or military escort and pose additional challenges to the project.

Pre-existing healthcare conditions: available information on the local healthcare system, such as mortality/morbidity rates as well as health statistics on the population published by WHO[11] and data on the present workload and activity of the beneficiary center(s) supporting the assessment of the context in which the MDs will be implemented.

Model of care: different countries have different organizations and operationalization of health services, including different referral systems, processes of care, providers' organization and services management. These differences directly impact the distribution of technologies in the health infrastructures according to their complexities. It is recommended that the BCEL adopts the vision of a supply chain: a patient with a specific disease can be progressively attended to in infrastructures of different levels according to the diagnosis of the severity of the illness, and thus, the complexity of the technology shall be planned accordingly.

Infrastructure and logistical conditions: Delivery of MDs in remote areas can be difficult due to poor road conditions or accessibility by boat only. Remote areas might also have limited or no access to reliable electrical or water resources, which might affect the utilization of MDs.[12]

Regulatory conditions: The BCEL working in developed countries is usually part of a multidisciplinary team including medical planners, clinical experts, architects, and engineers with an exhaustive background of norms, regulations, and guidelines. In opposition, the BCEL working in developing countries has to cope with a multidisciplinary team that is significantly reduced or sometimes absent in a context of international rules and regulations that may not apply to fragile contexts.

The presence of a local National Regulatory Authority (NRA) in the country and its level of maturity as defined by WHO facilitates the understanding and implementation of national regulations and the acceptance (or not) of

international standards in MDs procurement projects. The efforts of WHO and the Pan American Health Organization (PAHO)[13] to improve the capacities of NRAs in developing countries shall also be considered and monitored as part of the BCEL action in MDs procurement projects. The BCEL shall also be aware of the WHO Listed Authority,[14] which will assess and classify the maturity level of NRAs based on a transparent and objective set of indicators established in the WHO Global Benchmarking Tool.[15]

The role of the BCEL

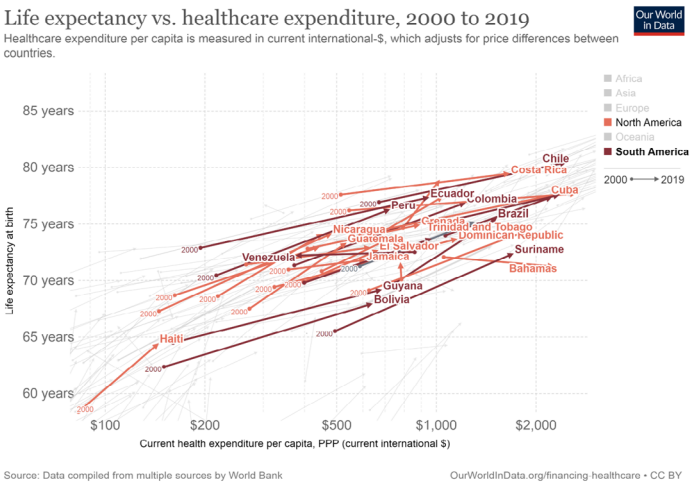

FIGURE 5. Life expectancy versus healthcare expenditure per-capita from 2000 to 2019 in Latin America and the Caribbean region.[10]

When a procurement project of MDs for an LIC is assigned to the BCEL, he should always consider the beneficiary country's conditions during all project steps. In fact, the knowledge and consideration of the local health realities is essential to ensure a sustainable result of the procurement process and, finally the purchase of sustainable MDs that will meet the needs of the local beneficiaries in the long term. The role and expertise of the BCEL are crucial in addressing the challenges related to the implementation of MDs and the promotion of sustainable procurement practices in developing countries. BCELs with adequate experience should participate right from the start of the planning phase of an MD procurement project to ensure that sustainability criteria will be considered.

THE NEEDS ASSESSMENT

The first pillar of sustainability is the needs assessment, which involves investigating the demand and the intended use of the MD requested by the beneficiary. Considering the user's needs is a central concept in the procurement process definitions of the 4 main UN agencies procuring MDs. WHO states that the benefits of good procurement include: *"the most economically advantageous terms for the equipment acquired – not necessarily the lowest price obtained through tender, but the best deal for the organization's needs"* and defines the needs assessment as the *"quantification of gaps between desired health service provision and the current situation"*.[16] UNICEF and UNDP also include the importance of meeting the needs of the end-user and the *"fit-for-purpose"* concept[17] in their procurement processes: *"The selected offers from a competitive tender should display the optimum combination of quality, whole life cost, effectiveness, and other factors such as social, environmental and other strategic objectives, to meet end-user needs."*[18] UNOPS also mentions to *"Re-consider the needs, i.e. consider specifically whether those goods or services need to be purchased."*[19] According to the clinical engineering handbook,[20] the first step in the planning phase of MDs acquisition projects is "Demonstrated needs and benefits". Effective and sustainable procurement is thus based on getting the right goods to respond to the needs. In fact, the whole procurement process is based on a needs assessment as its essential starting point. Public investment in MDs through the implementation of an international purchasing process is a long journey, and as *"most journeys we take are considered successful if we arrive at the right place, at the right time, and in good condition. The "right place" is vital. Identifying where you should head and justifying why you should get there will provide you with the critical data upon which to do planning, design, development, implementation, and monitoring and evaluation."*[21]

The objective of the needs assessment

The final objective of an MD procurement project is the intended impact on population health. Thus, the needs assessment's objective has to align with this intended impact on patient care.

It is important to clarify that the objectives and impact of an MD procurement project shall be designed and measured by clinical variables such as the number of patients treated or the reduction of waiting lists, rather than by the amount of equipment or money spent during the project. Therefore, performing a thorough needs assessment to define the project's objectives and identify the clinical variables upon which the project's success will be measured is essential. The project's objectives and clinical variables shall also be defined based on the country's health policy and statistics[22] as well as on the analysis of the context as developed in chapter 2.1. When possible, it is recommended to involve, right from this initial step of the project, the beneficiary country's health personnel that has, at different levels, a deep knowledge of the local technical capacities, conditions, and needs.

The role of the BCEL in the needs assessment

A medical planner usually carries out the analysis of the clinical needs along with the establishment of the project's clinical objective. The BCEL has to understand the clinical objectives and the process that has been carried out to define them by dialoguing with the medical planner. Therefore, the BCEL should deeply understand healthcare systems in developing countries and their dynamics. Profound knowledge of the healthcare needs and the locally and internationally available commercial solutions are essential for the BCEL to evaluate and propose technological solutions for the assessed clinical needs and objectives. Starting from this essential dialogue with the medical planner, the BCEL can complete the needs assessment by defining the objectives of the procurement process in terms of technologies. Based on the planned clinical activities and workloads, the BCEL can determine the equipment list. In fact, an equipment type that may be included in the list corresponds to an equipment class that requires a technological-level definition to associate the expected clinical throughput with its estimated value and technical requirements in terms of space, installation, electricity, etc.

EG3 *A 20L tabletop autoclave used to sterilize laboratory equipment performing a few analyses per day is technologically much different and less complex than a 500L pass-through autoclave of a surgery center, requiring more complicated installation steps. Still, often they are simply referred to as autoclaves in the purchasing lists provided to the BCEL.*

To define the project objectives, the needs assessment should be analyzed, validated, and updated in the planning phase of the procurement process. All stakeholders must be involved in the needs analysis, which must be as detailed and complete as possible. The scope of this assessment should also include present and future needs in a 5 to 10-year projection. By focusing on the specific use of the device, the procurement process can be tailored to meet the needs of the beneficiaries and select the most adequate equipment. The quality of the MD procurement process can be maximized when all the actions of the BCEL are coherent with the project's objectives.

In the planning phase of a procurement project, the BCEL should also consider the following conditions as recommended by the clinical engineering handbook:

''1. Demonstrated needs and benefits of the MDs
2. Available qualified users
3. Approved and reassured source of recurrent operating budget
4. Confirmed maintenance services and support
5. Adequate environment support
6. Regulatory compliance''[20]

Analyzing these conditions before purchasing the equipment allows the BCEL to prevent potential issues related to the use of the MD. These conditions are also included as part of the three pillars of sustainability. This process results in adequate equipment that meets the beneficiary's needs and thus is more likely to be used by the clinical personnel (Figure 6). To perform a proper needs assessment, the BCEL should always involve the clinical end-user as stakeholders and purchase MDs and services from local manufacturers whenever possible.

The sustainability risks related to a weak needs assessment

A reliable needs assessment conducted under the responsibility of the BCEL is, therefore, the central point of an effective health procurement process. It also helps minimize sustainability risks, such as insufficient adequacy

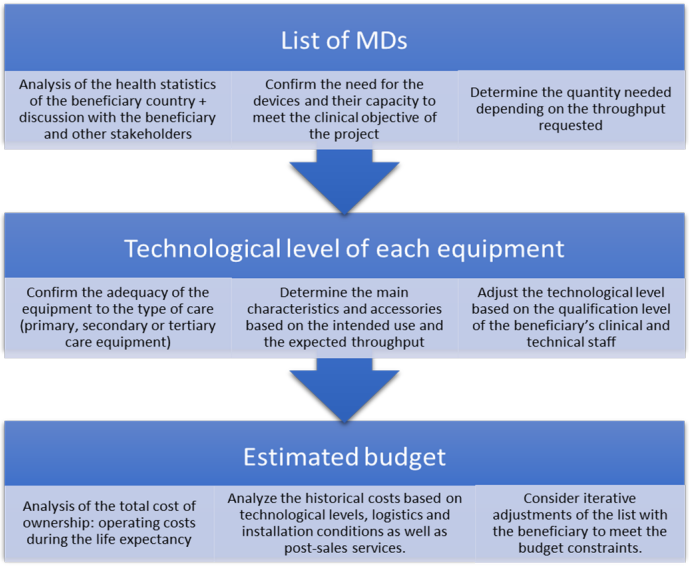

FIGURE 6. Description of the three main activities for each needs assessment deliverables that the BCEL shall focus on.

between the clinical personnel's needs and the purchased MD's characteristics, compromising its usage. However, this analysis can sometimes be difficult to achieve due to the following pitfalls:

- Inadequate involvement of the relevant stakeholders in the project is caused either by the difficulty of implicating all the necessary stakeholders in the needs analysis, deficient identification of the clinical beneficiaries, or lack of consideration of the position of the beneficiaries in the health system network.
- An outdated needs analysis caused by a significant delay between the completion of the analysis and the official launch of the project or by a change of the actors or some of their characteristics (evolution of the private sector, new government, new strategies in the distribution of health services, change in the clinical team, etc.).
- A short-term needs assessment does not consider future needs caused by an analysis that considers only the current necessities and lacks to foresee future perspectives for at least the next 5-10 years related to the new etiologies of diseases and the emergence of new diagnostic and therapeutic needs.

Depending on the project's starting point when the BCEL begins to be involved, the needs assessment may be included or not in the project scope. The projects that start from a list of MDs and technical specifications already defined are considered "purely transactional." They can be considered high-risk projects since the procurement project is separated from the needs analysis and the evaluation of the impact of the purchase on the local healthcare system. Implementing these transactional projects represents a high risk to the sustainable impact of the procurement project because no one in the project team is responsible for ensuring that the MDs to be purchased are genuinely needed and that the local conditions allow for their efficient use. The clinical needs are unknown to the project team, and the coherence of the implementation is jeopardized. Other types of projects, such as those where the dialogue between the BCEL and the medical planner who defined the clinical objectives is impossible, and has moderate risks. These risks shall be mitigated by the BCEL, which can revise and validate the medical planner's analysis when possible or at least the clinical objectives, focusing on the purchase of MDs.

Case studies

In the following discussion, 2 case studies of projects implemented in the Latin America and Caribbean region, one in Uruguay and the other in Haiti, representing extremes in terms of per-capita health expenditure differences in the region, will be presented. Uruguay has a high health expenditure and a mature public health system with established capacities to understand and properly use the funding for capital investment in MDs. On the other hand, Haiti has minimal health planning capacities and lacks technical experts.

In 2008, in Uruguay, as part of a project funded by a soft loan from Italian corporations, 34 types of MDs were purchased and destined for more than 300 health centers nationwide.[23] The needs assessment process carried out before the beginning of the project has been an example of good practice of sustainability (Figure 7). The project's agreement stated the general objective: "Sustain the capacity of the Uruguayan Public Health System to meet the population's needs while prioritizing the most vulnerable groups."

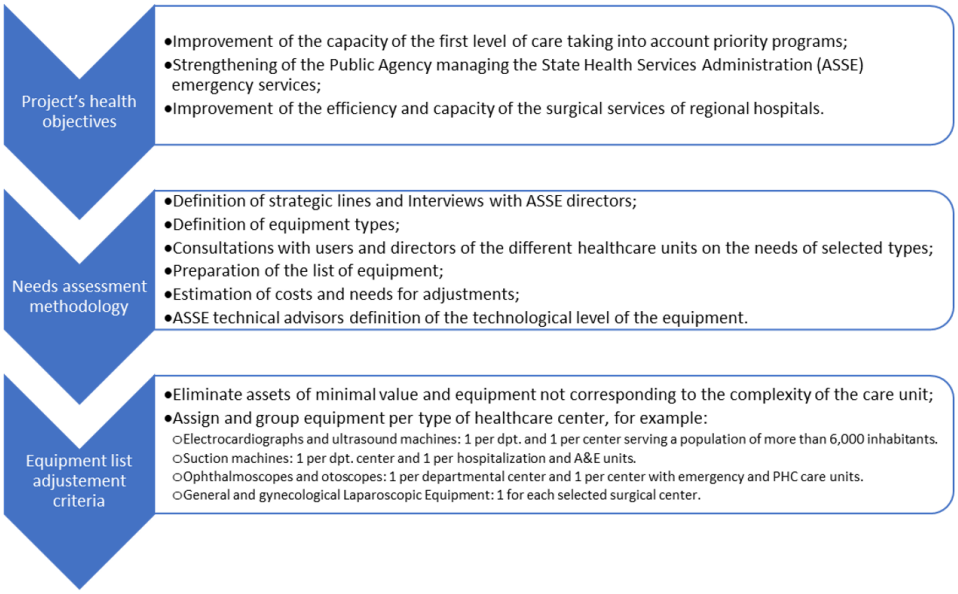

FIGURE 7. Methodology of the needs assessment of the project *"Italian Loan to support Uruguayan Health Services"* implemented in 2008, starting from the project's objectives definition and ending with the types of equipment included, the list of equipment requested by the beneficiary centers and its adjustment to meet the available budget.

This process, carried out transparently with an outstanding maturity by the central office of the Ministry of Health in contact with the regional directors, has produced the expected results: each center was aware and prepared to receive the equipment from the loan investment. The BCEL validated the needs assessment carried out by the beneficiary and assured coherence of the purchase with the needs assessed.

In 2012, in Haiti, during the design phase of the construction and medical equipment procurement project of the Gonaives hospital, no local medical counterpart was involved (Baio A. Gonaives Hospital Project - Raising from destruction - The challenge of building in Haiti - International Federation of Hospital Engineering. Buenos Aires, October 15th, 2014). The only person from the Haitian Ministry of Health participating in the technical dialogue was the recently appointed, but not yet contracted, director of the new hospital. In this case, the BCEL had to plan a methodology to define the list of equipment since no dialogue with the clinical beneficiary could plan medical equipment adequate to the intended level of care and size of the hospital (a regional hospital with a 200-bed capacity). To mitigate this risk, a workshop was organized involving all the stakeholders working on MDs in the country. This workshop resulted in a scheme to follow for the definition of the equipment list, primarily oriented towards implementing simple technologies to facilitate local maintenance (Figure 8). For example, manual operation tables rather than electrical ones were chosen to allow for ease of use and maintenance.

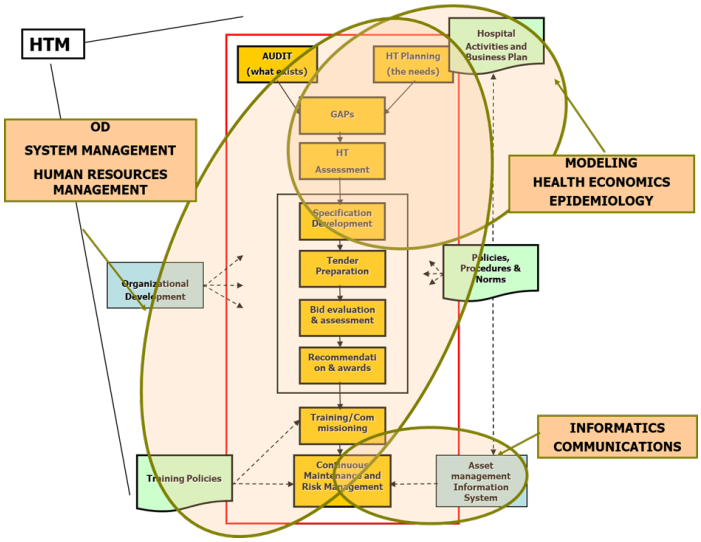

FIGURE 8. Health Technology Management Scheme (Nunziata E. Technical workshop on MDs - towards health technology management in Haiti. Haiti, June 15th 2012).

The demand for local maintenance support was solved during the tender process by asking the suppliers to establish a maintenance center in the country (at that time, no maintenance capacity - private or public - were present in the country). To help suppliers comply with this challenging requirement, the contracting authority included a financial incentive: an important advanced payment during the procurement process. Eight local technicians were also hired and trained under the guidance of international technical experts to open packages, assemble, and install all the hospital furniture purchased. At the end of the project, the hospital could recruit trained technicians as maintenance employees. This also reduced the costs for suppliers since they did not have to travel to Haiti to assemble the purchased furniture.

In both case studies, a component of the procurement project was focused on strengthening local technical capacities in terms of equipment maintenance to improve the project's sustainability. In Uruguay, maintenance tools were purchased and provided to regional hospitals where biomedical engineers trained during the project execution could use them to maintain and repair MDs.[23] In Haiti, training and tools for medical furniture repair was provided to local technicians, and an incentive for international suppliers to establish local maintenance centers was added to the procurement project. As a lesson learned, improving and strengthening local technical capacities is strongly recommended as an objective of MD procurement projects in developing countries to enhance sustainability.

CONCLUSION

Sustainability is essential in implementing an internationally funded project in a developing country to procure MDs. This factor determines if the project will improve the population's health conditions or the country's impoverishment.1 Sustainable procurement of medical devices shall be driven by the BCEL using the framework of the three pillars: assessing (1) the needs, (2) the local conditions, and (3) the conditions for the lifelong use of the MD. The BCEL is responsible for ensuring the quality of the project's results and, thus, its sustainability. This article presented the theoretical background of the first pillar, the needs assessment, that the BCEL can follow as a guideline in the project's planning phase. In this way, he can assume the responsibility for the quality assurance processes and the project's sustainability while raising awareness of the possible issues and discussing solutions with the rest of the team, the beneficiary, and the stakeholders to minimize the project's risks.

An international procurement project of MDs requires high technical specialties in a multidisciplinary team, including project management. The needs assessment step requires competencies and knowledge in public health, clinical aspects, hospital design, infrastructure, MDs, project planning, and market and technology analysis. The BCEL has to dialogue with several stakeholders and, therefore, understand and use their languages to integrate their points of view, perceived risks, and suggested mitigation measures. A good approach for the BCEL is to begin the project from a risk analysis perspective. While different stakeholders can raise any risk, the BCEL shall focus on quality risks, which in the light of the previous discussion means sustainability risks: the main risk being the investment of money in the purchase of MDs that are not or scarcely used because they do not respond to the needs of the beneficiary. During the analysis, the BCEL can integrate different viewpoints and brainstorm possible prevention and mitigation measures.

Considering sustainability as the center of their activity and responsibility, the BCEL's role in a project is much more important than simply writing technical specifications or performing technical evaluations. Therefore, the BCEL needs thorough professional preparation and progressive exposure to the complexity and the issues specific to the context of developing countries. In this sense, the peer review mechanism is a tool commonly used in organizational processes to assure higher quality in project implementation and the continuing education and professional growth of BCELs interested in leading international procurement projects.

When implementing a specific project, balancing the impact of time and budget constraints with quality assurance actions is the main goal that any BCEL has to focus on. The needs assessment should be included in the planning phase of the procurement project and coordinated by the BCEL, which can integrate the different stakeholders' points of view. The assessment of sustainability risks performed

during the project's planning phase allows the BCEL to identify the challenges and evaluate the potential risks that could impact the project's outcome.

CONFLICT OF INTEREST

The authors declare no conflict of interest regarding the publication of this paper.

ACKNOWLEDGMENTS

The authors would like to thank Antonio Baio, Enrico Nunziata, Cristina Nocetti and Federico Klappenbach for contributing to the examples and figures presented in this article and for the constructive technical discussions during project implementation.

REFERENCES

1. Di Virgilio, V., Bouchard Saindon, A., & Becerra Posada, F. C. G. (2023). Sustainable procurement of medical devices in an international context : Part 1 - background and definitions. Global Clinical Engineering Journal, 5(3), 29–39. https://doi.org/10.31354/globalce.v5i3.159
2. WHO. Sustainable Procurement. WHO; April 2022. Available at: https://apps.who.int/gb/MSPI/pdf_files/2022/04/Item5_11-04.pdf.
3. UNICEF. UNICEF Implements Sustainable Procurement. UNICEF Supply Division; September 2018. Available at: https://www.unicef.org/supply/sites/unicef.org.supply/files/2019-06/sustainable-procurement-information-note.pdf.
4. UNDP. Practitioner's Guide to Sustainable Procurement. Available at: https://popp.undp.org/UNDP_POPP_DOCUMENT_LIBRARY/Public/PSU_Procurement%20Overview_Sustainable%20Procurement.docx#:~:text=Several%20of%20factors%20influence%20sustainable,line%20with%20good%20financial%20management.
5. United Nations Office for Project Services Procurement Group. Sustainable Procurement Framework - Annex 1 to the Procurement Manual. UNOPS. 2021, July 1. Available at: https://content.unops.org/service-Line-Documents/Procurement/UNOPS-Procurement-Manual-Annex-1-2021_EN.pdf.
6. WHO. Guidelines for Healthcare Equipment Donations. Organization of Health Services Delivery. March 2000. Available at: https://apps.who.int/iris/bitstream/handle/10665/70806/WHO_ARA_97.3_eng.pdf?sequence=1&isAllowed=y.
7. Perry L, Malkin R. Effectiveness of medical equipment donations to improve health systems: How much medical equipment is broken in the developing world? Med Biol Engineer Comput 2011;49(7):719-722. Available at: https://doi.org/10.1007/s11517-011-0786-3.
8. The World Bank. Current Health Expenditure Per Capita. April 7th, 2023. Available at: https://data.worldbank.org/indicator/SH.XPD.CHEX.PC.CD.
9. OECD. Health at a Glance 2017. OECD Indicators. Available at: https://www.oecd-ilibrary.org/docserver/health_glance-2017-5-en.pdf?expires=1695829119&id=id&accname=guest&checksum=EEF8CB0C0EAD898F03D1BB9BD984B28A.
10. Ortiz-Ospina E, Roser M. Healthcare Spending. 2017. Available at: https://ourworldindata.org/financing-healthcare.
11. WHO. World Health Statistics. 2023. Available at: https://www.who.int/data/gho/publications/world-health-statistics.
12. Malkin R. Barriers for medical devices for the developing world. Expert Rev Med Devices. 2007. Available at: https://pubmed.ncbi.nlm.nih.gov/18035940/.
13. PAHO. PAHO and National Regulatory Authorities of Regional Reference Seek To Strengthen Regulation of Medical Products In The Americas. July 11, 2023. Available at: https://www.paho.org/en/news/11-7-2023-paho-and-national-regulatory-authorities-regional-reference-seek-strengthen.
14. WHO. WHO-Listed Authority (WLA). A Framework for Evaluating And Publicly Designating Regulatory Authorities as WHO Listed Authorities (WLA). Available at: https://www.who.int/initiatives/who-listed-authority-reg-authorities.
15. WHO. WHO Global Benchmarking Tool (GBT) for Evaluation Of National Regulatory Systems. Available at: https://www.who.int/tools/global-benchmarking-tools.

16. WHO. Procurement Process Resource Guide WHO Medical device technical series Available at: https://www.who.int/publications/i/item/9789241501378.

17. UNDP. Procurement for Sustainable Development Strategy 2022-2025. Available at: https://www.undp.org/procurement/strategy#:~:text=UNDP%20Procurement%20for%20Sustainable%20Development,one%20behind%2C%20and%20building%20resilience.

18. UNICEF. Sustainable Procurement Information Note. Available at: https://www.unicef.org/supply/reports/sustainable-procurement-information-note.

19. United Nations Office for Project Services Procurement Group. Sustainable Procurement Framework - Annex 1 to the Procurement Manual. UNOPS. 2021, July 1. Available at: https://content.unops.org/service-Line-Documents/Procurement/UNOPS-Procurement-Manual-Annex-1-2021_EN.pdf.

20. Dyro J, Cheng M. Good Management Practice for Medical Equipment. In: Dyro J. The Clinical Engineering Handbook. Setauket, NY: The Biomedical Engineering Series, Elsevier Academic Press. 31;108-113.

21. Kaufman R, Guerra-López I. Needs Assessment for Organizational Success. Alexandria(VA): ASTD Press; Feb 2013.

22. OECD. Health Policy In Your Country. Available at: https://www.oecd.org/health/health-systems/health-policy-in-your-country.htm

23. V. Di Virgilio, G. Ambroise; "Clinical engineering development in the Uruguayan public health system"; Proc. IEEE Engineering in Medicine and Biology Society, Buenos Aires, Argentina 31/08-4/09 2010.

Received July 24, 2023, accepted October 13 2023, date of publication December 5, 2023

Application of statistical processes control for the performance improvement of a clinical engineering department

By Edgar González Campos[1], Andrea Elizabeth Vázquez Rodriguez[2], Fátima Jaqueline Rodríguez Trujillo[2], Catherine Jazmín Ramírez Mendiola[2]

[1] Instituto de Salud Pública del Estado de Guanajuato, Mexico

[2] División de Ciencias e Ingenierías, Universidad de Guanajuato, Mexico

ABSTRACT

This article addresses the fundamental role of Statistical Process Control (SPC) as a quality tool in the field of clinical engineering, to improve and optimize internal processes. This study describes the methodology used to apply the SPC in a reference hospital's clinical engineering department. Data was collected over an extensive period, involving multiple medical equipment and verification procedures. These data were analyzed using various statistical tools, such as control charts, Pareto charts, and descriptive statistics.

The results showed stability in the department's processes, which made it possible to identify areas for potential improvement. Statistical analyses revealed behavior patterns and trends that were not previously apparent. Based on these conclusions, specific modifications were proposed in the department's processes to optimize efficiency, reduce costs, and improve service quality.

The implementation of these modifications based on evidence suggests that they would positively impact the general performance of the clinical engineering department if applied. Key indicators could improve significantly, reflecting increased medical equipment reliability and availability, decreased unscheduled downtime, and increased satisfaction for department staff and equipment users.

In summary, this study highlights the importance of using SPC as a powerful improvement tool in clinical engineering. By adopting an approach based on data and scientific evidence, clinical engineering departments can achieve more efficient and effective management of their processes, contributing to higher-quality medical care and patient safety.

Keywords – *Control chart, Equipment maintenance, SPC.*

INTRODUCTION

The performance and efficiency of clinical engineering departments can be influenced by various factors involving human, material, and financial resources. In the same way, the intellectual capital of "know how" to carry out critical activities i.e., to have a sound and effective standardized methodology to realize procedures within the department's operation, serves as an asset of great value in organizations.

Within these activities, equipment maintenance and continuous verification to ensure its correct operation emerge as critical activities. Although a series of classic activities are carried out in most clinical engineering departments, each department establishes its processes based on its conditions and scope. The standardization of methodologies that ensure the quality of the processes takes on significance in the impact these activities can have on the general operation of the department.[1,2]

The measurement of data on these processes and their statistical use represents a tool of great value in the search for improvement in their performance.[3] Statistical process control (SPC) represents a series of tools among which control charts stand out. This has traditionally been used within different industries to improve processes based on evidence generated by their own data.[4]

Within the healthcare field, it has been considered a tool for research and improvement issues,[5] as a tool for improving the culture of data measurement,[6] and even for improvements in clinical issues.[7–9]

There are many statistical tools with endless applications within the field of biomedical/clinical engineering to be used in the search for improvement of the efficacy, effectiveness, and efficiency of its activities.[10]

In the same way, there are studies in which tools used within the statistical control of processes, such as the Pareto diagram, are deployed to improve the activities of a clinical engineering department, as Cecchini, Masselli, et al. described.[11] Or the evidence-based maintenance method proposed by Wang[12] in which using data generated by a medical equipment maintenance program could modify the entire program itself. However, the use of control charts as a complement to traditional statistical techniques and those associated with quality improvement may represent a valuable option in the search for effective evidence-based improvements.

This article aims to exemplify what was previously explained through the use of SPC tools for formulating improvement strategies in standardized processes of a clinical engineering department.

METHODS

The methodology followed can be divided into the five main phases shown in Figure 1. Only procedures related to routine verification of medical equipment in different hospital areas were considered.

To find opportunity areas through SPC, it is necessary to comply with specific characteristics to be evaluated in the processes. The first two activities were focused on this: the definition of criteria, evaluation of these criteria and selection of procedures to be analysed. The next two phases correspond to the deployment of the statistical analysis, first through data capture, followed by the development of control charts. Finally, based on the results obtained, improvement proposals were made to the department's management to be evaluated and, where appropriate, implemented.

Each phase is explained in more detail below.

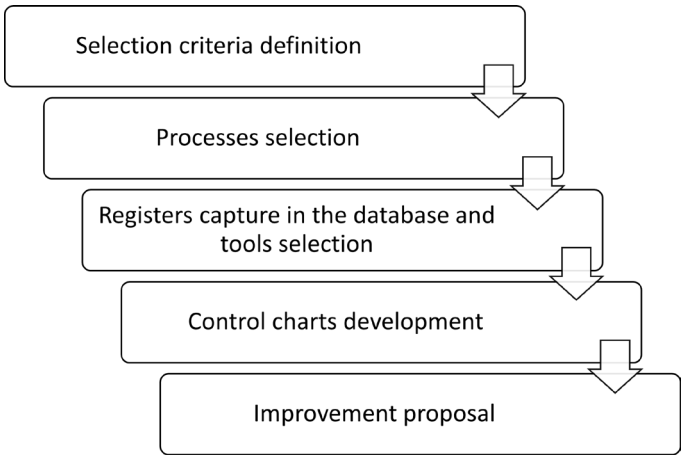

FIGURE 1. Followed methodology.

Selection criteria definition

Definition of selection criteria for the opportunity areas search was carried out considering the following factors:

- Standardized processes: The selected processes must be well standardized so that the data collection when performing them is carried out in a homogeneous way regardless of the personnel that carries it out, in addition to having written tools for capturing data generated during the routine.
- More than nine months of registers: Generated data by the processes in the lapse of the last nine months of operation were only considered to have an extended operation period, so the data reflects the closest possible reality of the department.
- Percentage compliance greater than 90% on the scheduled verification routines. The continuity and quantity of data in the measurements represent important factors in carrying out the statistical analysis of the processes since the consistency of the process with the generated data can be detected.

Processes selection based on the criteria of compliance

Once the selection criteria were defined, it determined which was compliant. Table 1 shows eight standardized procedures for carrying out verification routines in the department that met the first two selection criteria.

The routines for the vacuum and medical air systems imply verifying the work pressures for both hospital equipment. The operation theatres, intensive care units and emergency department routines demand the verification of technical aspects of the medical equipment installed in those areas, such as correct functioning, autotest, etc. This equipment ranges from vital signs monitors to stretchers.

Finally, the verification routine of the defibrillators involves physical and functional verification of all the defibrillators installed within the hospital through autotest and discharge proof.

After identifying the standardized processes, it verified the percentual compliance with carried-out routines. Figure 2 shows the results for this verification, obtaining compliance with the criteria in four of the eight processes; these correspond to:

- Emergency departments
- Defibrillators
- Medical air
- Vacuum systems

TABLE 1. Verification Routines Processes of the Clinical Engineering Department.

Verification routine	Registered time (months)	Number of routines per week	Expected done routines	Done routines
Vacuum system	9	2	78	72
Medical air system	9	2	78	72
Operation Theatre 1	9	4	156	119
Operation Theatre 2	9	4	156	119
Intensive care unit 1	9	1	39	26
Intensive care unit 2	9	1	39	23
Defibrillators	9	1	39	39
Emergency Department	9	1	39	41

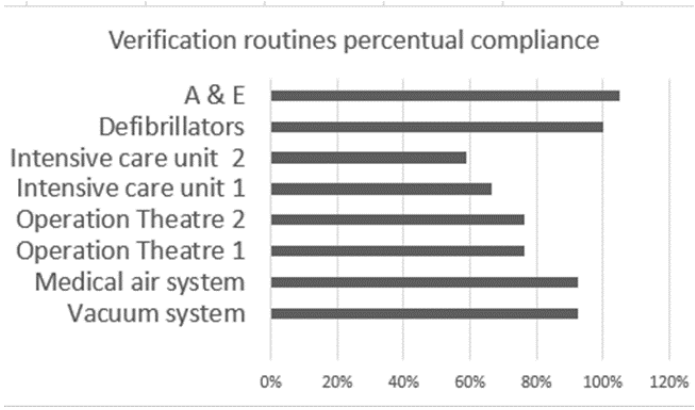

FIGURE 2. Percentual compliance of done routines.

These were the procedures on which the statistical study was studied further using SPC tools.

Record capture in the database and selection of tools

The next phase of the methodology implied the capture of the registered data in department formats in the form of verification sheets in a digital database within statistical software. In this stage, the types of control charts to be

used were selected based on the information generated by the verification routine.

Individual values and Moving range, or I-MR charts, were selected for medical air and vacuum system verification. This is due to the measured variable in each verification routine corresponding to an individual value, not a subgroup. In this way, the behaviour of the systems can be explored based on measurements made periodically to the pressure variable generated by the system itself. The moving range chart indicates the variability between each measurement caused by comparing it with the immediate previous measurement; this information makes it possible to verify the process stability statistically.

Nonconforming units, also known as NP charts, were selected regarding the verification routines of medical equipment in the emergency department and for the installed defibrillators. This chart evaluates the nonconforming portion of several measurements made. This chart was selected because there are a certain number of variables to be verified in each routine, which may be compliance or non-compliance. This number is constant in each routine. Each test variable was categorized depending on its result: "compliant" in case it was performed without problems or "non-compliant" in case it presented any detail.

Control charts development

The next phase consists of developing the control charts and the statistical analysis of the obtained results. Only I-MR charts were generated for the verification routines of the medical air and vacuum system; this is due to the results obtained that denote procedures in statistical control and it was not necessary to explore further.

Regarding the defibrillator verification routine, derived from the results obtained, the decision was made to go deeper through a Pareto diagram to make an improvement proposal that could impact the department's work.

Finally, in the case of the emergency area and derived from the results obtained, it was not necessary to carry out a significant analysis to make proposals.

Improvement proposals

After the analysis of the obtained results, proposals for improvements in the processes of the clinical engineering department were formulated. All based on evidence from the same information that this department generated.

RESULTS

Figure 3 shows the NP chart obtained for the emergency department's equipment verification routine. It can be seen that the upper control limit is located at a value of 1.008, which indicates a maximum of one non-conformity found per verification routine carried out in the period analysed. The nonconforming portion is located at the value of 0.093, which corresponds to a value of less than one non-conformity per verification routine performed. Lastly, the lower control limit is located at zero and corresponds to zero nonconformities found by the verification routine as the minimum value in the evaluated period. Within the presented values in the measurement period, only two values can be found in the upper control limit and one outside said limits. The value outside the control limits indicates two nonconformities in a verification routine. This value is considered atypical due to the stable trend of the evaluated process.

The emergency department dynamics implies an active role on the part of the equipment user in terms of continuous verifications; this is due to the high patient turnover in the service. This is reflected in the data in the control chart, and it is difficult to find technical failures related to the equipment.

Regarding the verification routines for hospital defibrillators, Figure 4 shows the obtained results. It has a value of 3.45 for the upper control limit, zero for the lower control limit, and 0.79 for the fraction nonconforming. The chart interpretation indicates that, on average, there can be a maximum of between 3 and 4 technical failures per verification routine for the 15 equipment distributed throughout the hospital, approximately one failure per routine performed, and a minimum of zero failures found. Two atypical values outside the control limits are identified, carrying out a study regarding the type of failures that led to these values; a special situation was detected where the supply of printing paper for the equipment presented a delay in delivery by the supplier. Derived from these results, it was decided to carry out a

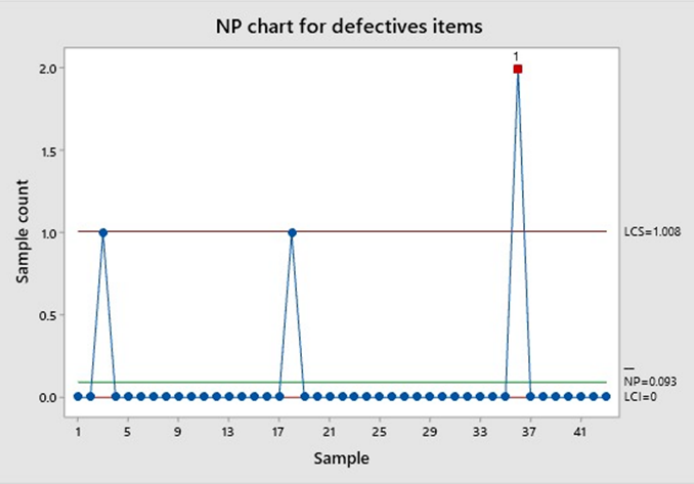

FIGURE 3. NP control chart for the emergency department.

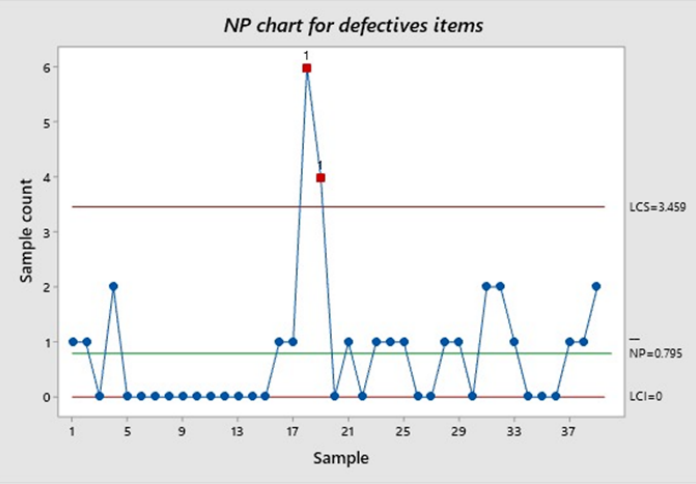

FIGURE 4. NP chart for the defibrillator verification routines.

deeper analysis that could offer a broader perspective of the behaviour of this process.

Figure 5 shows a Pareto diagram that identifies the equipment with the highest number of nonconformities in the measured period. It can be seen that 80% of the failures come from five specific defibrillators of the fifteen installed. These are installed in the areas of Nursery, Operating Theatre 1, Radiological Imaging, Emergency Department and Operating Theatre 2.

Finally, for the case of verification routines of the gas system, Figure 6 and Figure 7 show the I and MR control charts, respectively, for the case of the vacuum system.

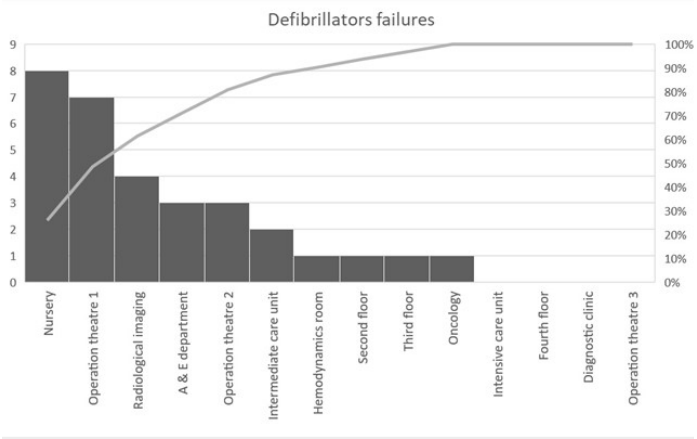

FIGURE 5. Pareto chart for defibrillator failures.

Chart I shows an upper control limit of -13.480 inHg, a lower control limit of -21.75 inHg, and an average value of -17.63 inHg. It is observed that there are no values outside the control limits; for its part, the system was programmed to operate at a value of -18 inHg, so this behavior presents reasonable statistical control.

On the other hand, the chart of moving ranges in Figure. 7 also denotes an excellent statistical control of the process with only one atypical data outside the control

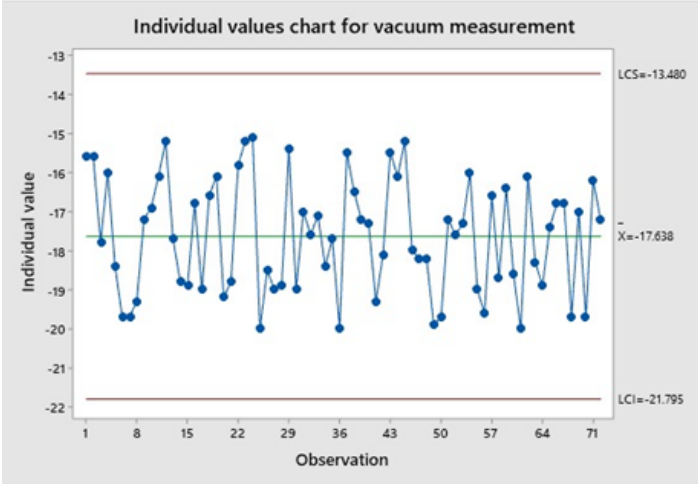

FIGURE 6. I chart for the vacuum system verification routines.

limits. Regarding this atypical value, a significant variation in the hospitalized patient number between one measurement and another was detected as a possible attributable cause. This issue caused variability in the

range of data. However, outside of said identified cause, the data presents consistency in the statistical control denoted in the chart of Figure 6.

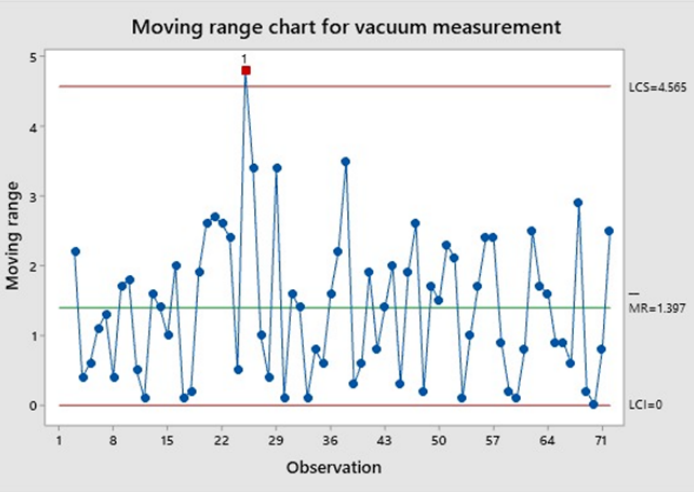

FIGURE 7. MR chart for the vacuum system verification routines.

DISCUSSION

The data obtained for the selected processes denote their stability over time. This means the data tends to behave similarly except for specific and atypical situations. However, it would be essential to conduct more extensive analysis in time. It is suggested to analyse the time of at least one year of data collection to rule out that the behaviour may be affected by temporary issues.

In the case of the verifications of the equipment in the emergency department and the gas systems, it was recommended to the clinical engineering department to extend the time between verifications so that they could focus their work on other activities that require higher priority. The stability represented in the control charts gives the certainty that no values will require monitoring as closely as it was carried out; therefore, it is possible to carry out fewer verifications with the certainty that the processes work correctly. If problems arise from implementing this strategy, it would be convenient to return to close monitoring.

Regarding the results obtained from the verification process of the hospital defibrillators, a proposal was made to the clinical engineering department to reinforce the monitoring of the equipment that represents the largest number of failures to control the nonconformities that the equipment could present. When dealing with life support equipment, a failure at the time of the operation could have serious consequences.

Once the failures have been solved or the processes regarding the nonconformities presented have been controlled, it could be considered to return to the weekly verifications or extend the time between them.

CONCLUSIONS

The results show good general statistical control for the selected processes. Based on these data, it can be assumed that the proposed strategies respond to real situations that occur in hospital operations.

However, it is important to highlight that the process selection was done to comply with the necessary characteristics mentioned for the data. The standardized collection of data and sufficient data over time encourage the behaviour description of the process to be as similar to reality as possible. In this context, it is possible to make effective suggestions for improvement strategies based on evidence, in the opposite case for the other processes whose data was insufficient to develop the tools satisfactorily.

Accomplishing all the data characteristics, statistical process control arises as an effective strategy for evidence-based efficiency improvement in the clinical engineering department.

The proposals to the clinical engineering department aim to guide its operation toward the needs detected through the statistical analysis of its generated data. If they were developed with insufficient or incorrect information, it is possible that the improvement strategies had been guided towards incorrect guidelines and were not effective.

Similarly, modifications could be considered to be done to all the department's verification processes so that while the verification times are prolonged in some of them, in others, they become more constant, focusing on priority points and detection based on evidence. However, it would be necessary first to achieve the correct standardization

of each process and capture sufficient data over time to deploy the same strategy.

Finally, it could be considered to go even deeper into the analysis of the statistics generated through individual studies of the non-conformities found. Through a categorization by type of non-conformity, improvement strategies regarding verification routines could be directed toward more specific issues.

ACKNOWLEDGMENTS

The research team acknowledges biomedical engineer César González for giving access to the clinical engineering department data to elaborate on this work.

REFERENCES

1. Correa M, Villalba MP, García JH. Protocolos para evaluación de desempeño en equipos médicos. Revista Ingeniería Biomédica [Internet]. 2017; 11(22):65-71.
2. Li J, Mao Y, Zhang J. Maintenance and Quality Control of Medical Equipment Based on Information Fusion Technology. Computational Intelligence and Neuroscience [Internet]. 2022.
3. Sherwood MK. Quality Assurance in Biomedical or Clinical Engineering. Journal of Clinical Engineering [Internet]. 1991;16(6):479-83.
4. Ropella KM. Introduction to Statistics for Biomedical Engineers. Synthesis Lectures on Biomedical Engineering. Cham: Springer International Publishing; 2007.
5. Benneyan JC. Statistical process control as a tool for research and healthcare improvement. Quality and Safety in Health Care [Internet]. 2003; 12(6):458–64. Available from: https://qualitysafety.bmj.com/content/12/6/458
6. Bareño J. GUÍA PEDAGÓGICA CONTROL ESTADÍSTICO DE PROCESOS COMO GENERADOR DE UNA CULTURA DE LA MEDICIÓN EN LAS ORGANIZACIONES DE SALUD (IPS) [Internet]. 27-87
7. Govindarajan R, Llueguera E, Melero A, Molero J, Soler N, Rueda C, et al. El control estadístico de proceso puede ayudar a prevenir los errores de tratamiento sin aumentar los costes en radioterapia. Revista de Calidad Asistencial [Internet]. 2010; 25(5):281–90.
8. van de Glind EMM, Willems HC, Eslami S, Abu-Hanna A, Lems WF, Hooft L, et al. Estimating the Time to Benefit for Preventive Drugs with the Statistical Process Control Method: An Example with Alendronate. Drugs & Aging. 2016; 33(5):347–53.
9. Baker AW, Haridy S, Salem J, Ilieş I, Ergai AO, Samareh A, et al. Performance of statistical process control methods for regional surgical site infection surveillance: a 10-year multicentre pilot study. BMJ Quality & Safety. 2017; 27(8):600–10.
10. Ropella KM. Introduction to Statistics for Biomedical Engineers. Synthesis Lectures on Biomedical Engineering. Cham: Springer International Publishing; 2007.
11. Cecchini A, Masselli GMP, Silvestri S. Evaluation and optimization of CES performances: application of Pareto principle to KPIs. Glob Clin Eng J [Internet]. 2021;4(1):14–21. Available en: http://dx.doi.org/10.31354/globalce.v4i1.87
12. Wang B. Evidence-Based Maintenance of Medical Equipment: An Outcomes-Based Method of Keeping Medical Equipment Safe and Reliable,1st edition. USA: Independently Published. 2019.

Received August 16, 2023, accepted November 18 2023, date of publication December 6, 2023

Clinical Engineering and health policies in Venezuela: challenges and achievements in a changing political context

By Rodrigo Mijares

Simón Bolívar University, Research and Development Foundation, Health Technology Management Unit (UGTS-USB), Caracas, Venezuela

ABSTRACT

This article summarizes the evolution of clinical engineering in Venezuela and its interaction with the political environment and health policies.

Method: The study consists of a comprehensive review of publications from the Health Technologies Management Unit of Simón Bolívar University throughout 1992-2023, organized into three thematic areas: Technological and Environmental; Relationship with Public Health Policies; and Influence of the Political System.

Conclusions: The early history of clinical engineering in Venezuela stands out for its impact on training and technological management to ensure quality and efficiency in the Venezuelan healthcare system. In the first area, it demonstrated the potential for improvement in medical technologies, generating high expectations. The second area focuses on the relationship between technologies and health policies, emphasizing the need to align public policies and technological management. However, challenges identified include the lack of evaluation and selection of appropriate medical technologies and political influence in acquisitions. The third area addresses political influence on the quality of medical care, emphasizing the importance of considering political and technological aspects in decision-making.

Keywords – *Clinical engineering, health technology, public policies, political systems.*

INTRODUCTION

Venezuela's humanitarian crisis, the resurgence of vector-borne diseases, and the implications of contagion in the region are well known [1]. What is little known is the struggle of the Health Management Unit to improve medical technologies. Health Technologies are attached to the Research and Development Foundation of the Simón Bolívar University (UGTS-USB).

For the last 30 years, UGTS-USB has conducted clinical engineering research. In this article, we will share how these investigations have been enriched thanks to the interaction with other areas of knowledge in a context marked by the political situation in Venezuela, like many Latin American countries. However, we want to point out that this experience is in Venezuela. The desire is to make known a little-known reality.

Our contribution in this field is especially relevant due to the challenges we have faced when researching in a country that has gone from a fragile democracy (1992-1999), authoritarianism (1999-2018), and finally, a dictatorship (2019 to the present). Initially, our focus focused exclusively on technology and the environment, aiming to develop technical capabilities and solve problems around clinical engineering. However, we soon realized that it was crucial to understand and consider the country's political system to have any impact on society.

Therefore, we broadened our perspective and understood that technologies originate through public health policy. In this way, our research took a new direction, incorporating health policy study, evaluation, and analysis.

This more holistic understanding allowed us to generate greater value in our research and, most importantly, better understand the results obtained for the national and international organizations requesting our work. By considering the country's political context, we were able to interpret the results of our contributions more accurately and how these may or may not be accepted to contribute to improving the health system in a challenging environment, as is often the case in countries of Latin America.

METHODOLOGY

The study consists of an exhaustive review of UGTS-USB publications covering the period 1992-2023, categorizing them into three thematic areas:

a) Technological and Environmental Approach:

We focus on advancing technical capabilities in the field of clinical engineering. We explore how these capabilities have delivered tangible results, particularly in a democratic context.

b) Intersection of Technologies and Public Health Policies:

This area delves into the integration of health technologies into public policies. Examines how this integration can influence the application and utilization of technologies, especially in a politically authoritarian system.

c) Influence of the Political System:

The third area focuses on analyzing how the political system, particularly a dictatorship, impacts the performance of public policies.

Since the article is a narrative, Table Number 1 is presented to analyze the essential elements that characterize it.

TABLE 1. Fundamental Elements of the Article Narrative.

Characters	
Protagonist	The Health Technologies Management Unit (UGTS-USB), affiliated with the Research and Development Foundation of Simón Bolívar University, is the central figure in this narrative.
Antagonists	During the research period, governments emerged as the primary antagonists. In secondary roles, national institutions, private companies, organized social entities, and non-governmental and international organizations that commissioned the research also feature, each playing a role that adds complexity to the narrative.
Setting	
Place	Venezuela, located in South America.

Historical period	1992-2023
Political conditions	Fragile democracy (1992-1999), authoritarianism (1999-2018) and finally a dictatorship (2019 to present).
Social conditions of the protagonists	The decrease in university salaries in the last 22 years in Venezuela reaches historic levels. At the end of 2001, a full-time professor had a salary equivalent to about $2,440. For January 2023, the salary of a top-level and dedicated teacher is $26.14, calculated at the official rate of the Central Bank of Venezuela (BCV).
Mood	
During the democratic period, hope, optimism, and confidence defined our days, even facing challenges. The transition to authoritarianism plunged us into a sense of "amazement" as we witnessed foreign professionals taking precedence over Venezuelans. In the dictatorship phase, tension gripped us. Regime sympathizers closely monitored the execution of projects with international organizations within hospitals. Aware that we could face disappearances or imprisonment upon completing our tasks, we lived under constant pressure. However, we keep the hope alive for a return to democracy in Venezuela and eagerly anticipate contributing to improving our healthcare system.	
Theme	
This article summarizes the evolution of clinical engineering in Venezuela and its interaction with the political environment and health policies.	
Point of view	
We opt for the first person, identifying ourselves with the acronym UGTS-USB. This approach immerses us in an intimate perspective, allowing us to explore the thoughts and emotions of the Management Unit throughout its research journey.	
Conflicts	
Inside the UGTS-USB	During the democratic era, internal harmony prevailed as we all belonged to the engineering field. However, resistance surfaced within the group with the onset of authoritarianism and the incorporation of areas related to public policies and knowledge of political systems. This juncture evolved into a phase of discussion and analysis, highlighting the imperative to address conflicts and integrate specialists in those areas.
External	In the democratic period, access to information was relatively straightforward. Yet, during authoritarianism, although we could gain entry to health institutions, formal requests for information often went unanswered. The challenge escalated during the dictatorship when we lacked access to public institutions and information. When access was finally secured during the dictatorship, it came through international organizations, with the commitment to maintaining information confidentiality—no direct or indirect disclosure to third parties without the prior written consent of the Contracting Party. The possession of sensitive information directly impacting the health of Venezuelans, coupled with the inability to disclose it, poses an ethical and moral conflict. Nevertheless, we maintain hope that these highly esteemed organizations will carry out effective work.
Style	
We adopt a realistic approach reflected in the faithful and detailed representation of reality over time, as depicted in our published research. Our narrative authentically portrays everyday life and organizational dynamics. Before publication, many of our investigations underwent public discussions, hoping they would be subject to contradictions and debates, fostering a broadening of perspectives. However, our resource constraints and the necessity to meet established deadlines added an additional challenge to this process.	

Source: table prepared by the researcher. Information on social conditions can be detailed in: Human Rights Observatory (2023), on its website.

HISTORICAL BACKGROUND

The early history of clinical engineering in Venezuela is characterized by three fundamental milestones that have shaped its evolution. In the 1970s, a technical health training program known as "Hipólito Unanue" was established, which impacted not only Venezuela but throughout Latin America, laying the foundations for the training of personnel in the management of technologies. In 1993, a survey conducted among engineers from the Foundation for the Maintenance of Medical Assistance Infrastructure

(FIMA) revealed the pressing need for training in medical devices, underscoring the importance of continuous training in this constantly evolving field.[2]

However, the highlight was the introduction of clinical engineering in Venezuela in 1992 under the visionary guidance of Professor Luis Lara Estrella. His focus on technological management as an integral part of health care led to the creation of the Health Technology Management Unit (UGTS), which became a fundamental pillar in optimizing technological aspects in health institutions. His definition of clinical engineering as integrating various engineering and management processes, seeking efficient and effective technological management with high availability and satisfaction, reflected the holistic vision necessary to ensure quality and efficiency in medical care.[3]

These historical milestones marked the beginning of clinical engineering in Venezuela and underlined the crucial relevance of technical training in health. The combination of technical training and sound technological management became the cornerstone to ensure the quality, availability, and efficiency of medical infrastructure and devices used in the country's health system.

RESULTS

a) The first area was technological and environmental.

In the first area, which spanned since 1996, the Venezuelan health system observed a push toward technological and environmental modernization. A notable milestone was the transformation of the JM de Los Ríos Children's Hospital into an autonomous service as part of the decentralization of the health system. The newly assumed administration decided to work with the UGTS-USB to improve the hospital's technological capacity, which resulted in a significant increase in the hospital's operational level, rising from 26% to 64% in just one year.[4] The operational level refers to recovering installed technologies, which require corrective maintenance.

The fundamental points that generated this positive and encouraging result have to do with a) financing; b) political decentralization; c) transparency, by having scrutiny by the press or any interested organization; and d) the link between the hospital authorities (public world), the university (knowledge), and the private world.

On the other hand, the European Community generously offered financing to continue the modernization process. However, the political dynamics changed under the new administration led by Mr. Hugo Chávez. The proposal to involve the Cuban government in the project caused disagreements and tensions, ultimately preventing this opportunity from materializing. This disruption negatively impacted the hospital's ability to provide quality care to patients by limiting their access to technology and resources that would have significantly improved medical services.

To understand the decision of President Hugo Chávez, to create a new healthcare model in Venezuela, directed and inspired by Cuba; An investigation was carried out with another group of colleagues from the USB. One of the most important conclusions was that the quantitative data found did not allow for measuring the impact of the Cuban mission, expressed in the population's improvements in health conditions and the prevention of diseases.[5]

In 2001, an evaluation of the Ministry of Health's main hospitals revealed a common deficiency in their technological management, highlighting recurring problems in key areas such as the electrical system, elevators, and air conditioning systems. This lack of adequate technology management posed significant challenges to providing an optimal healthcare environment.[6]

In 2019, evaluations were carried out in two hospitals in Caracas by the UGTS-USB, under the observation of international organizations. Although the results were not published due to confidentiality requests, it can be noted that the hospital infrastructure experienced a deterioration concerning the evaluation narrated in the previous paragraph. This decline was exacerbated by a drinking water shortage and environmental sanitation deficiencies resulting from inadequate cleaning practices. Additionally, a worrying 23% rate of healthcare-associated infections was recorded. The work was presented to the country's health authorities and international organizations.

In 2001, the Essential Public Health Functions (FESP) of the Ministry of Health of Venezuela were evaluated. "Guarantee and improvement of the quality of individual and collective health services" obtained the lowest score.[7] These results highlighted the importance of addressing technology management in health policy planning. These results prioritized our future work.

The UGTS-USB prioritized the creation of a protocol for the evaluation of medical devices, which, after its development, obtained approval from the Ministry of Health as official policy. However, despite these established regulations, devices purchased by public entities do not undergo evaluations before use, raising concerns about the effective implementation of such a policy.[8] Likewise, it should be noted that the medical devices used and acquired by Cuba were not subjected to evaluation either.

The UGTS-USB included the incorporation of the environmental aspect in the studies. The disposal of hospital waste and mercury by dental personnel were evaluated. The findings pointed out deficiencies in waste management and potential health risks in the hospital environment, underlining the importance of addressing environmental aspects in the management of technologies.[9-10]

In 2013, a study carried out in collaboration with an oil company exposed the relationship between technological management and health infrastructure by identifying damage to medical equipment due to fluctuations in the electrical supply. This example highlighted the systemic challenges in technology management and its impact on public service delivery.[11]

Finally, with the emergence of the COVID-19 pandemic in 2020, the capacity for collaboration between health organizations (private clinics), private companies, and universities in creating essential medical devices was demonstrated. The response to the crisis led to the development of mechanical ventilators and protective equipment prototypes, evidencing the importance of clinical engineering in critical moments of public health. Although the work was presented to the Red Cross and communication was maintained with government entities, the expected viability was not achieved, highlighting possible challenges in promoting and accepting innovations in the health system.[12-13]

These episodes highlight the evolution of clinical engineering in Venezuela over the decades, marked by technological advances, political challenges, and the importance of technical training and effective management to ensure quality and efficiency in medical care.

b) The second phase includes the relationship between technologies and public health policies.

Research and health policies adopted by developed nations significantly influence public health strategies in developing nations. Typically, this process involves adaptation, collaboration, and consideration of local needs. Effective public policies in health must be based on scientific evidence, local context, and international collaboration.

Our first work on this topic took place in 2003, in collaboration with the Venezuelan Society of Cardiology, when the institutional performance of a Cardiology service was evaluated from 1990 to 2000. This analysis found that the service complied with 73% of the guidelines established by the American College of Cardiology and the American Heart Association (AHA).[14] It should be noted that technological considerations were not addressed in this study.

In 2004, we developed a conceptual and methodological proposal in the context of a medical technology management project sponsored by the Ministry of Health. The main objective was to establish coherence between public health policy and medical technology management.[15]

Subsequently, after a year of studying the health system in France at the University of Nancy, we wrote an article in 2005 to conceive a political-management model, supported by two specific experiences: a) the execution of projects in various health institutions in Venezuela and b) an in-depth analysis of the European health system, particularly the French system.[16]

Our approach is built on a series of crucial steps that allow for a more effective and sustainable intervention: defining objective morbidity and mortality, analyzing the determinants of health, evaluating current public health

policies, delimiting the geographic and local context, and selecting the relevant technologies. Without a doubt, it is imperative to have the participation of all the actors involved to carry out this work.

Delimiting the geographical and local context is essential due to the great differences in Venezuela. Our study considers data from various sources and finds relevant differences between territorial entities when designing national public policies based on evidence.[17]

Throughout our work in public health policies related to the cardiovascular system, we have observed a lack of evaluation and even less in selecting appropriate medical technologies. In this sense, it has been identified that the acquisitions of technologies after 1999 have been carried out through agreements with ideologically related allied nations. In many cases, they are selected by another country without due evaluation of their quality and relevance.

An example of acquisitions from ideologically related countries was observed in the adoption of radiotherapy and nuclear medicine rooms in 19 public centers through a bilateral agreement with Argentina in 2011. This agreement revealed that numerous pieces of equipment lost their five-year maintenance guarantees because they were at customs. In addition, several regulations related to radiotherapy and those of the Health Comptroller's Office were not complied with. Unfortunately, the clause relating to the training of human resources was not adhered to.[18]

In October 2000, the Cuba-Venezuela Comprehensive Cooperation Agreement was established, a strategic mechanism that would impact both countries' health, economy, education, sports, and culture. The relationship between them is determined by two fundamental variables: politics and economics.

In the political sphere, both nations share a socialist ideology. However, economically they seek progress through cooperative advantages, through the exchange of goods and services according to their respective capabilities. Venezuela provides oil, while Cuba provides its human capital.[19]

If we focus on the technological aspect in the health area, although Venezuela has its own human resources, as a financial provider, it could be expected that its personnel would have a dominant position in the relationship. However, it is totally passive. Currently, due to the economic situation that Venezuela is going through, experts warn of a notable technological lag in the field of medical technologies. More than 60% of medical equipment is estimated to be obsolete.[20] No other situation could be expected because, in both authoritarian and dictatorial periods, the positions of the Venezuelan specialists who had decision-making were postulated, not because of their capacity but because of their ideological affinity.

Other specialists think that the Venezuelan government found in Cuba great support to develop its regional political project, involving the military sphere to remain in power, avoid uprisings, and fight against internal opposition and international pressure that advocates for a regime change in Venezuela.[21]

c) The third area will analyze how the political system influences the quality of medical care.

We are fully aware of the importance of considering political and technological aspects when making sound decisions. For a broader understanding, it is enriching to examine the work of Togerson.[22]

An illustrative example is evident in evaluating the quality of cardiology services in a hospital during the study period (1990-2009). In the first stage (1990-1999), a decline in the quality of care is observed, decreasing from 73% to 58% in the second stage (1999-2009), influenced by two contrasting political systems.[23]

In the second stage, despite implementing improvements in the environmental setting and acquiring medical devices (unfortunately, we lacked information on the entity responsible for these acquisitions and on the evaluation of the quality of these devices, in compliance with Health Oversight), a decrease in the quality of medical care was observed. The increase in coverage by 75%, without conducting fundamental studies to structure the local care offering [16] effectively, resulted in a decline in quality. The results were shared with authorities and patients. In

2014, hospital authorities decided to revert to the same coverage they had in 1999, indicating a lack of preparedness to manage a 75% increase in the population served in the second stage.

Likewise, we conducted a comparative analysis of the management status of the JM de Los Ríos Children's Hospital about its situation two decades ago (1996-2016). In 1996, a significant improvement in operational capacity was evident, increasing from 26% to 64%. However, by 2016, a reduction in operability was observed, falling below 25%. Additionally, unsanitary conditions were identified, such as contamination of freshwater sources.[24] It is worth mentioning that, in 1999, despite the European Community seeking collaboration on the technological improvement project alongside the USB, this initiative did not receive government approval.[4]

These unsanitary conditions, among other pieces of evidence, were used by the non-governmental organization "Prepara Familia" to request the adoption of measures to protect the rights to life and personal integrity of the children hospitalized at the JM de Los Ríos Hospital. Consequently, in February 2018, the Inter-American Commission on Human Rights (IACHR-OAS), in its Resolution 8/2018, issued precautionary measure No. 1039-17, which was expanded in Resolution 43/2019 dated August 21, 2019.[25-26]

In 2018, we shared our first experience with an organized civil society that had the desire to collaborate in improving the healthcare system in their municipality. UGTS-USB gathered information and transformed it into a "Social Agenda" aligned with the Constitution. Subsequently, this agenda was discussed with various regional social and political stakeholders.[27] The regime rejected the support.

Later, with the support of an international agency (which we are prohibited from identifying), we managed to secure adequate funding to improve the living conditions of healthcare professionals in the locality. Subsequently, the Civil Association took the initiative to create its own spaces to provide medical care to the region's citizens.

In 2021, two international organizations hired UGTS-USB to conduct research to assess the situation of hospitals. However, restrictions limiting the disclosure of the resulting information made it impossible to make the obtained results public. We do not want to speculate on the reasons for this limitation. Nevertheless, it is important to note that censorship impacts the discussion of issues concerning the problems in Venezuela in the context of a dictatorial government situation.

Finally, based on our experiences, we propose conducting "Longitudinal Analysis of the Intersection between the Political System, Public Policies and Technological Management in the Context of Health", abbreviated as "policy-tech." However, the challenges we face in this type of research are notable, especially regarding information acquisition.

Describing a political system seems like a relatively accessible task. When it comes to public policy, a review of medical records (when possible) reveals a loss of 47% of such records. However, collecting technological information in a longitudinal analysis is the real challenge. Critical data such as annual inventory, operational status of the equipment, life history of the equipment, operation and maintenance manuals, experience evaluations of technical personnel, selection procedures, and contracting of service companies, among other fundamental aspects, are non-existent. The absence of this data represents a substantial obstacle to achieving a complete and accurate evaluation.

Exploring the works cited in our bibliography provides suggestions for addressing these challenges. For example, in public policy, we seek guidance from statistical experts. Regarding technological management, we condense our strategies into the following activities: identify colleagues or companies with experience in the institution, carry out systematic literature reviews, and establish dialogues with doctors, nurses, and technicians who manage these technologies. Notably, many of these institutions had been previously evaluated by the UGTS-USB, which allowed comparisons to be made that would facilitate decision-making.

CONCLUSION

The health system is suffering degradation as a dictatorship consolidates, resulting in a currently complex humanitarian crisis. While the general situation is widely recognized, the clinical engineering narrative is poorly understood.

Clinical engineering in Venezuela is characterized by three fundamental milestones: the establishment of the "Hipólito Unanue" technical health training program in the 1970s, laying the foundation for medical technology training throughout Latin America; the introduction of clinical engineering in 1992 under the visionary direction of Professor Luis Lara Estrella, focused on comprehensive technological management in health; and the evolution towards technological and environmental modernization of Venezuelan hospitals, although hindered by political challenges and inadequate management.

In the first realm, clinical engineering in Venezuela experienced notable technological advancements, political challenges, and the constant need to adapt to ensure quality healthcare. Collaboration between the public and private sectors and efficient management emerge as crucial elements to overcome these challenges.

The second domain underscores the importance of coherence between health policies and technological management, the necessity of considering the local context in policy formulation, and the challenges associated with technology acquisitions lacking proper evaluations. Additionally, the strategic relationship with Cuba has significantly influenced the landscape of clinical engineering in Venezuela.

The third domain highlights how political changes can directly impact healthcare quality. Instances such as the decline in the quality of cardiology services, the management of JM de Los Ríos Children's Hospital, and collaboration with civil society emphasize the complexity and challenges associated with the interaction between the political system and public health. The presence of censorship in a dictatorial context underscores the limitations in discussing and evaluating the healthcare situation in Venezuela.

Finally, the narrative underscores the imperative of overcoming challenges in the "policy-tech" research. However, the lack of essential data poses a substantial obstacle. Nevertheless, it is recommended that these challenges be addressed by exploring cited works in the bibliography. In the realm of public policies, seeking the expertise of statistical experts is suggested to overcome the loss of records. For technological management, concrete strategies are proposed, including locating colleagues or companies with experience in the healthcare institution, conducting systematic literature reviews, and engaging in direct dialogues with healthcare professionals.

The mention of previous evaluations by UGTS-USB provides valuable insights to facilitate future decisions. A proactive and collaborative approach is emphasized to tackle the inherent challenges in the proposed research.

REFERENCES

1. Grillet ME, Hernández-Villena JV, Llewellyn MS, Paniz-Mondolfi AE, Tami A, Vincenti-Gonzalez MF, Marquez M, Mogollon-Mendoza AC, Hernandez-Pereira CE, Plaza-Morr JD, Blohm G, Grijalva MJ, Costales JA, Ferguson HM, Schwabl P, Hernandez-Castro LE, Lamberton PHL, Streicker DG, Haydon DT, Miles MA, Acosta-Serrano A, Acquattela H, Basañez MG, Benaim G, Colmenares LA, Conn JE, Espinoza R, Freilij H, Grat-erol-Gil MC, Hotez PJ, Kato H, Lednicky JA, Martinez CE, Mas-Coma S, Morris JG Jr, Navarro JC, Ramirez JL, Rodriguez M, Urbina JA, Villegas L, Segovia MJ, Carrasco HJ, Crainey JL, Luz SLB, Moreno JD, Noya Gonzalez OO, Ramírez JD, Alarcón-de Noya B. Venezuela's humanitarian crisis, resurgence of vector-borne diseases, and implications for spillover in the region. Lancet Infect Dis. 2019 May;19(5):e149-e161. doi: 10.1016/S1473-3099(18)30757-6. Epub 2019 February 21. Erratum in: Lancet Infect Dis. 2019 Feb 27;: PMID: 30799251.
2. Mijares R. 1993. Fortalezas y debilidades de la Fundación para el Mantenimiento de Infraestructura Médico Asistencial (FIMA). I Congreso Nacional de Bioingeniería en Venezuela. Realizado en la Universidad Simón Bolívar, Caracas Venezuela.
3. Lara Estrella, Luis. (2013) La gestión tecnológica como parte integrante de la atención en salud

(Profesionalización de la Ingeniería Clínica en Venezuela). Rev. Fac. Ing. UCV [online]. 2013, vol.28, n.4, pp.101-115. http://ve.scielo.org/scielo.php?pid=S0798-40652013000400012&script=sci_abstract

4. Mijares Rodrigo, Lara Luís. Establishment of a Clinical Engineering Department in a Venezuelan National Reference Hospital. Journal of Clinical Engineering. Vol. 22, No. 4, pág: 239-248. Año: July/August 1997. https://pubmed.ncbi.nlm.nih.gov/10169900/
5. Rodríguez Yudey, González Marino, Rincón Elena, Mijares Rodrigo. (2012). Misión Barrio Adentro, Balance y Perspectivas. Revista Mundo Nuevo. Año IV, N.º 10, 2012, pp. 139-181. https://www.researchgate.net/publication/321870300_Mision_Barrio_Adentro_balance_y_perspectivas
6. Mijares R, Lara L, Silva R, Berutti L, Pineda M, Lugo R (2001). La Infraestructura de los Hospitales Venezolanos. Segundo Congreso Latinoamericano de Ingeniería Biomédica. Habana (Cuba). https://www.researchgate.net/publication/237594972_LA_INFRAESTRUCTURA_DE_LOS_HOSPITALES_VENEZOLANOS
7. Mijares R, Lara L, Rincón E (2002). Evaluación del Desempaño de las Funciones Esenciales de Salud Pública: caso Venezuela. I Congreso Venezolano de Bioingeniería. Coro. Venezuela. Igualmente fue publicado en la I Edición del informativo del Consejo Regional de Ingeniería Biomédica para América Latina (CORAL) en la página electrónica http://www.proexcel.fiocruz.br/inalteraveis/Avaliacao%20em%20Saude/2.1.Evaluacion%20desempeno%20MSDSvenezuela.pdf
8. Mijares R, Utrera N, Sierra Z, González M, Lugo R, Rincón M, Mijares R. (2020). Quality Certification of Medical Devices in Venezuela: Process Developed by Simón Bolívar University, Caracas-Venezuela. J Global Clinical Engineering. Vol.2 Issue 3, pp 8-14. https://www.globalce.org/index.php/GlobalCE/article/view/83
9. Mata Ana, Reyes Rosa, y Mijares Rodrigo. Título: Manejo de desechos hospitalarios en un hospital tipo IV de Caracas, Venezuela. Revista: Interciencia, Vol. 29 N0 2, pág. 89 – 93. Febrero 2004. https://www.redalyc.org/pdf/339/33908906.pdf
10. Morales Fuentes Ivelin, Reyes Gil Rosa E, Alvarado José, Domínguez José, Mijares Rodrigo. Diagnóstico de la contaminación por mercurio en el personal de una unidad odontológica de Caracas, Venezuela. Acta Odontológica Venezolana. 2007 Sep; 45(3): 369-374. http://ve.scielo.org/scielo.php?script=sci_arttext&pid=S0001-63652007000300008
11. Mijares R, L Hernández. (2013). "Aproximación a las condiciones de salud de un municipio petrolero de Venezuela" Rev. Salud Pública 15 (5): 743-752. https://www.scielosp.org/pdf/rsap/2013.v15n5/743-752/es
12. Ventilador Mecánico, Prototipo desarrollado en la USB. Página web de FUNINDES USB: https://funindes.com/productos/ventilador-mecanico/
13. Moreno, E. Pedraza, F. Morales, R. Mijares, R. Boccardo and M.A. García. (2020) Redesigning protective gear for health workers during the COVID-19 pandemic: leveling up the "aerosol box". J Global Clinical Engineering Vol.3 Issue 1. file:///C:/Users/Rebeca/Downloads/editor-in-chief,+Redesigning+protective+gear+-for+health+workers+during+the+COVID-19_final%20(1).pdf
14. Mijares Rodrigo. Evaluación del desempeño institucional del Servicio de Cardiología del Hospital Militar "Dr. Carlos Arvelo". Revista: Avances Cardiológicos, Vol. 23 (1), pág. 2 – 12. Año: 2003. https://pesquisa.bvsalud.org/portal/resource/pt/lil-392249
15. Mijares Rodrigo, Lara Luis, Della Valle Patricia, Rincón Elena. Gestión Tecnológica en un Ministerio de Salud: Caso Venezuela. Revista: Sanidad Militar de México. Vol. 58 (6). Pp. 434-442. Nov-Dic: 2004. https://www.imbiomed.com.mx/articulo.php?id=30273
16. Mijares Rodrigo, y Elena Rincón (2005). Establecimiento de un modelo político gerencial en las instituciones de salud de los países en desarrollo: Caso Venezuela. Revista: Médica de la Universidad Pontificia Bolivariana de Colombia (Medicina UPB) 24 (2): 139-158. https://revistas.upb.edu.co/index.php/medicina/article/view/2435
17. Buitriago-Boret S, Marinez-Rivas R, Flores-Diaz J, Mijares R, & Rincón, E. (2023). Using cluster analysis on municipal statistical data to configure public policies about Water, Sanitation and Hygiene in Venezuela. https://arxiv.org/abs/2301.12604

18. Transparencia Venezuela. (2012). Cáncer en los equipos. https://transparenciave.org/project/cancer-en-los-equipos/

19. Tapias L. (2010). Análisis de las relaciones bilaterales entre Cuba y Venezuela en materia política y económica. Período de estudio 2000-2008. Monografía de grado presentada como requisito para optar al título de Internacionalista. Universidad Colegio Mayor de Nuestra Señora del Rosario. https://repository.urosario.edu.co/server/api/core/bitstreams/56195b19-a92c-4d82-b4a3-c7070362681e/content

20. Urbina H. (Octubre 2023). Alertan sobre atraso tecnológico, más del 60% de equipos médicos en el país "estarían obsoletos". Prensa La Caraota Digital. https://www.caraotadigital.net/venezuela/alertan-sobre-atraso-tecnologico-mas-del-60-de-equipos-medicos-en-venezuela-estarian-obsoletos/

21. Ledesma L (2010). Las Relaciones Económico-Comerciales entre Cuba y Venezuela. Trabajo de grado presentada como requisito para optar al título de Internacionalista. Universidad Pontificia de Madrid, España. https://repositorio.comillas.edu/xmlui/bitstream/handle/11531/41122/TFG-%20Munoz%20Ledesma%2C%20Laura.pdf?sequence=1

22. Togerson Douglas. "Between Knowledge and Politics: Three Faces of Policy Anatysis", en Policy Sciences, number 19, 1986, pp. 33-59. https://www.jstor.org/stable/4532067

23. Mijares R, González M, Rincón E y Oropeza A. (enero-junio 2012). Sistema político, políticas públicas, y calidad de la atención médica a las enfermedades cardiovasculares: caso de estudio en Caracas-Venezuela. Revista Gerencia y Políticas de Salud, 11 (22): pp. 107-122. file:///C:/Users/Rebeca/Downloads/adminpujojs,+3306-11914-1-CE%20(7).pdf

24. Mijares R, Utrera N, Castro N, Lugo R, y Méndez (2018). Evaluación Tecnológica del Hospital de Niños José Manuel de Los Ríos. Rev Hisp Cienc Salud, 4(2): 78-83. https://dialnet.unirioja.es/servlet/articulo?codigo=6786507

25. Prepara Familia (2019). El Estado debe garantizar a los niños el derecho a la vida. Boletín Reto País. Disponible en: https://retopaisvenezuela.org/prepara-familia-el-estado-debe-garantizar-a-los-ninos-al-derecho-a-la-vida/

26. Comisión Interamericana de Derechos Humanos. (2019). Resolución 43/19, MC 1039/17 - Niños, niñas y adolescentes pacientes en trece servicios del Hospital José Manuel de los Ríos, Venezuela, Ampliación. Disponible en: http://www.oas.org/es/cidh/decisiones/pdf/2019/43-19MC1039-17-VE-Ampliacion.pdf

27. Mijares, Rodrigo, Utrera, Nestor, Castro, Noel, Lugo, Rubén, Sierra, Zaida, Rincón, Elena, Azpurua, Luís, García, Beatriz, & Mijares, Alfredo. (2018). Agenda Social para mejorar el desempeño de un sistema de salud: caso de estudio. Revista de Salud Pública, 20(4), 430-437. https://www.redalyc.org/articulo.oa?id=42258472005

Received September 15, 2023, accepted November 28 2023, date of publication December 10, 2023

Internet of Things and Digital Twin Technology-Based Management System of Medical Equipment

By Wanrong Liu, Bin Li, Zhiyong Ji

Shanghai Sixth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine, Shanghai 201306, China

ABSTRACT

Background: In recent years medical technology has progressed with the rapid development of medical services and required optimization of medical equipment. However, a lack of effective management methods has led to the inefficient use of medical equipment. Therefore, an effective medical equipment management mode is urgently needed to address these problems and challenges.

Methods: The Internet of Things and digital twin technology are applied to intelligent medical equipment management as the current standard of medical equipment management.

Results: The intelligent perception terminal can realize the dynamic acquisition of real data, such as the location, process, and efficient use of medical equipment, and help carry out digital, networked, and intelligent monitoring and analysis. Meanwhile, applications such as dynamic management software, real-time positioning software, and space-environment quality monitoring software are being developed.

Conclusion: Automatic, intelligent, and visual management of medical equipment configurations, operations, and performance evaluation, combined with good management based on digital twinning, can improve collaborative management efficiency and operation resource support.

Keywords – *Internet of Things, Medical equipment, Digital Twin Technology.*

INTRODUCTION

Throughout the past, the history of human society is a history of struggle between human beings and diseases. From blood-letting therapy in ancient times to modern medicine based on scientific experiments, the health industry has gradually become an incredibly complex system with deep integration of multiple sectors. New technologies such as cloud computing, big data, artificial intelligence, 5G, biotechnology, and detection-based technology continue to develop and mature, and the intelligent modern health industry, based on new technologies, is booming with increasingly high requirements for rational allocation of medical equipment. At a time when the quality of information provided by medical device management is poor and facing many challenges, the Internet of Things (IoT) improves the ability to transfer important healthcare data in the new century. However, most existing hospitals have adopted IoT technology to track patients' health status, and there is a lack of understanding of the use of IoT technology for medical equipment management. Secondly, a hospital's nature determines that medical equipment use may change at any time, so an effective dynamic management mode for medical equipment use is urgently needed.[1]

Medical equipment is the core component of medical resources and is very important to the quality of medical service and the health protection of the people. Intelligent management of medical equipment resources plays a crucial role in the scientific and effective rational allocation of medical equipment resources.[2]

Traditional medical equipment management has the following pain points and difficulties[3]:

1. The rapid development of technology has led to a wide range of equipment, clinical needs, users, supervisors, and management personnel involved in the equipment's use and allocation;
2. The location and ownership of medical equipment are scattered, which leads to inconsistency between the physical object and their recorded use.
3. The overall level of medical equipment asset management in most hospitals is weak due to the monopoly of technical data of imported products, a lack of real-time management information, insufficient allocation of professional personnel, and an emphasis on procurement over maintenance;
4. The long product cycle of medical equipment and heterogeneous and complex types of information systems and data sources make it impossible to develop accurate and dynamic statistical analyses of medical equipment data configuration and use benefit, efficiency, and effect.

Some hospitals have affixed asset bar codes to medical equipment, reducing labor intensity to a certain extent and improving efficiency. However, problems, such as difficulty in accurately positioning equipment, the overallocation of equipment, and untimely deployment, lead to low work efficiency and high error rates. Hospital managers face a difficult problem in breaking through the bottleneck of extensive traditional manual management.

The development of 5G, IoT, mobile Internet, industrial Internet, and other technologies has provided technical support for the refined management of medical equipment and new solutions for intelligent management.[4-7] Medical equipment exists as "things," IoT is a self-information expression and management method based on "things" itself. The earliest idea for the "Digital Twins" is an "Information Mirroring Model," named by Michael Grieves of the University of Michigan, also known as digital mapping. In 2012, the National Aeronautics and Space Administration gave the concept description of digital twinning: Digital twinning refers to integrating multi-disciplinary and multi-scale simulation processes by fully using physical models, sensors, operation history, and other data. As the mirror image of the physical product in the virtual space, it reflects the "whole life cycle process" corresponding to the physical product. In 2021, Pylianidis et al. pointed out that digital twins are being adopted by increasingly more industries, transforming them and bringing new opportunities.[8] To summarize, a digital twin is a dynamic digital clone created for one or more devices or systems.[9] It is possible to use IoT and digital twin technology to help managers manage medical equipment.

This paper discusses a medical equipment management system based on IoT and digital twin technology. The overall technical design architecture includes 5G networking, cloud on medical equipment asset data, and

medical operation support resource coordination management platform based on spatial digital twin. Promote the development of medical equipment management in the direction of intelligence and automation. This management system has been tested in practice during the COVID-19 pandemic, which has infected many people worldwide and overwhelmed healthcare systems. Life support equipment is important as the "main force" of this outbreak. Use the medical equipment management mode based on IoT and digital twin technology to grasp the use of life support equipment in real time, including but not limited to Airvo series respiratory humidifiers, ECG monitors, and other medical equipment. Therefore, the life support equipment of clinical departments is coordinated and deployed, providing a sound decision-making basis for the rational allocation of medical equipment and greatly reducing equipment redundancy.

METHODS

To solve the problem of efficient hospital medical equipment management. We will fully use 5G and IoT, combining mobile Internet, big data, and cloud computing. A smart management platform for medical equipment in the IoT has been built.[10] The overall technical design architecture includes 5G networking, cloud on medical equipment asset data, and a medical operation support resource coordination management platform based on spatial digital twinning, as shown in Figure 1.

First, the equipment state perception terminals and space environment quality perception terminals are used to complete the field big data acquisition. Then, equipment networking can be achieved through Bluetooth, WiFi, cable networks, and other hybrid networking technology. A communication connection is established with the cloud management platform through 5G technology to complete massive data interaction. Different data acquisition models are considered for different types of medical equipment. The data acquisition model completes training and iterative optimization on the platform side and is dynamically delivered to the edge node. The edge node applies the acquisition model to complete data acquisition and upload. After that, it connects the management platform, the device management platform, and the data distribution, storage, and computing platform. It provides users with dynamic management software, real-time positioning software, space environment quality monitoring software, and other applications. Realize the intellectualization of resources, information sharing, and interconnection. Finally, the sharing and collaboration between the mobile and computer ends are realized through the innovative use of digital twin technology in hospital buildings, equipment, other physical and virtual processes, and mechanism modeling. The index system of multiple dimensions is integrated and presented allowing managers to make decisions.

5G Networking Scheme

5G combined network scheme as the primary support for application exploration. Realize the operation data acquisition of hospital equipment assets with ultra-high frequency and large data volume. The algorithm system is trained on this basis. With the help of 5G technology, the application value in medical scenarios can be jumped. As shown in Figure 2.

It is deployed in band, protected band, and independent cellular network carriers with very small bandwidth. Give full play to the mature technological advantages of narrowband IoT, including strong flexibility and adaptability, low power consumption, wide coverage, multi-connection, and low cost. Realize the dynamic management of hospital equipment assets, location, emergency management, and other applications.

With edge computing, all data generated by the terminal need not be uploaded to the cloud data center. Instead, edge nodes deployed at the network's edge and process it quickly. Dynamic recognition of equipment state is carried out by edge computing. Intelligent status identification and data reporting are performed directly on the collection side. It can reduce computing delay, device power consumption, and cloud servers' power consumption, thus significantly reducing application barriers and costs. It gives full play to Mind Evolutionary Computation (MEC), which is good at searching and solving.[11] To realize the innovative integration of MEC and industrial Internet data application systems, and gradually realize intelligent algorithm optimization and online distribution. Realize the solution of sensitive data in medical institutions, and realize the security isolation of data within the Intranet.

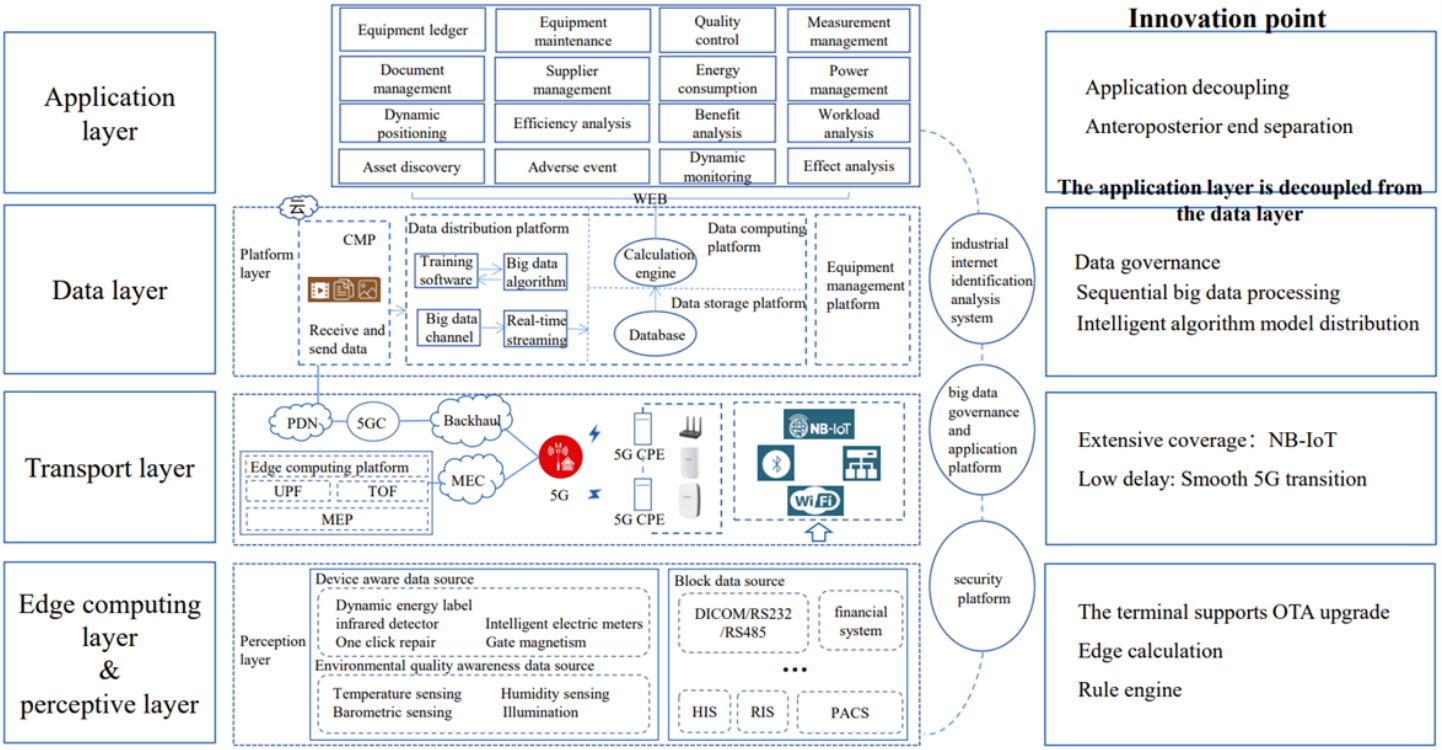

FIGURE 1. Systematic structure.

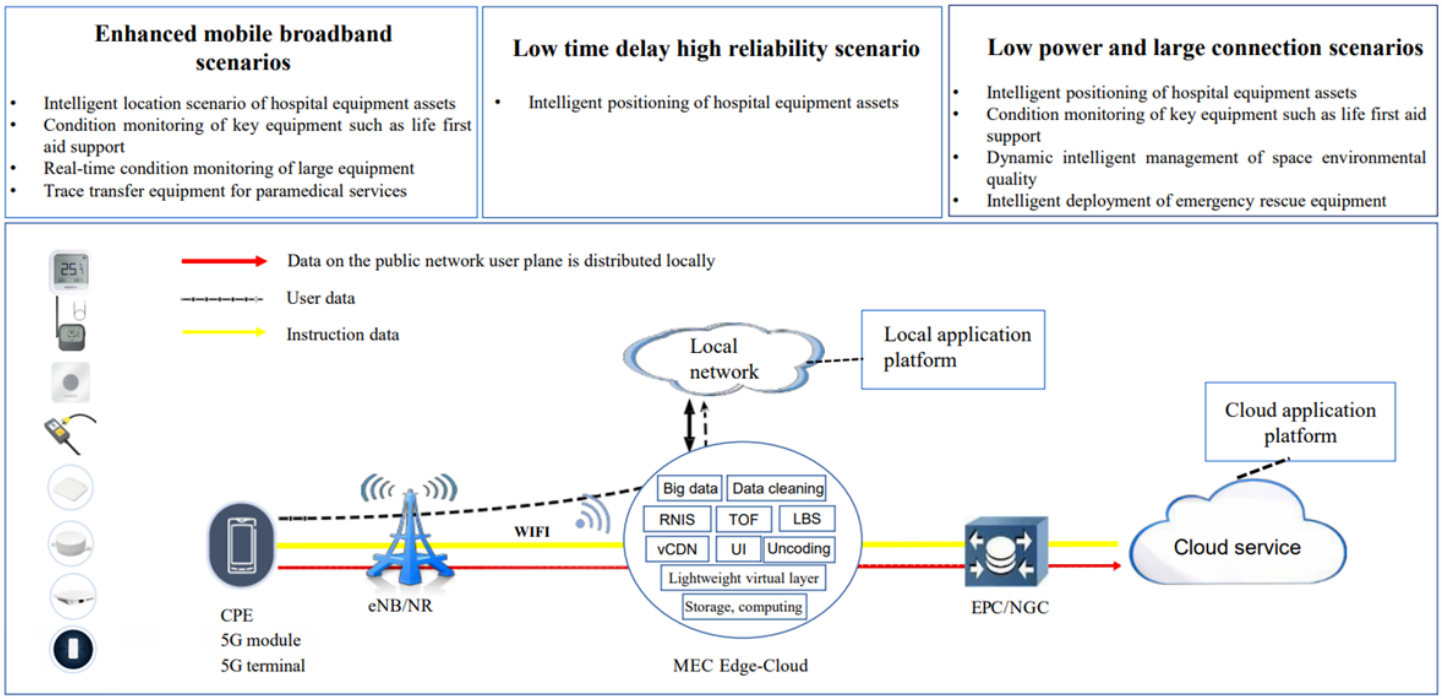

FIGURE 2. 5G networking scheme.

Medical device asset data is stored in the cloud

The key to implementing related applications based on IoT is to realize the data collection of perception terminal and the data binding of object equipment assets. Typical industrial Internet identification of three terminals:

1. Dynamic energy identification is a medical equipment running state dynamic monitoring terminal. A dynamic energy marker is deployed for each active medical device. After the device is powered on, its operating status can be collected and uploaded in real time as shown in Figure 3;

2. Dynamic environment identification is a monitoring terminal for the environmental quality of medical space. With low power consumption and wide area communication capability, a dynamic environment identifier is deployed in each medical space to collect and upload medical space environmental indicators in real time. As shown in Figure 4;

3. Proactively locating and marking the terminal completes the space master data binding and distribution. This combines with the medical device status dynamic monitoring IoT terminal to achieve the room-level dynamic positioning of the equipment and links the data service to the hospital inventory equipment assets ledger information and the hospital's existing equipment assets deployment for a professional dynamic two-dimensional code identification. This will build a cloud database of equipment assets with logos as links. The identification image information, location image information, original asset card image information, and other image information for medical equipment assets are collected. At the same time, based on the management norms of special medical equipment, an equipment assets benchmark database, in line with the latest management requirements, is established to complete the inventory equipment assets information.

FIGURE 3. Dynamic energy identification.

FIGURE 4. Dynamic environment identification.

Medical operation support resource coordination management platform based on spatial digital twin

Digital twinning is a digital method to establish a virtual model representing a physical entity. And through the simulation analysis to simulate the real activities of these physical entities. The master data model of the real physical space of medical institutions is established to complete the datatization of objects such as organizations, hospitals, buildings, floors, rooms, and spaces. As an effective solution, digital twin technology gives full play to timely, fast, and intelligent information services. The comprehensive use of virtual-real interaction, data fusion analysis, decision-making process iterative optimization, and other technical means helps realize the interactive integration and intelligent control from physical entity to the virtual digital model and intelligent management of support equipment location, inventory, environmental warnings, fault repairs, fault locations, and other applications.

RESULTS

Fine management based on the IoT and digital twin can be realized and refined to the room level, improving data acquisition and transmission coverage and improving the efficiency of collaborative management of operational resource support.

Environmental and location monitoring management

IoT terminals are deployed in every room to allow dynamic monitoring of the room or designated area for temperature, humidity, pressure, volatile organic compounds, harmful gasses, particulate matter, and other parameters. Room-level real-time positioning of

medical equipment can be realized, as shown in Figure 5. Meanwhile, environmental warnings, electrical safety warnings, position change warnings, and overall building temperature information on medical equipment are also provided.[12]

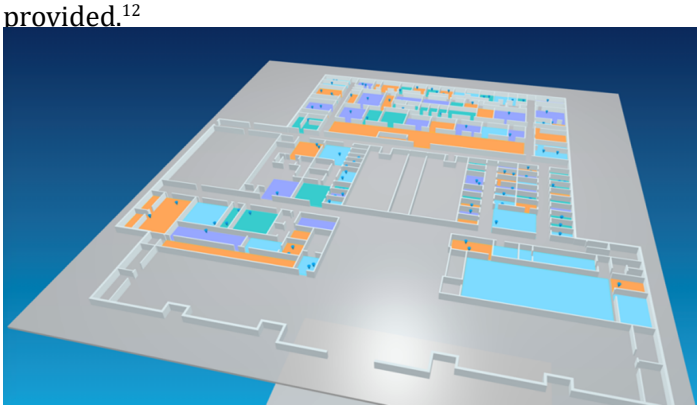

FIGURE 5. Schematic diagram of room-level positioning of medical equipment.

Equipment operation and maintenance monitoring

In the *Medical Equipment Maintenance Programme Overview* report, the WHO states that maintenance steps include identifying fault phenomena and causes, maintenance, post-maintenance testing, and completing maintenance reports. Traditional equipment warranties are reported by telephone; however, maintenance reports are mainly on paper, which multiple departments must review and sign. Maintenance information also needs to be counted manually monthly which is inefficient.

Traditional management methods have been unable to meet the needs of hospital refinement, digitization, and network management.[13] The system can realize the whole process management from repair reporting to maintenance and evaluation through code scanning, quickly locate the repair reporting area, and objectively record the fault phenomenon, maintenance emergency, response time, process, and quality, which allows the development of an annual maintenance report.

Digital image visual management

3D visualization of medical equipment deployment service position and state was realized based on digital twin. Digital twinning of hospital building appearance, hierarchical structure, and other factors is carried out to integrate medical equipment positioning, energy efficiency, and other IoT data.[14] As shown in Figure 6, the user can monitor queries, viewpoint adjustments, and scene switches, strengthening closed-loop traceability management.

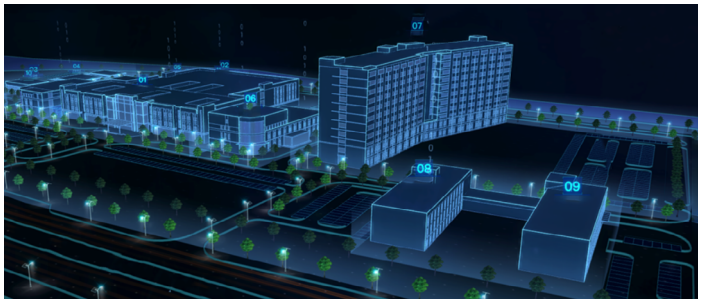

FIGURE 6. The hospital-integrated management platform based on digital twin.

Improve the efficiency of collaborative management of operational resource support

On December 5, 2022, the Shanghai epidemic was lifted, and the number of patients with respiratory tract infections increased sharply. The utilization rate of life support equipment in hospitals, especially Airvo series respiratory humidifiers, has grown rapidly. Considering that the use status of medical equipment changes in real time, this paper takes the monitoring situation of a respiratory humidification therapy instrument in Shanghai Sixth People's Hospital at 10:00 a.m. from December 1, 2022 to December 30, 2022 as an example. The monitoring of equipment used in the system is shown in Table 1. The system can not only display the use status of the device in real time, but also realize accurate positioning synchronously. This ensures the prompt deployment of the unused devices from Department A to Department B, shortening the deployment time from 30 minutes to about 10 minutes. It helps decision-makers realize online, networked, and intelligent medical equipment management, replacing traditional manual paper records. Reduce the repeated purchase caused by unreasonable allocation of medical equipment, improve the efficiency of equipment use, and improve the efficiency of cooperative management of operational resources.

TABLE 1. Monitoring Situation of Airvo Series Respiratory Humidifiers Used in the Whole Hospital from December 1st to December 30th at 10:00 AM Sharp

Time	Actual quantity	Available quantity	Quantity in use	Usage rate
December 1	37	36	10	27.78%
December 2	37	36	11	30.55%
December 3	37	37	10	27.02%
December 4	37	37	12	32.43%
December 5	37	36	28	77.77%
December 6	37	37	28	75.67%
December 7	37	36	33	91.67%
December 8	37	37	35	94.59%
December 9	46	46	40	86.96%
December 10	46	46	44	95.65%
December 11	46	44	36	81.82%
December 12	46	45	43	95.56%
December 13	46	46	44	95.65%
December 14	46	43	43	100%
December 15	46	46	45	97.83%
December 16	46	44	40	90.91%
December 17	46	46	42	91.30%
December 18	46	46	39	84.78%
December 19	46	43	40	93.02%
December 20	46	46	37	80.43%
December 21	46	46	39	84.78%
December 22	46	45	40	88.89%
December 23	46	46	42	91.30%
December 24	46	45	42	93.33%
December 25	46	46	36	78.26%
December 26	46	44	38	86.36%
December 27	46	45	40	88.89%
December 28	46	46	34	73.91%
December 29	46	46	35	76.08%
December 30	46	46	39	84.78%

CONCLUSION

The configuration and optimization of medical equipment, especially life support and other large medical equipment, is an important task of hospitals. The basis of good resource configuration management is to grasp the actual running status of the current device completely in real time. Provide an objective basis for device configuration to support configuration decisions.[15–16] This paper proposes a new medical equipment management mode. Compared with traditional medical equipment management, this mode not only realizes the information of archives simply with the help of the IoT and digital twin technology. It is important to ensure the real-time dynamic update and maintenance of medical equipment to improve the management efficiency of hospital medical equipment to boost the continuous development of hospital medical treatment, teaching, and scientific research.

ACKNOWLEDGMENTS

The authors thank and acknowledge the anonymous reviewers for their valuable comments.

REFERENCES

1. Shamayleh A, Awad M, Farhat J. IoT based predictive maintenance management of medical equipment. J Med Syst 2019; 44(4).
2. Liu WR, Li B, and Ji ZY. Application of telemedicine technology in the prevention and treatment of respiratory infectious diseases. China Med Equip 2020,35(06):108-111,120.
3. Liu TZ, Shen AZ, Hu XJ, et al. SPD-based logistics management model of medical consumables in hospitals. Iran J Pub Health 2016;45(10):1288-1299.
4. Ranjbar E, Sedehi RG, Rashidi M, and et al. Design of an IoT-Based System for Smart Maintenance of Medical Equipment. In 3rd International Conference on Internet of Things and Applications (IoT), Univ Isfahan, Isfahan, IRAN, APR 17-18, 2019.
5. Akkaoui R. Blockchain for the management of internet of things devices in the medical industry. IEEE Transact Intell Transport Sys 2021;1-12.

6. Zhang GD, Navimipour NJ. A comprehensive and systematic review of the IoT-based medical management systems: Applications, techniques, trends and open issues. Sustain Cities Soc 2022;82.
7. Shen CD, Ye K, Liu QC. The intelligent management system of medical equipment based on the Internet of things was applied. Digital Med China 2022;17(2):7-11.
8. Pylianidi C, Osinga S, and Athanasiadis IN. Introducing digital twins to agriculture. Comput Electron Agriculture 2021;184.
9. Zuo R, Wang MY, Zhu SR, et al. Practice and exploration of the construction of hospital intelligent display and analysis platform based on digital twin technology. Digital Med China 2022,17(08):65-69.
10. Peng RJ, Wu XJ, Liu L, et al. Research and development of medical equipment life cycle management application system. Chinese Med Equip 2019;16(06):102-107.
11. Deng F, Wen K, Zeng H, and et al. Novel metal-oxide arrester monitoring technology based on RFID sensor and mind evolutionary computation. Elect Power Syst Res 2020;192.
12. Pires F, Pedrosa A, Alegria J, et al. Clinico-Environmental System for Personal Monitoring. Digital Personalized Health and Medicine 2020;(270):103-107.
13. Umbelino V, Coutinho F, Fonseca I, and et al. Standards about Medical Equipment Maintenance - A Survey, In 6TH IEEE PORTUGUESE MEETING IN BIOENGINEERING (ENBENG), ISEL, Lisbon, PORTUGAL, FEB 22-23, 2019.
14. Tao F, Xiao B, Qi QL, et al. Digital twin modeling. J Manufact Sys 2022;(64):372-389.
15. Chen LH. Application of Mathematical Modeling in Cost Control of Medical Equipment Procurement in Public Hospitals. Computat Mathemat Methods Med 2022;12.
16. Wang ZH, Guo HT, Gan MJ, et al. Progress analysis of medical equipment information management. Biomed Engineer Clin 2020;24(01):87-90.