Global Clinical Engineering Journal

Vol.7 Issue 3

Publisher International Medical Sciences Group, LLC

GlobalCE

www.GlobalCE.org

open access

ISSN: 2578-2762

Editor's Corner

Leadership in Clinical Engineering: Navigating Complexity, Driving Innovation

Twenty years ago, during a visit to China with Professor Bill Hyman (R.I.P.), we were graciously hosted by Professor Jiang Yuanhai (R.I.P.). Together, we debated a crucial gap in academic preparation — particularly the need to develop **leadership competencies** among new Clinical Engineers. Those powerful dialogues left a lasting impact on me. In recognition of their legacy, the Global Clinical Engineering Alliance (GCEA) established the Y**uanhai & Hyman Academic Award** to honor exceptional contributions in academic advancement.

In today's dynamic healthcare landscape, the Clinical Engineer has evolved from being a guardian of equipment functionality to becoming a **strategic architect** of safe, effective, and sustainable health systems. This transformation demands more than technical proficiency — it calls for **visionary leadership**.

"Clinical Engineers are no longer only problem-solvers—they are solution designers at the highest level of healthcare."

The Expanding Role of Leadership

Leadership in Clinical Engineering means moving beyond the familiar, beyond just tools and troubleshooting, and embracing **strategic influence**. It is about shaping policy, mentoring future leaders, and ensuring health technologies serve all communities, everywhere.

"Leadership is not defined by a title — it is defined by your capacity and willingness to influence systems and inspire progress."

A forward-thinking Clinical Engineer must grasp procurement systems, regulatory frameworks, digital health transformation, and environmental impact. It's a role that requires **systems thinking**, fluency in both **medical** and **management** languages.

"The most effective Clinical Engineering leaders speak the language of both medicine and management."

From Basement to Boardroom

The traditional view of Clinical Engineers as behind-the-scenes support is fading. Today, leaders in our profession are found in **boardrooms, ministries of health, and international forums**, shaping policies, budgets, and national strategies.

"From the basement to the boardroom, Clinical Engineers are now partners in shaping the future of healthcare delivery."

Leadership now demands s**oft skills**—emotional intelligence, communication, collaboration, and cross-cultural understanding—as much as it does technical mastery. Equally vital is **visibility**: presenting, publishing, mentoring, and advocating. This is where GCEA and the Global Clinical Engineering Journal become critical enablers.

E Pluribus Unum — *"Out of many, one stronger profession."*

Global Voices, Shared Lessons

Leadership in Clinical Engineering is not confined to any one nation. Around the world, we see shining examples that inspire and guide us:

- **Italy**: Regional healthcare systems have integrated Clinical Engineers into decision-making processes for technology planning, procurement, and deployment—ensuring continuity, quality, and sustainability.
- **Mexico:** Clinical Engineers are leading national health technology program.
- **Africa:** Bold leadership in education and capacity building has strengthened local engineering expertise and fostered self-reliance through context-aware training programs.
- **Asia:** During the COVID-19 pandemic, Clinical Engineers led innovative asset management strategies, care facilities construction, improving response times, optimizing resources, and supporting continuity of care.

These successes illustrate the **global readiness** of Clinical Engineers to lead in diverse settings.

"Every Clinical Engineer has the potential to lead—when equipped, encouraged, and empowered."

One Voice, One Alliance: GCEA

True leadership also means **unifying voices** across continents. That's the vision of the Global Clinical Engineering Alliance: building a **cohesive, representative community** that collaborates across borders and disciplines.

Through GCEA, national societies, academic institutions, and individual professionals join forces—to develop best practices, shape policies, and promote global solidarity.

"From many comes one."

This is not merely a slogan — it is a **call to action**. Alignment enables collective impact, shared standards, stronger advocacy, and a clearer pathway for developing **future leaders** in Clinical Engineering.

"The future of Clinical Engineering leadership depends on the strength of our alliance. GCEA is that strength."

Looking Ahead: Three Leadership Priorities

As we move forward, three core leadership imperatives emerge:

1. **Championing Sustainable Innovation**

   Lead in adopting cost-effective, environmentally responsible, and adaptable technologies.

2. **Advancing Equity and Access**

   Advocate for inclusive solutions, closing the healthcare technology gap between urban centers and underserved communities.

3. **Building Global Solidarity**

   Strengthen international networks to harmonize training, regulation, and practice standards for the benefit of all.

"Leadership in Clinical Engineering is a global responsibility—we rise by lifting each other."

Final Thought

The age of passive participation is over. Clinical Engineers must be **agents of transformation**. The Global Clinical Engineering Journal offers both a **mirror and a megaphone**: reflecting who we are and amplifying who we can become.

"If we want better healthcare systems, we must develop better engineering leaders."

We invite every Clinical Engineer to **step up**—publish, present, mentor, and support. And most importantly, join and support the GCEA.

Let's continue building a strong profession that speaks with **one voice**—in Italy, Ghana, Singapore, and around the world.

Because **together, we are stronger. From many, comes one.**

Take advantage of the GCEA Recognition Program before the August 31 deadline and nominate a deserving colleague for one of the global leadership awards!

Yadin David

EdD, PE, CCE, FAIMBE, FACCE

Editor-in-Chief

Global Clinical Engineering Journal

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Received March 12, 2025, accepted May 30 2025, date of publication July 14 2025.

Original Research Article

Sustainable Procurement of Medical Technologies: Equipping 85 Modular Healthcare Systems in Argentina

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ABSTRACT

Context and objectives: This article presents the planning, construction, and equipping of 85 modular healthcare systems (MHS) in Argentina as a medium-term response to the pandemic emergency. The objective is to describe the implementation and analyze the results of this large-scale national project and its investment component for the acquisition of hospital equipment, highlighting the design, outcomes, and lessons learned in the process with a focus on long-term sustainability. **Materials and methods:** Nine different phases of the implementation process of the project are described and analyzed as components of the sustainable procurement methodology. Within the framework of the planning, construction, and commissioning of the NHS, data were collected and analyzed to qualitatively and quantitatively assess the experience of planning, designing, and procuring equipment for modular health centers. Data analysis was conducted by categorizing the acquired goods into active and passive medical devices (MD), furniture, support equipment, and installation equipment. **Results:** The analysis of the equipment acquired for the 85 MHS shows that the distribution of assets aligns with specific needs and follows similar patterns across all units. Among the 19,600 medical goods purchased, over 60% of the investment was allocated to MD, reaching 87% in centers with higher critical care activity. Visits to operating MHS confirmed their general functionality and user satisfaction with the infrastructure and equipment. Strengths identified include well-designed facilities and decentralized healthcare delivery, which has reduced the burden on central hospitals. At the same time, some lessons have been learned and risks identified, such as specific shortages of specialized personnel, minor quality issues with equipment reception, and the storage of some unused or little-used devices. The need for active post-delivery management was also observed as lessons learned for future large-scale operations. **Discussion:** It was highlighted that passive MD, mainly medical furniture, while accounting for 64% of the equipment, only represents 13% of the investment. However, their appropriate selection and maintenance are crucial for patient perception and quality of care. Furthermore, the high cost of medical technology was demonstrated by an analysis of investment per square meter. **Conclusion:** The implementation of this project focused on medical technologies, analyzing design, equipment investment, outcomes, and lessons for long-term sustainability. The high cost of medical technologies confirms the opportunity to evaluate not only the purchase price but also operational, maintenance, and disposal costs. A comprehensive approach to equipment planning and management is an essential requirement for sustainability and efficiency in LMICs. Evidence-based needs analysis, crucial for sustainable acquisition and to align the equipment with intended use, and post-implementation visits, crucial for continuous quality improvement, are recommended for the implementation of future projects. The presented lessons

learned contribute to establishing a methodological base for future MD procurement projects.

Keywords—*Sustainable procurement, Medical devices, Modular hospitals, Public investment, Argentina, Results assessment, Project management, Medical device planning, Accessibility.*

INTRODUCTION

Since Brunel's resilient hospital concept, based on prefabrication and modular construction—exemplified by the Renkioi Civil Hospital built in 1855,[1] modular hospitals have significantly evolved as an architectural solution within healthcare design. They provide new or existing health facilities with the flexibility to adapt to changing medical care needs and public health emergencies. Depending on the context, modular hospital construction may serve temporary purposes, such as increasing isolation units in densely populated urban areas. In other cases, modular expansion in existing hospitals ensures uninterrupted facility operations, significantly enhancing the efficiency of medical response.[2]

In Argentina, as in many other countries, modular healthcare systems (MHS) were rapidly developed in response to the COVID-19 pandemic to provide swift solutions and prevent overcrowding at hospitals and community healthcare centers. Over time, with positive implementation experiences, MHS has become a sustainable solution[3] to strengthen healthcare systems in the medium and long term, improving medical service accessibility in vulnerable areas, including penitentiary services, and expanding coverage in strategic locations such as tourist areas and border crossings.

This report is based on the experience gained since 2020, under the "Federal Infrastructure Improvement" project. The United Nations Office for Project Services (UNOPS) was commissioned by the Secretariat of Public Works of Argentina, Ministerio de Obras Públicas (MOP), to implement 85 MHS in various locations across the country. The project scope followed a "turnkey" model, requiring UNOPS to provide infrastructure, installations, and material goods such as medical and general furniture, accessories, etc. When writing this report, 85 MHS had been awarded and constructed. Eighty out of 85 (94%) have also been equipped and are functioning. In addition, the project has equipped another 19 MHS, where the construction of the centers, installed in tourist areas, was the responsibility of government authorities in Argentina.

This study focuses on the equipment acquired for the execution of UNOPS Project 20313, detailing the procurement process, quantitative and qualitative analysis of the equipment, and post-delivery visits to assess usage and impact.[4]

GEOGRAPHIC DISTRIBUTION AND SOCIAL IMPACT

Argentina is a vast country with a surface area of 3,761,274 km² and over 46 million inhabitants.[5] However, its population distribution is unbalanced, with 92% of the population residing in urban areas and 70% concentrated in the 31 largest urban agglomerations in the country.[6]

The distribution of MHS under Project 20313 was carried out nationwide, adapting to each area of influence, their specific characteristics and needs. The number of centers correlates to the country's most densely populated regions: Buenos Aires Province (20.69 million inhabitants, including the capital) and Córdoba Province (3.84 million inhabitants). These two provinces collectively account for 53% of the national population, where 45% of the MHS were constructed. Figure 1 shows the geographical distribution of the 85 centers within Argentina highlighting the Buenos Aires and Cordova provinces.

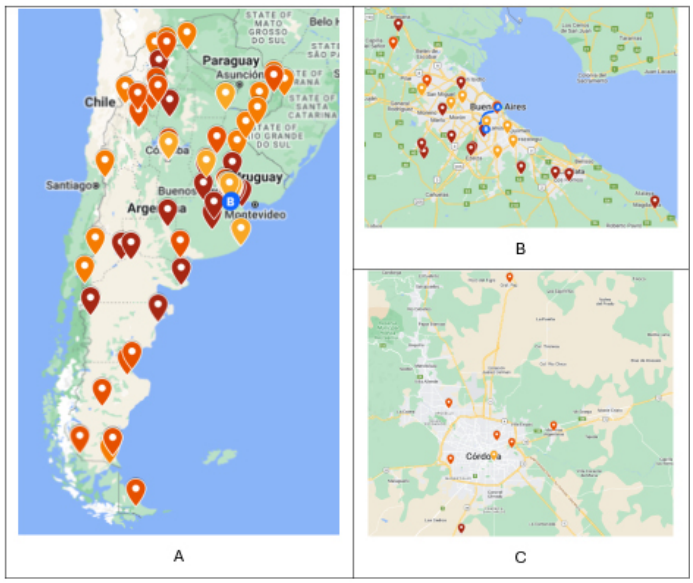

FIGURE 1. (A) Geographical distribution of the 85 MHS, detailing the centers in the provinces of (B) Buenos Aires and (C) Córdoba.

Infrastructure

Because of Argentina's diverse geographical and socioeconomic characteristics, healthcare needs vary significantly across the country. To adapt the architectural designs, infrastructure, and functional integrations of the MHS to each specific context, the MOP technical team conducted an assessment on the use of prefab solutions and a consequent needs assessment for each case. Adapting responses to particular requirements was a key element in ensuring project sustainability.[7]

Modular centers were conceived as entry points to the healthcare system in response to the COVID-19 pandemic. The different types of infrastructure provide primary, intermediate, or critical care services—either permanently or temporarily—until patients can be transferred to more complex healthcare facilities. Each modular center addresses these needs through its design and infrastructure, despite diverse site locations and contextual conditions.

Some MHS were designed to operate independently from preexisting healthcare infrastructure while still being integrated into the broader healthcare network. This was the case for centers located at border crossings and tourist areas. At first, these centers have outpatient consultation rooms, inpatient rooms, diagnostic imaging areas, and clinical laboratories.

An example of this model is the Modular Healthcare System Maldonado | HPA San Jorge | Córdoba IV, located 12 km east of Córdoba city center, as illustrated in Figure 2. It includes a shock room, observation beds, an inpatient room, an X-ray room, consultation rooms, a clinical analysis laboratory, an extraction box, a nursing station, and a pharmacy, as illustrated in Figure 3.

FIGURE 2. MHS Maldonado, HPA San Jorge, Córdoba.

Other MHS served as support areas integrated into preexisting structures and operational frameworks. These include those annexed to existing healthcare centers or those that expanded medical areas within penitentiary facilities.

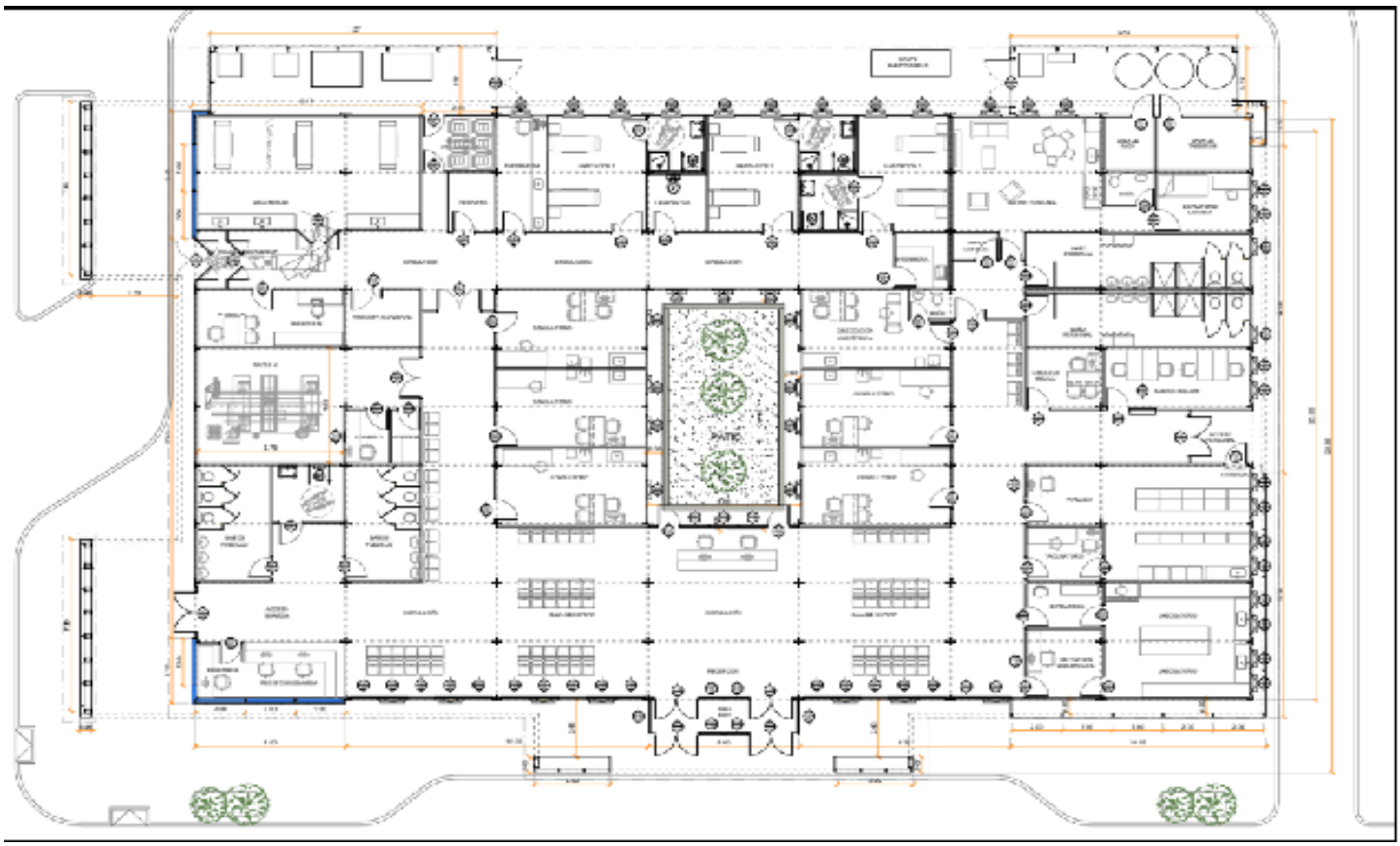

FIGURE 3. Floor plan of the MHS in Maldonado, HPA San Jorge, Córdoba.

An example of this model is the MHS at the Federal Complex Rehabilitation Center for Young Adults in Marcos Paz, Buenos Aires Province, as illustrated in Figure 4.

It includes a nursing station, pharmacy, laundry, guardroom, clinical analysis laboratory, and 12 rooms, as illustrated in Figure 5.

A third example of an MHS, in this case, complementing a preexisting healthcare center, is MHS No. 9 in Almirante Brown, Buenos Aires, which directly collaborates with the adjacent Unidad de Pronta Atención (UPA) No. 5, as illustrated in Figure 6.

It has been designed with a capacity of 76 beds for critical care and hospitalization, as illustrated in Figure 7.

FIGURE 4. MHS federal complex rehabilitation center for young adults, Marcos Paz, Buenos Aires.

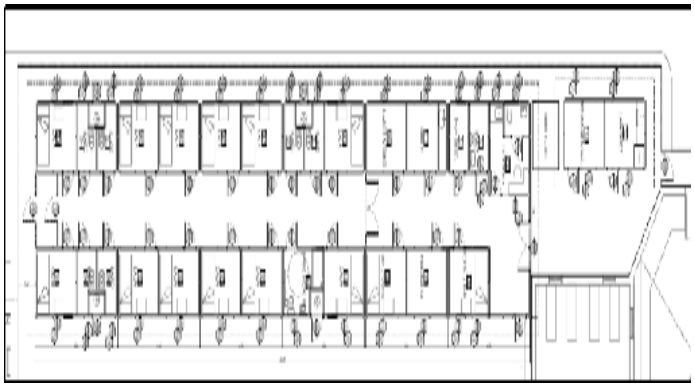

FIGURE 5. MHS federal rehabilitation complex for young adults' floor plan, Marcos Paz, Buenos Aires.

FIGURE 6. MHS No. 9, Almirante Brown, Buenos Aires. A prefab module to complement an existing center.

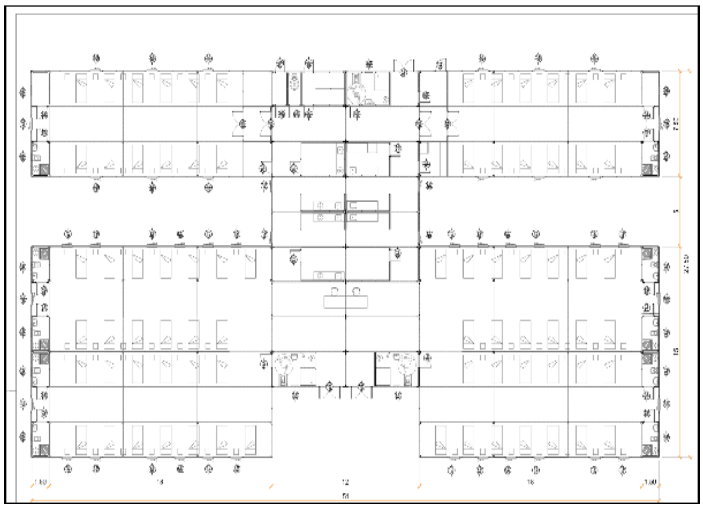

FIGURE 7. MHS No. 9, Almirante Brown, Buenos Aires. A prefab module to complement an existing center.

METHODOLOGY

Planning, designing, and procuring the equipment of the 85 MHS have been accomplished using the PRINCE2 methodology.[8] Before project closure, a phase to analyze the results has been implemented with organization visits to a few centers, as samples, several months after their commissioning, to assess the results and the impact of the project on the healthcare system.

Several months after their commissioning and before the closure of the project, a sample visit to 10 centers has been carried out to analyze the project's results.

Procurement Process

The project's implementation considered a multistep procurement methodology:

1)Grouping the procurement process for multiple MHS according to execution timelines and type. A total of nine procurement processes were conducted for the 85 MHS between 2020 and 2023, as described in Table1.

TABLE 1. Nine procurement processes carried out to equip the eighty-five health centers.

#	Process	Number of Sites	Year
1.	Modular Healthcare Systems	11	2020
2.	Modular Healthcare Systems for Penitentiary Services	6	2020
3.	Modular Healthcare Systems for Penitentiary Services	12	2020
4.	Modular Health Centers for Border	16	2020
5.	Health Isolation Centers for Penitentiary Services	10	2021
6.	Modular Healthcare Systems Phase 1	12	2021
7	Modular Healthcare Systems Phase 2 and Modular Healthcare Systems for Penitentiary Services	7	2022
8	Modular Healthcare Systems Phase 3	6	2022
9	Modular Healthcare Systems Phase 4	5	2023

Note: For the 19 MHS where UNOPS was only responsible for supplying material goods, the equipment was organized into five further procurement processes during 2020 and 2021.[9,10]

2)Determination of **requirement lists:** Based on infrastructure analysis and functional programming, using the room-by-room methodology, which designs the optimal set of equipment and furniture for each environment, considering space size and internal operational workflows.

3)Consolidation of **procurement needs:** Grouping similar or identical goods into packages according to complexity and usage characteristics, considering the local and international hospital equipment markets.

4)Definition of **technological level:** Through continuous dialogue with end users, the type of technology and complexity level of the equipment to be acquired were determined.[11]

5)Specification of **equipment requirements:** To ensure minimum acceptable quality thresholds, procurement processes followed the lowest-price principle, requiring careful assessment of local and international markets.

6)**Procurement process compliance:** Adhering to the UNOPS Procurement Manual,12 focusing on promoting local production. For Class I or A medical devices (MD) (EU and US regulations) manufactured locally in Argentina, only the local regulatory agency certification: ANMAT was required. For higher equipment of higher complexity, certifications from stringent regulatory entities such as those in the United States, Europe, Japan, Australia, and Canada were required.

7)Receipt of goods by medical units and installation of complex equipment by suppliers.

8)Certification by the national regulatory authority for fixed radiological units.

9)Analysis of procurement and installation outcomes in 10 selected centers, as a sample of the 85 centers, with different characteristics.

Equipment Requirements

- **MD and In Vitro Medical Devices (IVD)** defined according to IMRDF13 were classified as active or passive.

  - Active devices: Depend on an external energy source (other than the human body or gravity) and modify or transform that energy.

  - Passive devices: Do not require an external energy source beyond that generated by the human body or gravity.

- Support Equipment: Items not classified as MD but requiring electrical power (e.g., bedpan washers, industrial dryers, compressors, standard refrigerators, and computers).

- **Support Furniture:** Items related to general human activities or medical practice support, specifically designed for healthcare environments (e.g., dining tables, chairs, stairs, and carts).

- **Facilities-related equipment:** Supply systems supporting medical equipment and patient care (e.g., power generators and medical gas plants).

MDs, both active and passive, were classified into four functional groups:

- **Basic Care:** Equipment used in low-complexity areas, mainly for screening or primary care, such as blood pressure monitors, hospital beds, and scales. These represent 75.2% of the total medical equipment acquired for all CMS, accounting for 24.6% of the total investment.

- **Critical Care:** This category includes MDs used in critical patient care, such as ventilators, defibrillators, and infusion pumps. This group constitutes 19.2% of the medical equipment acquired and 40.2% of the total investment.

- **Sterilization:** Equipment used to eliminate pathogens from medical tools and devices, which includes hydrogen peroxide sterilizers and dry heat sterilization ovens. It represents 0.36% of MD but accounts for 5.4% of the total investment.

- **Imaging and Laboratory Diagnostics:** Internal body images for diagnostic, prognostic, and treatment purposes are generated with diagnostic imaging. Because of the nature of these healthcare centers, the acquired

equipment in this category includes fixed and mobile X-ray machines and ultrasound devices. Clinical laboratory equipment includes centrifuges for test tubes, microscopes, micropipettes, and medical refrigerators. This group accounts for 5.4% of the MD acquired but represents 29.8% of the total investment, reflecting the high cost of imaging technology.

Results and Outcome Measurement Visits

Biomedical Engineers from UNOPS personally conducted results-measuring visits to the selected 10 MHS to ensure the effectiveness of public procurement in healthcare. The results measurement phase evaluated the qualitative and quantitative impact of investment on population health while identifying lessons learned for continuous improvement.[14]

As part of this framework, site visits were planned to assess the condition and usage of delivered medical equipment and collect user feedback. A sampling methodology was used, resulting in 10 visits. At least one modular unit from each of the first eight processes outlined in the Section "The Acquired Equipment" was inspected. However, for Process 9, mentioned in Table 1, the modular units had not been equipped, making it impossible to include them in the assessment. The visits were conducted in person by one or two biomedical engineers from UNOPS.

Phase 1: Selection of Centers and Pre-Visit Planning

Before each visit, the medical coordinator of each site was contacted to ensure that the information collected at each center was representative and sufficient. This way, the visit would occur at a date and time, when the maximum number of users (e.g., X-ray technicians and ultrasound physicians) were available, and full access to all medical equipment was granted.

Phase 2: Information Gathering

Before conducting each visit, a thorough review of procurement and delivery documentation was performed. This included the examination of published procurement processes, received bids, evaluations, awarded contracts, purchase orders, and delivery receipts. All this information was organized into specific templates for each center, facilitating traceability and serving as a reference during the visits.

Phase 3: Structured Interview

A structured interview approach to ensure comparable data collection has been used. When addressing satisfaction with the proposed subjects, the referents were asked to categorize their answer using the following options: strongly disagree, disagree, neither disagree nor agree, agree, strongly agree. The structured interview comprising eight questions was submitted to the director of the visited modular unit or the person in charge during the visit, resulting in a talk of approximately half an hour.

Section a: Equipment satisfaction and suitability

1. Overall satisfaction: "The received equipment in terms of its quality, functionality, and quantity relative to your experience and expectation, is satisfactory."

2. Technology level: "The technology level of the received equipment meets the clinical needs of your patient population and the capabilities of your staff."

3. Completeness: "The equipment was delivered with all necessary accessories, components, and software required for its intended functionality and immediate use."

Section b: Personnel and training

4. Presence of personnel: "The center has sufficient and adequate staff to use the purchased medical equipment."

5. User training adequacy: "The training provided to clinical users on the operation and application of the new equipment was adequate and effective."

6. Technical training adequacy: "The training provided to technical staff (biomedical engineers and technicians) on the maintenance, troubleshooting, and repair of the new equipment was adequate and effective."

Section c: Supplier support

7. Supplier contact information: "You have clear and readily accessible information on how to contact the

supplier for warranty claims, technical support, and spare parts."

8. Warranty claim satisfaction: "If you have submitted a warranty claim, you are satisfied with the supplier's responsiveness, the speed of resolution, and the overall outcome."

Section d: Impact on healthcare infrastructure

9.Impact on higher-level facilities: "The presence of this center and its equipment has reduced the burden or demand on higher-level healthcare facilities in the province."

Phase 4: On-Site Assessment

The duration of in-person visits varied depending on the center's size, the quantity of installed medical equipment and furniture, the number of interviews conducted, and the specific operational conditions at the time of the visit. The evaluation process included:

1. Verification of serial numbers for all MDs.

2. Assessment of equipment integrity.

3. Documentation of each item's location.

4. Capturing photographic records of relevant documentation.

5. Identification of any potential issues affecting equipment usability.

6. Confirmation of appropriate user training provided for equipment operation.

7. Evaluation of supplier responsiveness in cases where technical support was requested.

The organization of the assessment tasks according to the complexity was as follows:

Type A assessments, applicable to high-complexity equipment:

- Verify the presence of the equipment.
- Check installation conditions.
- Verify the validity of the warranty and whether it has been used.
- Confirm whether the training required by the award contract has been provided.
- Ensure the presence of user manuals.
- Verify the delivery of accessories, if applicable.
- Take at least three photographs of the equipment: one showing its placement within the facility, one close-up of the equipment, and one of the serial number plate.
- Assess the equipment's functionality and gather user experience feedback.
- If possible, determine the number of patients examined or treated using the equipment.

Type B assessments, applicable to low-complexity equipment:

- At a minimum, verify the presence of the equipment, installation conditions, and warranty status.
- Take at least one close-up photograph of the equipment.

Type C assessments, applicable to medical furniture:

- Verify the presence of the furniture.
- Photograph and document any identified issues or anomalies related to its delivery.

Phase 5: Reporting and Lessons Learned

After each visit, a detailed report was compiled summarizing findings and observations. These findings were then consolidated into a final report, listing the visits chronologically and highlighting key insights for future improvements.

RESULTS

The Acquired Equipment

With the definitions explained in the methodology, the analysis of the acquired equipment and furniture allows us to demonstrate the distribution of quantity and values, as reported in Figures 8–11.

Of the goods and services directly related to medical practice and patient care, 78% correspond to MD, representing 78.9% of the investment in this category.

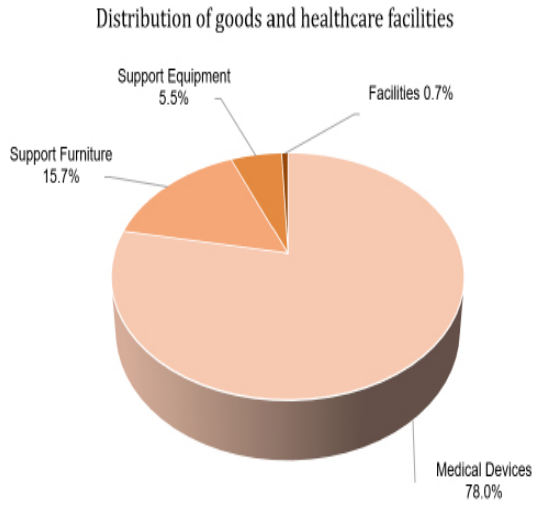

FIGURE 8. Distribution of facilities-related equipment, medical devices, support equipment, and support furniture.

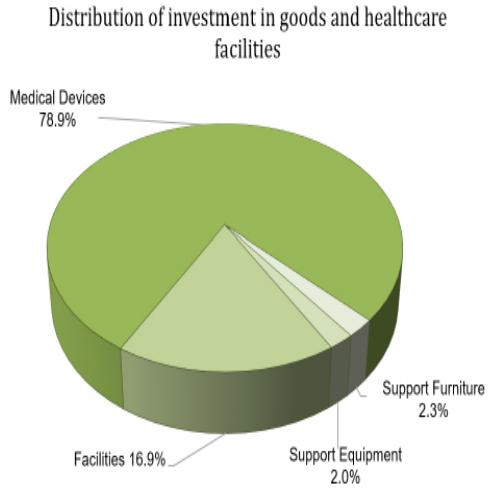

FIGURE 9. Distribution of investment in facilities-related equipment, medical devices, support equipment, and support furniture.

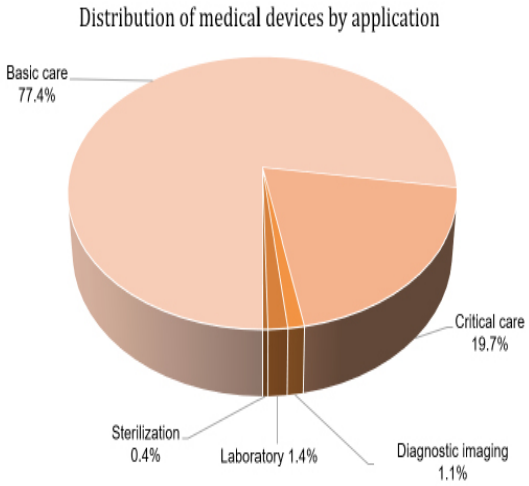

FIGURE 10. Distribution of medical devices by application.

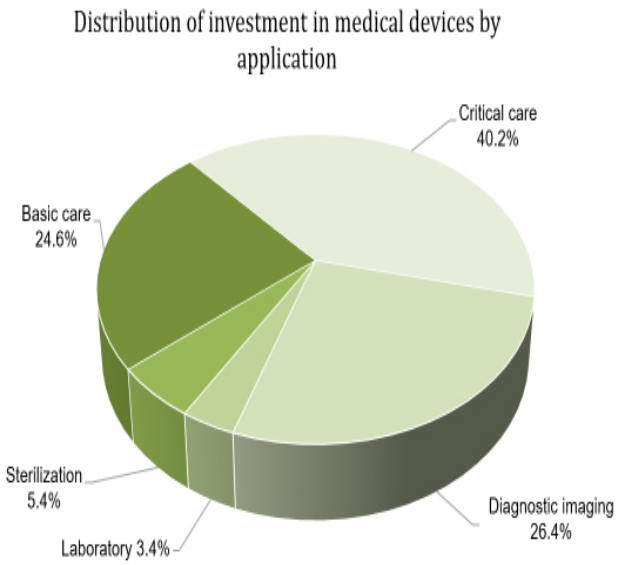

FIGURE 11. Distribution of investment in medical devices by application.

The MHS were constructed in geographical locations with dissimilar characteristics and needs; therefore, the quantity and characteristics of the assets are not homogeneous across all centers but rather respond to the epidemiological needs of each case. Nevertheless, analyzing examples from each of the MHS typologies, it is observed that their distribution follows similar patterns in all cases.

More than 60% of the investment allocated to goods directly related to medical practice, in all analyzed cases, corresponds to MD, reaching 87% in units with higher critical care activity, as higher cost devices.

Regarding MD characteristics, the largest group corresponds to basic care equipment, exceeding 62%. This is consistent with the conception of health centers as gateways to the health system. The percentage reaches 94% in Penitentiary Services Centers, where immediate and low-critical medical care is expected to be provided.

Visit Results

The objectives set for the MHS visits were met, allowing for the assessment of installed equipment conditions, its usage, and supplier responses to users. In all cases, it was possible to interview coordinators or medical officers and obtain information on current situations and future projections. The results of the structured interview carried out with the eight questions presented in "Section 2, Phase 3: Structured Interview" are presented in Table 2, as percentages of answers for each question.

TABLE 2. Results of the structured interview.

	Strongly Disagree (%) Strongly Disagree (%)	Disagree (%)	Neutral (%)	Agree (%)	Strongly Agree (%)	N/A (%)
Q1	0	40	0	10	40	10
Q2	0	10	0	60	20	10
Q3	0	0	0	30	50	20
Q4	0	25	0	25	0	50
Q5	0	30	10	10	30	20
Q6	0	10	10	0	0	80
Q7	0	30	0	10	30	30
Q8	0	0	0	0	10	90
Q9	0	0	0	10	20	70

The eight questions are presented in "Section 2, Phase 3: Structured Interview" and the results are categorized as Strongly Disagree, Disagree, Neutral or Neither Agree or Disagree, Agree, Strongly Agree, N/A: not applicable or not answered. The percentage of each answer is shown in table 2 and the statistical analysis of the answers is reported in Table 3.

Assigning numerical values from 1 to 5 allows for the calculation of mean values and standard deviations to gauge the level of agreement. Based on these metrics, the MHS

Directors' responses suggest the following:

- Technical and clinical staff training: The directors do not generally support the idea that adequate training of the technical staff has been carried out. However, they show slight support for the notion that the center has sufficient and adequately trained staff for equipment use.

- Equipment quality and support: There is some agreement among the directors regarding the quality, functionality, and quantity of the received equipment. They also agree on the availability of information for contacting the supplier when needed.

- Equipment adequacy and impact: The directors generally agree that the level of equipment is adequate for both clinical needs and staff capabilities. They also acknowledge the good condition of the equipment upon arrival and recognize that the center and its equipment have reduced the burden on higher-level healthcare facilities.

- Warranty satisfaction: In the one instance where the warranty was activated, the supplier's response was rated as very satisfactory.

TABLE 3. Statistical analysis of the results of the structured interview.

Question	Average Level of Agreement	std dev
Q6: Adequate and effective training provided to technical staff	2.5	0.7
Q4: The center has sufficient and adequate staff to use the equipment	3.5	1.4
Q5: Adequate and effective training provided to clinical users	3.5	1.4
Q1: Received equipment in terms of its quality, functionality, and quantity is satisfactory	3.6	1.5
Q7: Clear and readily accessible information on how to contact the supplier in case of need	3.6	1.5
Q2: The level of the equipment is adequate to the clinical needs and staff capabilities	4.0	0.9
Q3: The equipment was delivered in good condition for its intended functionality and use	4.3	1.0
Q9: The center has reduced the burden or demand on higher-level healthcare facilities	4.5	0.6
Q8: Supplier's responsiveness to warranty claims, satisfactory speed of resolution, and overall outcome	5.0	N/A

Note: Results below 3 show a disagreement (pink), results between 3 and 4 show a certain agreement (yellow), and results between 4 and 5 show high levels of agreement (green). N/A: not applicable. Std dev: standard deviation.

Figures 12–17 show some of the hospital areas and equipment inspected during the visits.

FIGURE 12. Equipment and facilities-related equipment installed in a critical care unit, MHS No. 9—Almirante Brown, Buenos Aires.

FIGURE 13. Equipment installed in a clinical analysis laboratory, MHS No. 28—Exaltación de la Cruz, Buenos Aires.

FIGURE 14. Equipment installed in a gynecological room, MHS No. 28—Exaltación de la Cruz, Buenos Aires.

FIGURE 15. Equipment and facilities-related equipment installed in an observation sector, MHS San Jorge, Córdoba.

FIGURE 16. Equipment and facilities-related equipment installed in a hospitalization room, MHS No. 9—Almirante Brown, Buenos Aires.

FIGURE 17. Equipment installed in an emergency office, MHS No. 28—Exaltación de la Cruz, Buenos Aires.

Although in a few cases, clinical services were found to be not operational because of a lack of clinical specialists, like cardiologists or pediatricians, end users expressed satisfaction in quality, quantity terms, and supplier responsiveness toward the available technology. They also highlight the improvements that equipment and facilities-related equipment have brought to their daily work. In addition, the new medical specialties and practices introduced in some MHS have reduced patient waiting lists in central hospitals.

The following four strengths of the implemented project were identified:

Strengths:

1. Well-designed facilities with spacious areas and adequate lighting.

2. High user satisfaction with received goods and their positive impact on daily work.

3. Reduced demand in central hospitals because of decentralized healthcare services.*

4. Properly stored and managed equipment, all of them are in good working conditions.

*Note: Reduced demand in central hospitals because of decentralized healthcare services is a qualitative finding from Question 8 of the structured interview: "To what extent has the presence of this equipment at your center reduced the burden or demand on higher-level healthcare facilities in the province?"

Lessons Learned

The following six lessons learned have been identified during the visit and an analysis of their results:

1. It is essential to establish a dedicated process ensuring sufficient personnel/specialists for MHS operation. In some cases, the absence of clinical personnel has delayed implementation and affected the warranty, since the equipment has been stored for a long time.

2. It is essential to establish a formal process to inspect the quality and integrity of each delivered equipment. In a couple of cases, the visit detected missing accessories (one wheel of one examination lamp and few shelves) and the problem was solved with the suppliers.

3. It is essential to prepare the equipment list based on the real existing or projected needs. It was observed that few equipment (about 2%), like humidifiers to support mechanical ventilation, were not used because of a lack of specific needs. The presence of some underutilized equipment may be a consequence of misalignment between the specific needs of MHS facilities-related equipment and the equipment provided as well as changing needs during a project's implementation.

4. As a result of the structured interview, it is recommended that the training process is monitored and certified. It was identified that some end users were unaware that they could request training from the equipment suppliers. In addition, they did not know how to contact the suppliers. Compounding the issue, internal training sessions were conducted by other users of similar equipment, with the risk of incorrect concepts leading to an improper use of the devices.

5. It is recommended that all the local regulatory requirements are properly managed in advance. Specifically, the necessary authorizations from the Radiological Health Authority of the Argentine Ministry of Health (Radiología Sanitaria), responsible for verifying and approving radiology rooms, were not processed from the beginning, with the risk of delays in the start-up of radiology services. In this specific case, a prompt reaction and a proactive management of this specific risk have avoided delays.

6. It is recommended to streamline the communication of the contractual conditions with the final users. In most cases, the misconception that equipment belongs to UNOPS and not to the final users prevented the possibility of its redistribution according to changing needs.

Finally, the case of MHS No. 9 in Almirante Brown, Buenos Aires Province, can be reported as a remarkable success. Originally conceived as a SARS-CoV-2 pandemic response unit, it has since been integrated into the local healthcare network, coordinating with the "Dr. Lucio Meléndez" General Acute Hospital and the adjacent "Unidad de Pronta Atención" (UPA) No. 5. It currently receives patients requiring hospitalization through the

UPA and referrals from the main hospital. During the second quarter of 2024, it recorded 695 patient admissions, with a projection of 2.800 patients/year, becoming key in relieving and decentralizing the demand for critical and intermediate care hospitalizations.

DISCUSSION

Replicability for Different Contexts

Some key parameters can be identified to help similar projects estimate budgets and workloads in the inception phase.

Within the MD acquired for all MHS, passive equipment accounts for 64% but represents only 13% of the investment in medical equipment, as shown in Figures 18 and 19.

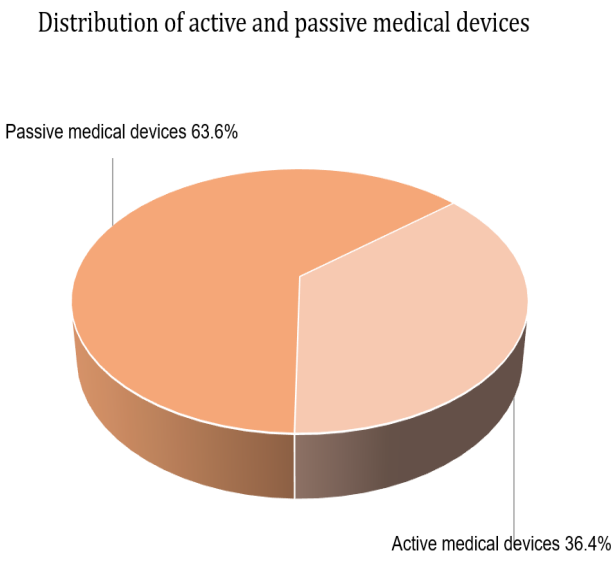

FIGURE 18. Distribution of active and passive medical devices.

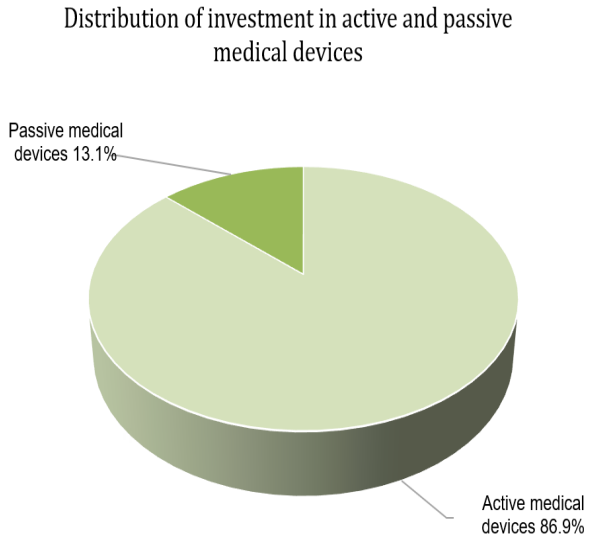

FIGURE 19. Distribution of active and passive medical devices.

The passive device group primarily consists of inpatient beds, stretchers, wheelchairs, blood pressure monitors, and stethoscopes, all of which are low-cost and low-complexity items. This could lead to underestimating the time dedicated to their evaluation and acquisition.[15] However, it is important to note that these devices are in contact with the patient for a significant portion of their stay in healthcare centers. Since the patient's perception of the environment impacts their treatment outcomes,[16–18] it is relevant to dedicate adequate human and economic resources to the selection and maintenance of these assets.

An analysis of the investment in MD, medical furniture, support equipment, and facilities-related equipment per square meter (m^2) shows that for the individual modular centers analyzed, the highest investment per m^2 corresponds to MD, followed by investment in facilities-related equipment.

Table 4 presents the MHS data for various centers with different surface areas. Four MHS typologies with different surface areas were selected to analyze the parametric cost of the equipment. These typologies range from the largest surface area (MHS #1 of 1,100 m^2) to the smallest (MHS

#4 of 285 m^2); two intermediate cases (MHS #2 and MHS #3) have also been selected.

As shown in Table 4, MHS for penitentiary services, MHS# 3 and MHS# 4, have a lower relative investment in MD in comparison with the other centers. Smaller centers of the same type have a greater relative investment in MD compared to larger ones.

TABLE 4. Investment per square meter for the different types of facilities and for four MHS, each representing different sizes and types of centers.

MHS type	# 1	# 2	# 3	# 4
Area (m^2)	1,100	990	660	285
Medical devices*	533.9	259.4	182.8	336.6
Medical furniture*	11.6	11.8	1.9	2.2
Support equipment*	6.1	0.5	22.1	25.5
Facilities-related equipment*	100.4	25.2	96.6	136.0
Total equipment investment*	**652**	**296.9**	**303.4**	**500.3**
Percentage of medical devices in total equipment cost	82%	87%	60%	67%
equipment cost				

* Investment [U$S/($m^2$)]

In table 4 MHS type #1 corresponds to MHS annexed and integrated into preexisting healthcare centers, MHS type #2 corresponds to MHS designed to operate independently from preexisting healthcare infrastructure, and MHS types #3 and #4 correspond to MHS for penitentiary services of different sizes, which respond to the size of the beneficiary population.

This evidence underscores the high cost of medical technology that is independent from the specific size and type of center and reinforces the importance of conducting a needs analysis as a starting point for the acquisition process based, among other factors, on the intended use of the assets.

Similarly, costs associated with the entire life cycle of medical technology within the healthcare center must be considered, from the initial purchase expenses to the final disposal costs. The purchase price is only the tip of the iceberg concerning associated costs. A proper medical technology cost analysis requires considering not only the purchase price but also installation, operation, financing, disposal, and other costs generated during the useful life of the device.[19]

A detailed analysis of medical technology costs throughout its life cycle will require further investigation. The Pan American Health Organization considers preventive and corrective maintenance costs to represent between 3% and 7% of the equipment's purchase cost per year when performed by the healthcare center's staff; and between 8% and 15% when external services are contracted.[20] Costs associated with the devices' operation vary depending on the technology, and their origin is very diverse. Clinical analysis laboratory equipment may have high costs in reagent consumption, while imaging equipment will have large consumption in electricity and cooling supplies. The analysis and observation of all costs associated with medical equipment during its useful life is a fundamental part of sustainable acquisition.[21]

CONCLUSION

In conclusion, as a medium-term response to the pandemic, Argentina undertook a national project to plan, construct, and equip 85 MHS. This article describes the project's implementation for the medical technologies component and analyzes its results, focusing on the design, equipment investment, outcomes, and lessons learned within the objective of long-term sustainability.

The evidence presented highlights the significant impact of MD investment on healthcare facility costs, emphasizing that the purchase price is merely the initial expense in a device's lifecycle.

Considering the significant financial implications of medical technology, as highlighted by the consistent costs across various facility types, conducting a needs analysis is a crucial first step in sustainable acquisition, ensuring that the selected equipment aligns with its intended use and the facility's long-term goals.[22]

The six identified lessons learned can serve as a valuable checklist for future healthcare infrastructure planning and medical equipment deployment, enabling hospital planners, policymakers, and health authorities to deliver effective and sustainable healthcare solutions. These lessons, when integrated with the three pillars for MD procurement—selecting equipment that meets beneficiary clinical needs, considering human resource capabilities, and assessing local infrastructure conditions, all while prioritizing the asset's lifelong use—collectively form a robust methodology for implementing future projects.

As the post-implementation visit was not included in the original project's plan and has been carried out with limited resources, to ensure continuous quality improvement process for the MD procurement implementation strategy, we recommend scheduling such visits in the design phase of future projects, including in the agreement a provisions for the regulated sharing of anonymized access data related to the project's infrastructure to measure its impact rigorously.

AUTHOR CONTRIBUTIONS

Conceptualization, V.D.V., PMC and M.A.B.; **Methodology**, V.D.V., PMC and M.A.B; **Software**, V.D.V., PMC and M.A.B; **Validation**, V.D.V., PMC and M.A.B; **Formal Analysis**, V.D.V., PMC and M.A.B; **Investigation**, V.D.V., PMC and M.A.B; **Resources**, V.D.V., P.E.G., I.L.C., PMC and M.A.B; **Data Curation**, V.D.V., P.E.G., I.L.C., PMC and M.A.B; **Writing–Original Draft Preparation**, V.D.V., PMC and M.A.B; **Writing–Review & Editing**, V.D.V., P.E.G., I.L.C., PMC and M.A.B; **Visualization**, V.D.V., PMC and M.A.B; **Supervision**, P.E.G., I.L.C.,; **Project Administration**, P.E.G., I.L.C.,; **Funding Acquisition**, P.E.G., I.L.C.

ACKNOWLEDGMENTS

Not applicable.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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Received March 12, 2025, accepted June 5, 2025, date of publication July 23, 2025.

Original Research Article

Implementing Clinical Engineering Departments in a Small Hospital: A 2017–2021 Regulatory Compliance and Organizational Analysis

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ABSTRACT

The integration of clinical engineering into healthcare systems is increasingly recognized as a key factor in improving regulatory compliance, equipment management, and patient safety. However, many hospitals in developing countries still lack formally established clinical engineering departments, leading to operational inefficiencies and safety risks. This longitudinal study evaluates the impact of implementing a clinical engineering department in a 10-bed secondary-level hospital between 2017 and 2021. Using a mixed-methods approach, regulatory compliance was assessed through two comprehensive audits conducted before and after the department's implementation, based on 423 standards derived from national regulations. Regulatory compliance increased from 54.61% in 2017 to 78.72% in 2021. A two-sample Z-test for proportions confirmed that this improvement was statistically significant ($Z = 7.44$, $p < 0.001$) with a 95% confidence interval of 17.95% to 30.27%, suggesting that the change was unlikely because of random variation. Although the same set of standards was evaluated in both audits, the 4-year interval and lack of item-level tracking justified the use of this approximation. An organizational analysis revealed that while the department contributed significantly to equipment oversight, process standardization, and regulatory compliance, its participation in high-level strategic decision-making remained limited. The dual role in both operational and strategic tasks posed ongoing challenges in prioritization and impact. Semi-structured interviews with clinical, administrative, and technical staff supported the quantitative findings. A total of 93% of participants were aware of the department, 87% understood its functions, and 86% rated its performance as "Good" or "Very Good". The majority also considered it essential or considerably necessary for hospital operations. Together, the quantitative and qualitative findings confirm that the creation of a clinical engineering department can significantly enhance hospital regulatory compliance, operational performance, and staff engagement with safety processes. These results provide a replicable model for healthcare institutions in similar contexts seeking to strengthen medical technology management and regulatory alignment.

Keywords—*Clinical engineering, Regulatory compliance, Medical equipment management, Patient safety, Longitudinal study, Healthcare quality.*

INTRODUCTION

Clinical engineering plays a fundamental role in the quality of hospital care, patient safety, and the optimization of both administrative and healthcare processes. Its importance has grown exponentially as medical technology has become an essential component for the proper functioning of healthcare institutions.[1] However, in developing countries, such as Mexico, the implementation of clinical engineering departments in hospitals faces major challenges because of the absence of standardized regulations, resource limitations, and a general lack of awareness about their impact on healthcare service delivery.[2]

In the context of the COVID-19 pandemic, the relevance of clinical engineering in Mexico became more evident than ever, demonstrating its critical role in medical technology management, the maintenance of essential equipment, and the implementation of strategies to optimize hospital resources.[3] The World Health Organization (WHO) has recognized that the presence of trained clinical engineers is key to ensuring effective investment in healthcare technology and achieving better patient care outcomes.[4] Furthermore, international studies have shown that the participation of clinical engineers in hospitals has a direct and positive impact on indicators of patient safety and efficiency of care.[5]

Despite the growing evidence on the benefits of clinical engineering, healthcare technology management in Mexico still faces structural and administrative barriers. Previous research has identified that many private hospitals lack formalized clinical engineering departments, leading to inefficient management of medical devices and posing a risk to the quality of care.[2] Moreover, the absence of clear regulations and standardized data on the operation of these departments has hindered their effective integration into the public sector.[6]

This longitudinal study builds upon prior research evaluating regulatory compliance with healthcare standards,[7] which analyzed compliance with Mexican Official Standards (Norma Oficial Mexicana, NOM) in infrastructure and equipment before the implementation of a clinical engineering department in a private hospital. In 2021, these standards were reevaluated, revealing significant improvements in regulatory compliance, which translated into safer and more efficient medical care. These findings reinforce the importance of clinical engineering as an essential component for the modernization of the healthcare sector in Mexico and other developing countries.

Recent literature confirms that regulatory frameworks, especially when aligned with accreditation programs or national standards, can significantly improve safety, process efficiency, and equipment reliability.[8] Studies have shown that hospital accreditation and standardized maintenance protocols not only reduce equipment downtime but also improve risk management, patient outcomes, and resource utilization.[9,10] In this regard, the presence of trained clinical engineers and the implementation of comprehensive medical device management systems, grounded in national and international standards, are considered fundamental to quality assurance in modern healthcare systems.[8]

This paper aims to provide evidence on the need to standardize healthcare technology management and promote the establishment of clinical engineering departments in hospitals as an effective strategy to improve the quality of care and patient safety.

MATERIALS AND METHODS

This longitudinal study employed a mixed-methods approach to evaluate the impact of establishing a clinical engineering department in a secondary-level hospital in a developing country, between 2017 and 2021. The hospital is a privately managed institution operating as a secondary-level facility with a capacity of 10 beds, serving a population of medium to low socioeconomic status. Before 2017, the absence of a formal clinical engineering department resulted in deficiencies in medical device management and regulatory compliance.

Regulatory Audits and Compliance Assessment

The analysis was based on two comprehensive audits, conducted in 2017 (pre-implementation) and 2021 (post-implementation), following the guidelines of the applicable Mexican Official Standards (NOMs) for hospital infrastructure and equipment (Table 1). A total of

423 regulatory standards were assessed, covering key aspects of medical equipment, infrastructure, safety, and hygiene in critical hospital areas. The selection of the 423 NOM items focused on infrastructure, equipment, and regulatory criteria that fall within the typical scope of clinical engineering responsibilities in hospitals. Standards were drawn from six Mexican Official Standards (NOMs) covering areas such as electrical safety, intensive care, emergency services, anesthesiology, and hazardous waste management. Emphasis was placed on items related to the physical environment, medical devices, and safety procedures, where clinical engineering interventions are most relevant. In addition, selected regulatory aspects were included to reflect areas where the department may influence institutional regulatory compliance.

On-site inspections of equipment and infrastructure were performed using checklists derived from the NOMs to evaluate the physical condition of devices and the adequacy of facilities. In addition, document reviews of records, logs, and service orders were conducted to assess the management and maintenance of medical devices.

The first regulatory audit was conducted in September 2017, prior to the establishment of the clinical engineering department. The department was formally implemented in June 2018, and the follow-up audit was conducted in February 2021, resulting in a total observation period of 3 years and 5 months between the baseline and the post-implementation assessment.

No major organizational changes occurred during the implementation of the clinical engineering department that could have influenced the audit results or staff perception. The hospital's leadership, governance structure, and departmental management remained stable throughout the observation period, ensuring continuity in operational processes.

To ensure methodological consistency across both time points, the audits conducted in 2017 and 2021 were carried out by the same evaluation team, using identical checklists and assessment procedures. The 423 regulatory standards assessed remained unchanged throughout the study period, as no modifications were introduced to the applicable national regulations. Both audits followed a standardized protocol involving documentary review, on-site inspections, and structured interviews. This consistency in evaluators, instruments, and regulatory criteria minimized the potential for measurement bias and ensured a reliable longitudinal comparison.

TABLE 1. List of Mexican Official Standards (NOM) used to evaluate regulatory compliance in hospital infrastructure, medical devices, and safety procedures relevant to clinical engineering.

Standard	Field of Study
NOM-001-SEDE-2012	Electrical Installations (use).
NOM-016-SSA3-2012	Establishes the minimum infrastructure and equipment requirements for hospitals and specialized medical consultation facilities.
NOM-025-SSA3-2013	For the organization and operation of intensive care units.
NOM-087-ECOL-SSA1-2002	Biological-infectious hazardous waste classification and handling specifications.
NOM-006-SSA3-2011	For the practice of anesthesiology.
NOM-027-SSA3-2013	Establishes the criteria for operation and care in emergency services of medical facilities.

Organizational Analysis

To complement the regulatory audits, a qualitative organizational analysis was performed to assess the impact of the clinical engineering department on hospital structure, roles, and operational processes. Three key aspects were evaluated:

1. Structure: The organizational hierarchy of the hospital was reviewed to determine the position and influence of the clinical engineering department in strategic and operational activities.

2. Responsibilities: The roles and delegated tasks of the clinical engineering department were analyzed, focusing on its contributions to infrastructure management, regulatory compliance, and interdepartmental collaboration.

3. Processes: The study examined how hospital workflows evolved following the implementation of the clinical engineering department, specifically improvements in medical device oversight, standardization of procedures, and staff training programs.

Semi-Structured Interviews

To further explore the perception of these changes, semi-structured interviews were conducted with clinical, technical, and administrative staff selected based on their involvement in hospital operations. These interviews examined staff perceptions regarding operational improvements, safety culture, and interactions with the clinical engineering department. The questions were designed to capture both individual experiences and broader perspectives on the department's contribution to hospital efficiency and patient safety.

A total of 15 hospital staff members participated in the interviews, which were conducted anonymously to promote candid responses. Participants were selected from all shifts, including weekends, to ensure extensive representation. The interviewees included clinical, technical, and administrative personnel, covering a wide range of services and time blocks.

Based on institutional records and operational estimates, the hospital operates with a total staff of approximately 40 members, including all departments. During the observation period, the clinical engineering department was composed of one full-time staff member and two interns. The sample of 15 interviewees includes all three technical staff members, two administrative staff, and a substantial portion of the clinical team.

Given the hospital's small size and the deliberate inclusion of all functional roles and operational shifts, the sample is considered sufficiently diverse and representative to support meaningful qualitative insights.

Study Design and Statistical Analysis

The study design is illustrated in Figure 1, which outlines the main stages of the investigation. The process began with an initial audit in 2017 to establish a baseline for regulatory compliance. Following the implementation of the clinical engineering department, key actions included the appointment of specialized staff, the creation of internal policies, and the adoption of management systems. In 2021, a final audit was conducted to evaluate the effectiveness of these interventions.

To assess the statistical significance of the observed improvements, we compared regulatory compliance rates between the 2017 and 2021 audits using a two-sample Z-test for proportions. Although both audits assessed the same set of 423 regulatory standards, they were conducted 4 years apart under distinct operational conditions and with separate data collection processes. Given

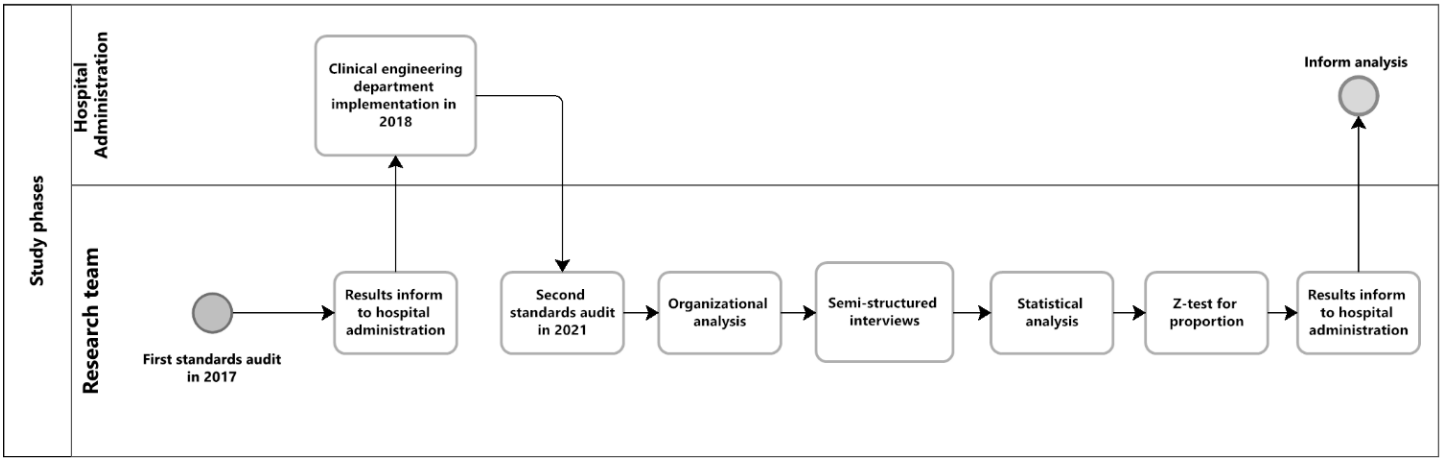

FIGURE 1. Study methodology outlining the main phases of the intervention, including baseline audit, implementation of the clinical engineering department, follow-up audit, and staff perception analysis.

the absence of item-level longitudinal tracking, the audits were treated as independent cross-sectional evaluations. We recognize that this method assumes independence and may slightly underestimate the standard error. A 95% confidence interval for the change in compliance proportion was also calculated. This methodology provides a model that can be replicated by other institutions facing similar challenges in medical technology management and regulatory compliance. The results offer empirical evidence on how the integration of clinical engineering contributes to enhancing hospital safety, operational efficiency, and regulatory alignment.

RESULTS

Normative Assessment

In the emergency department, regulatory compliance showed significant improvement between 2017 and 2021. During the initial evaluation in 2017, compliance was at 49%, while by 2021, it increased to 91%. This improvement was achieved through targeted interventions in critical infrastructure and processes, particularly regulatory compliance with key standards such as NOM-016-SSA3-2012 and NOM-025-SSA3-2013. These advancements are summarized in Table 2, which consolidates compliance data for the emergency department, intensive care unit (ICU), and the overall hospital level between 2017 and 2021

TABLE 2. Summary of regulatory compliance improvement in key hospital areas between 2017 and 2021.

Area/Level	2017 Compliance (%)	2021 Compliance (%)	Change (%)
Emergency Department	49	91	+ 42
Intensive Care Unit (ICU)	39	79	+ 40
General Hospital	54.61	78.72	+ 24.11

Note: The emergency department and ICU showed the most substantial gains, with increases of 42% and 40%, respectively. The overall hospital compliance improved by 24.11%, reflecting the impact of structured interventions in infrastructure, equipment management, and process standardization.

In the case of the ICU, the initial situation also presented significant deficiencies, with regulatory compliance at 39% in 2017. Following the implementation of corrective actions, including infrastructure improvements and strengthened operational protocols, compliance reached 79.27% in 2021. This progress highlights the importance of prioritizing standards related to critical infrastructure, particularly NOM-025-SSA3-2013. These values are included in Table 3, highlighting the ICU's significant improvement alongside other key hospital areas.

TABLE 3. Regulatory compliance with NOM-016-SSA3-2012 and NOM-025-SSA3-2013 in the intensive care unit.

Standard	Evaluated Standards	Compliant	Non-compliant	Percentage
NOM-016-SSA3-2012	59	50	9	84.75%
NOM-025-SSA3-2013	23	15	8	65.22%
Total	82	65	17	79.27%

Note: Compliance improved to 84.75% and 65.22%, respectively, following the implementation of corrective actions in infrastructure, safety protocols, and medical device oversight. The combined compliance rate for both standards reached 79.27%.

At the general level, the hospital's regulatory compliance increased from 54.61% in 2017 to 78.72% in 2021, evaluating a total of 423 regulatory standards. This corresponds to an increase from 231 regulatory standards of compliance in 2017 to 333 regulatory standards of compliance in 2021, reflecting an absolute improvement of 102 items. This significant progress resulted from strategic interventions in the most critical areas, such as the emergency department and ICU, as well as the implementation of corrective measures related to standards like NOM-016-SSA3-2012 and NOM-025-SSA3-20. The overall evolution of regulatory compliance is also reflected in Table 2, providing a comparative overview of key improvements across hospital areas.

Furthermore, an analysis of noncompliances by type revealed that 63% of deficiencies were related to materials,

34% to infrastructure, and only 3% to processes. This breakdown allowed prioritization of areas with the greatest potential impact on hospital safety and operability. Details of this distribution are shown in Figure 2 (Breakdown of noncompliances by type).

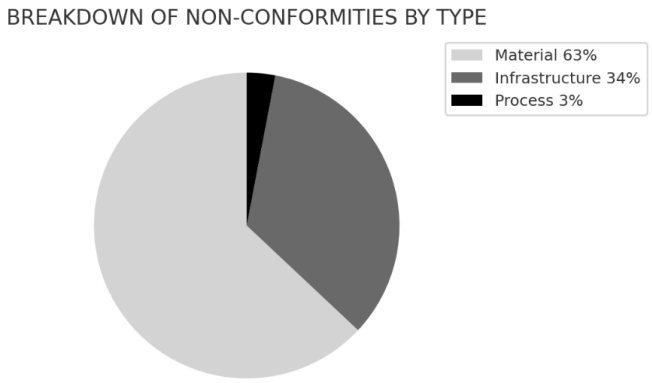

FIGURE 2. Distribution of noncompliances by type in the 2017 audit. Material-related issues represented 63%, infrastructure 34%, and process-related only 3%, guiding targeted corrective actions.

A Pareto analysis demonstrated that addressing deficiencies related to NOM-016-SSA3-2012 and NOM-027-SSA3-2013 would resolve over 80% of the identified noncompliances. This highlights the criticality of these standards in achieving overall regulatory adherence and improving hospital performance. The Pareto distribution is presented in Figure 3.

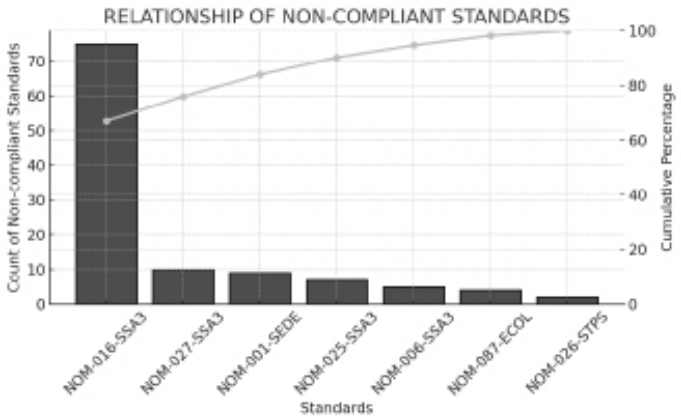

FIGURE 3. This chart illustrates the distribution of noncompliant standards, highlighting the most critical areas for improvement.

NOM-016-SSA3 accounts for the highest number of noncompliances, significantly impacting overall compliance. The cumulative percentage curve indicates that addressing the top three noncompliant standards—NOM-016-SSA3, NOM-027-SSA3, and NOM-001-SEDE—would resolve a majority of regulatory gaps.

Overall, the results demonstrate how the most critical areas, such as the emergency department and ICU, served as examples of the impact that implementing a clinical engineering department can have. These advancements contributed significantly to improving overall regulatory compliance and provided a roadmap that can be replicated by other institutions with similar characteristics.

Statistical Analysis: Impact of the Clinical Engineering Department on Regulatory Compliance

To determine whether the observed improvement in regulatory compliance was statistically significant, we conducted a two-sample Z-test for proportions. This test evaluated whether the difference in compliance between 2017 (prior to the implementation of the clinical engineering department) and 2021 (following its implementation) was due to chance or represented a meaningful improvement.

Hypothesis Formulation

Null hypothesis (H_0): There is no significant difference in regulatory compliance between 2017 and 2021 ($p_1 = p_2$).

Alternative hypothesis (H_a): There is a significant difference in regulatory compliance between 2017 and 2021 ($p_1 \neq p_2$).

Statistical Test and Results

Using the total number of regulatory standards evaluated in both years ($n_1 = n_2 = 423$), the proportion of compliant standards was calculated:

$$2017: p_1 = \frac{231}{423} = 54.61\% \quad (1)$$

$$2021: p_1 = \frac{333}{423} = 78.72\% \quad (2)$$

A two-tailed Z-test for proportions was performed at a 95% confidence level, yielding the following results:

- Z-score = 7.44
- Critical value ($Z_{critical}$): ± 1.96
- p-value: 8.96×10^{-14}
- Confidence interval (95%) for the difference in proportions: 24.11% (95% CI: 17.95% to 30.27%)

Since the Z-score (7.44) exceeds the critical value (1.96) and the p-value is significantly lower than 0.05, we reject the null hypothesis. This indicates that the increase in regulatory compliance is statistically significant and unlikely to be because of random variation.

However, although the same set of standards was assessed in both audits, the lack of item-level tracking and the 4-year interval justified the use of an approximate method based on cross-sectional comparisons. This limitation is further discussed in the Discussion section.

Interpretation and Conclusion

The statistical analysis confirms that the implementation of the clinical engineering department had a measurable impact on regulatory compliance. The rate of compliance increased from 54.61% in 2017 to 78.72% in 2021, a difference of 24.11 percentage points. This change was found to be statistically significant ($Z = 7.44$, $p < 0.001$), with a 95% confidence interval ranging from 17.95% to 30.27%, indicating that the observed improvement is unlikely to be because of random variation.

Although the same set of regulatory standards was assessed in both audits, the absence of item-level tracking and the time gap between evaluations justified the use of a cross-sectional approximation. This finding aligns with improvements observed in critical areas, such as the emergency department and the ICU, further enhancing hospital regulatory performance and ensuring sustained improvement of quality.

Results of the Organizational Analysis

Organizational analysis was conducted through qualitative interviews with collaborators from the administration, clinical engineering, and hospital management areas. Key areas of inquiry included the organizational structure, departmental responsibilities, and the impact of new processes implemented by the clinical engineering department. The investigated aspects are summarized below:

Investigated Aspects

1**. Structure:** Reviewed current and previous organizational charts, departmental hierarchy, and participation in strategic activities such as acquisitions and decision-making.

2. Responsibilities: Analyzed the current and delegated responsibilities of the clinical engineering department.

3. Processes: Compared operational processes before and after the creation of the department, focusing on the changes implemented and interdepartmental impacts.

The analysis revealed the following findings:

1. Structural Challenges: The hospital lacks a formally defined and approved organizational chart. The clinical engineering department operates with dual roles, contributing to strategic functions such as technology evaluation and acquisitions, while simultaneously managing operational tasks like equipment repairs and supplier management. This duality often limits the department's ability to optimally focus on either strategic or operational tasks.

2. Limited Strategic Participation: Although the clinical engineering department is integral to specific decisions, such as technology acquisitions, its participation in high-level meetings is restricted. This limits its ability to influence broader hospital policies and initiatives.

3. Process Improvements: Before the creation of the department, different hospital areas managed equipment needs independently, leading to inconsistent approaches. The introduction of systematic routines, such as equipment verifications and staff training sessions, has standardized processes, improving equipment safety and operational efficiency.

A detailed representation of these findings is provided in Table 4, which illustrates the comparative roles of the department before and after its formal establishment.

This analysis underscores the critical need for institutional support to address structural and strategic gaps, enabling the department to maximize its contributions to hospital operations and patient safety.

Results of the Situational Analysis

The situational analysis was conducted to assess the level of knowledge and perception among hospital staff regarding the clinical engineering department. Key stakeholders from administration, technical staff, and clinical personnel were included to provide a comprehensive view of the department's relevance and performance in hospital operations.

Interviews were conducted anonymously with staff from all operational shifts, including weekends, to ensure a representative sample across the hospital. A total of 15 staff members, covering all technical staff, two administrative personnel, and a diverse portion of the clinical team participated. Based on staffing estimates, this sample represents approximately 40–50% of the total hospital workforce.

Interview questions focused on staff perception of equipment management, operational efficiency, and safety culture, including prompts such as: "What changes have you noticed in equipment availability?" or "How would you rate the department's support in your daily work?"

Awareness and Understanding

Most respondents (93%) were aware of the department's existence, and 87% understood its core functions. These results highlight a generally high level of visibility, though the gap between awareness and understanding suggests a potential opportunity to strengthen internal communication.

Perceived Contribution and Necessity

Participants broadly recognized the department's value, with 84% rating its contribution to workplace safety as "Significant" or "Considerable". Furthermore, 80% considered the clinical engineering department to be "Significantly" or "Considerably" necessary for hospital operations (Figure 4).

TABLE 4. Comparison of the clinical engineering department's role before (2017) and after (2021) its formal implementation.

Point of Analysis	Before Implementation (2017)	After Implementation (2021)
Structure	No defined or authorized organizational chart. Previous charts were unavailable, and the department lacked a clear position within the hospital. Its participation in strategic decisions was limited.	The clinical engineering department now has a mixed hierarchy, combining strategic and operational levels. It participates in technology evaluations and acquisitions, although its presence in management meetings remains limited.
Responsibilities	No formal assignment of responsibilities. Decisions regarding medical equipment were made in a dispersed manner across different areas without a defined responsible party.	The clinical engineering department now plays a key role in medical equipment management and contributes knowledge in infrastructure and regulations. It collaborates with other areas such as quality, administration, and IT.
Processes	Corrective maintenance was handled by various areas without a designated responsible party. There were no structured verification routines or training plans for the use of medical devices.	The clinical engineering department now supervises maintenance, provides medical equipment training, and ensures regulatory compliance, consolidating more structured and efficient processes.

Note: Key improvements include a defined organizational structure, clearer responsibilities, and more structured processes for the management of medical equipment and regulatory compliance.

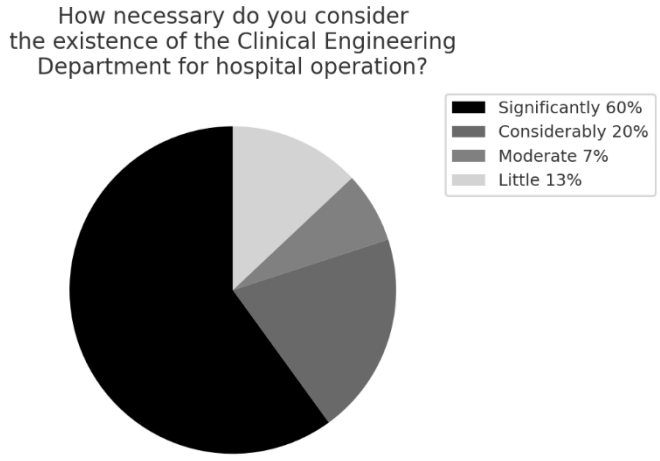

FIGURE 4. Perceived necessity of the clinical engineering department for hospital operations.

A total of 80% of respondents considered the department to be "Significantly" (60%) or "Considerably" (20%) necessary for the hospital's functioning, while only 7% selected "Moderate" and 13% "Little". These results highlight the strategic value attributed to the department by the hospital staff.

Staff Satisfaction

Satisfaction with the performance of the department was high: 86% rated it as "Very Good" or "Good", while only 14% rated it as "Fair" or "Poor". This overall positive perception reinforces the credibility of the department within the institution, though there is room for improvement in specific areas such as clinical training on equipment use.

Summary of Results

The full set of response distributions is summarized in Table 5, showing detailed percentages across each topic assessed.

TABLE 5. Summary of staff perceptions regarding the clinical engineering department.

Topic	Response Options	Result (%)
Awareness of CE Department existence	Yes/No	93% | 7%
Awareness of CE Department functions	Yes/No	87% | 13%
Contribution to workplace safety	Significant/ Considerable/ Moderate/ Low	50% | 34% | 8% | 8%
Necessity for hospital operations	Significant/ Considerable/ Moderate/ Low	60% | 20% | 7% | 13%
Evaluation of CE staff performance	Very Good/Good/ Fair/Poor	46% | 40% | 7% | 7%

Note: The table presents the response distributions for key dimensions evaluated in the situational analysis, including awareness, perceived contribution, institutional necessity, and performance evaluation. Percentages reflect the proportion of respondents selecting each option in a sample representing approximately 40–50% of the hospital workforce.

DISCUSSION

This methodology provides a model that can be replicated by other institutions facing similar challenges in medical technology management and regulatory compliance. The results offer empirical evidence on how the integration of clinical engineering contributes to enhancing hospital safety, operational efficiency, and regulatory alignment.

The findings of this study provide clear evidence of the positive impact that the implementation of a clinical engineering department has on regulatory compliance, operational efficiency, and staff perception in a secondary-level hospital in Mexico. The increase in regulatory compliance from 54.61% in 2017 to 78.72% in 2021 is a direct result of structured processes in medical technology management, infrastructure audits, and staff training.

The improvement in adherence to Mexican Official Standards (NOMs) is one of the key outcomes of this study.

The application of critical standards such as NOM-016-SSA3-2012 and NOM-025-SSA3-2013 has been fundamental in strengthening hospital safety. A deeper analysis of noncompliance issues showed that 63% of deficiencies were related to materials, 34% to infrastructure, and only 3% to processes, indicating that most problems can be addressed through investments in equipment and structural maintenance.

The observed improvement in regulatory compliance reflects a meaningful institutional change following the implementation of the clinical engineering department. While statistical analysis supports this interpretation, the absence of item-level tracking and the 4-year gap between assessments required treating both audits as independent observations. This approach, though limited, was methodologically justified as a cross-sectional approximation.

A Pareto analysis further demonstrated that addressing deficiencies in just three key standards (NOM-016-SSA3, NOM-027-SSA3, and NOM-001-SEDE) would resolve over 80% of the identified regulatory compliance issues, highlighting the importance of a strategic approach in prioritizing regulatory efforts.

Beyond regulatory compliance, the creation of the clinical engineering department has driven significant organizational changes. The standardization of procedures and the introduction of periodic equipment verifications have strengthened patient safety and operational efficiency. However, structural challenges remain, particularly regarding the department's integration into high-level hospital decision-making.

Despite its critical role in medical technology management, the clinical engineering department continues to operate under a hybrid model, balancing both operational and strategic responsibilities. This dual role may limit its ability to influence high-level decisions and maximize its potential impact on the quality of hospital service.

The semi-structured interviews reflect a high level of acceptance and recognition of the department among hospital staff. A total of 93% of respondents acknowledged the department's existence, 87% understood its functions, while 84% considered it essential or significantly necessary. This level of recognition suggests that the work of the department has generated a tangible impact on organizational culture and the perception of hospital safety. However, the results also revealed areas for improvement. Fourteen percent of respondents perceived the department's performance as "fair" or "poor", suggesting that certain aspects, particularly in training and communication with clinical and administrative staff, require further optimization.

Although the findings are encouraging, the applicability of this model to other types of healthcare institutions requires further consideration. While the results of this study are promising, they must be interpreted within the context of a small, secondary-level hospital with a capacity of 10 beds. The operational dynamics, staffing patterns, and regulatory oversight in such a facility differ significantly from those in larger hospitals with higher patient volume, broader departmental structures, and more complex governance systems. However, the structured methodology used for implementing the clinical engineering department—focusing on regulatory alignment, equipment management, and process standardization—offers a foundation that can be replicated and adapted to institutions of greater scale. Future multisite studies, particularly those involving tertiary care hospitals and diverse healthcare systems, would provide valuable comparative data to validate and refine the model presented in this study.

It is also important to consider the broader healthcare context in which this study was conducted. Between 2019 and 2021, the COVID-19 pandemic introduced unprecedented changes in hospital operations, resource allocation, and regulatory enforcement. These changes may have influenced the results observed in the post-implementation audit, particularly in critical departments such as the ICU and emergency room, which were directly impacted by the pandemic. While the observed improvement in regulatory compliance can largely be attributed to the establishment of the clinical engineering department, it is possible that heightened regulatory scrutiny, emergency preparedness protocols, and resource mobilization related to COVID-19 contributed in part to this progress. However, the absence of a parallel audit in a comparable

hospital without a clinical engineering department limits the ability to isolate these external influences. Future studies incorporating multicenter comparisons could help clarify the independent effect of clinical engineering interventions under varying external conditions.

Despite these positive results, this study has certain limitations. The analysis was conducted in a single secondary-level hospital, which may limit the generalization of the findings to other healthcare settings. In addition, although the same 423 standards were evaluated in both audits, they were assessed independently without item-level tracking. This limits the ability to apply paired-data statistical tests such as McNemar's test, which could have provided a more precise estimation of the intervention's effect. Future research should consider structured item-by-item longitudinal tracking to enable the use of paired analyses and strengthen the causal attribution of observed improvements. Furthermore, while the study included both quantitative and qualitative methods, future research could benefit from a longer follow-up period to assess the sustainability of the implemented improvements.

The implementation of a clinical engineering department has proven to be an effective strategy for enhancing regulatory compliance, optimizing processes, and strengthening hospital safety. The statistical validation and confidence interval analysis confirm that the impact of the intervention is both meaningful and statistically significant. To maximize its long-term contribution, it is essential to promote the department's integration into hospital governance and ensure its consolidation as a strategic actor within the organizational structure. This study provides a transferable model that may inform future initiatives aimed at strengthening healthcare systems in Mexico and other developing regions.

CONCLUSIONS

This study provides strong empirical evidence that the implementation of a clinical engineering department in a secondary-level hospital in Mexico significantly improves regulatory compliance, operational efficiency, and staff perception of hospital safety. The increase in compliance with Mexican Official Standards (NOMs) from 54.61% in 2017 to 78.72% in 2021 demonstrates the effectiveness of structured interventions in medical technology management, infrastructure standardization, and staff training.

These findings reinforce the effectiveness of the intervention and its direct impact on regulatory performance. Although both audits assessed the same set of standards, they were conducted under different operational conditions and without item-level tracking, warranting the use of a cross-sectional approach. Future studies should apply paired-data statistical methods—such as McNemar's test—supported by longitudinal tracking, to strengthen the attribution of observed improvements.

Beyond compliance metrics, the study highlights the positive impact of the department on hospital workflows and organizational structure. The standardization of medical equipment management and verification processes contributed to a safer and more efficient hospital environment. However, despite these improvements, the department's limited participation in strategic decision-making remains a challenge that could hinder its long-term effectiveness.

Staff perception of the clinical engineering department was overwhelmingly positive, with 93% of the hospital personnel acknowledging its role and 86% rating its performance as "Good" or "Very Good". However, the study also identified areas for further optimization, particularly in training programs and internal communication strategies to ensure a deeper understanding of the functions and contributions of the department.

The findings suggest that the successful integration of clinical engineering into hospital systems can serve as a model that can be replicated by other healthcare institutions facing similar challenges in regulatory compliance and medical equipment management. However, for long-term sustainability, hospitals must ensure institutional support, continuous staff training, and periodic evaluations to maintain compliance and drive continuous improvement.

Although this study presents a compelling case for the role of clinical engineering in hospital optimization, it is not without limitations. The research was conducted in a single hospital, which may limit the generalizability of

its findings. In addition, the lack of paired data prevents the use of more precise statistical methods that account for dependency across time points. Future research could benefit from broader sampling, item-level tracking, and longer follow-up periods to further validate and expand upon these results.

In conclusion, the integration of a clinical engineering department significantly enhances hospital compliance, operational processes, and safety perceptions. To fully capitalize on its benefits, hospital administrations must ensure strategic inclusion of clinical engineers in decision-making processes, adequate resource allocation, and long-term institutional commitment. These measures will be crucial for consolidating the department's role as a fundamental pillar in hospital quality and patient safety in Mexico and beyond.

AUTHOR CONTRIBUTIONS

Conceptualization, G.C.E. and R.P.L.A.; **Methodology,** G.C.E.; **Validation**, G.C.E., R.P.L.A., and V.G.A.; **Formal Analysis,** G.C.E.; **Investigation**, G.C.E. and R.P.L.A.; **Resources**, V.G.A.; **Data Curation**, G.C.E.; **Writing – Original Draft Preparation**, G.C.E.; **Writing – Review & Editing**, R.P.L.A. and V.G.A.; **Visualization**, R.P.L.A.; **Supervision**, G.C.E.; **Project Administration**, G.C.E.

ACKNOWLEDGMENTS

The authors would like to thank engineer Daniela Castro for her invaluable support during the execution of this study.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Because of ethical and institutional restrictions, the datasets generated during this study are not publicly available.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest related to this study.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study did not involve human subjects, animals, or identifiable personal data. Ethical approval was not required.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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Received January 3 2024, accepted June 9 2025, date of publication September 2 2025.

Original Research Article

Characterization of Odor Profiles Through the Simplified Binary Matching Algorithm for Disease Diagnostics

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ABSTRACT

Background and Objective: This study investigates the characterization of body odor signatures for early disease detection, aiming to demonstrate the feasibility of using simulated olfactory profiles within a computational diagnostic framework. The motivation arises from the growing interest in non-invasive diagnostic alternatives based on volatile organic compounds (VOCs) emitted by the human body. **Materials and methods:** A simulation-based approach was implemented using validated VOC datasets to construct binary odor profiles. These profiles were encoded as binary vectors, with each bit indicating the presence or absence of a specific compound. A simplified binary matching algorithm, excluding mutation and crossover operations, was employed to simulate pattern matching. The Hamming distance was used as the fitness function to quantify the similarity between profiles. **Results and Discussion:** The results indicate that the simplified binary matching algorithm reliably identified pathological odor profiles, producing high similarity scores with reference signatures. Despite the absence of conventional genetic operators, the method consistently converged to optimal or near-optimal matches. These findings emphasize the potential of binary odor encoding for distinguishing between healthy and pathological states, underscoring the robustness of the simplified computational framework. **Conclusion:** This work presents a novel and interpretable computational model for olfactory-based disease detection using simulated binary VOC patterns. It supports the development of low-cost, non-invasive diagnostic tools in medical contexts. Future research should explore extending the method by incorporating continuous VOC encoding, integrating evolutionary operators, and validating the results with semi-experimental or clinical data.

Keywords—*Body odors, Diseases, Early detection, computational diagnostics, Simplified binary matching algorithm, Volatile organic compounds (VOCs).*

INTRODUCTION

The improvement of early disease detection methods is of crucial importance for public health.[1] Traditional approaches to medical diagnosis may be limited by cost, accessibility, and reliability. In this context, research is increasingly focusing on innovative methods based on artificial intelligence to enhance disease detection and prevention.[2] The genetic algorithm, an artificial intelligence technique inspired by the principles of natural evolution, holds promising potential in the field of early disease detection. By leveraging the adaptive and evolutionary capabilities of living organisms, this algorithm optimizes solutions for complex problems.[3]

In this context, this article examines the application of the genetic algorithm for early disease detection, with a specific focus on analyzing body odors composed of volatile organic compounds (VOCs). Recent research suggests that certain diseases can alter specific odor profiles of the human body,[4] providing an opportunity to use olfactory information as an early indicator of health issues.

The objective of this article is to present a methodology based on a simplified pattern-matching algorithm, inspired by the principles of genetic algorithms, for analyzing body odors and detecting diseases at an early stage. Unlike conventional genetic algorithms that incorporate selection, crossover, and mutation operations, the method implemented here deliberately omits these evolutionary components. Instead, it evaluates binary-encoded odor profiles using Hamming distance to identify the closest match to a target profile. This simplification aims to enhance interpretability, reproducibility, and computational efficiency within a purely simulation-based framework. By integrating expertise in genetics, artificial intelligence, and medicine, this approach could contribute to revolutionizing medical diagnostic methods by enabling faster, more accurate, and less invasive disease detection.

LITERATURE REVIEW

Body Odors

Volatile organic compounds (VOCs) are chemical substances released by the human body, playing a significant role in body odor.[5,6] In ancient societies, body odors were more prevalent and accepted, regarded as part of individual and social identity. Over time, attitudes toward body odor have evolved alongside scientific advances and social norms.[7] In medieval Europe, body odor was associated with notions of sin and decadence due to religious beliefs, and perfumes were commonly used to mask undesirable odors. In the modern era, hygiene and cleanliness became priorities, leading to the development of personal care products to control body odor. However, these products may alter natural odors by adding fragrances.[8] Recently, certain movements have advocated for the acceptance of natural body odor, and challenged social norms that aim to eliminate it. Body odors vary among individuals due to various factors, and perceptions of body odor differ across cultures.[9]

Early Detection of Diseases

The early detection of diseases plays a crucial role in preserving health and well-being. It enables prompt intervention by identifying early signs and symptoms, leading to more favorable outcomes in terms of treatment, management, and even cure.[10] Numerous benefits are associated with the early detection of diseases.[11] Firstly, it allows for rapid medical intervention, helping prevent disease progression and reduce potential complications.[12] Secondly, it increases the likelihood of treatment success, as interventions are often more effective when administered at an early stage of the disease. Additionally, it helps reduce long-term healthcare costs, as early treatments are typically less invasive and less expensive than those required at an advanced stage of the disease.[13]

To detect diseases early, various methods are employed. Regular screenings and health examinations are essential for identifying early signs of common diseases such as breast, cervical, and colon cancers. Technological advancements have led to the development of sophisticated blood tests and medical imaging techniques, which can aid in detecting diseases at an early stage, even in the absence of apparent symptoms.[14] Furthermore, genetics and personalized medicine have opened new possibilities by identifying genetic markers associated with certain conditions.[15]

Early disease detection helps limit potential complications, improve patients' quality of life, and reduce the burden on healthcare systems.[12,16]

Genetic Algorithm

Genetic Algorithms (GAs) were first described by John Holland in the 1960s and later developed by him, his students, and colleagues at the University of Michigan during the 1960s and 1970s. Holland's objective was to understand the phenomenon of adaptation as it occurs in nature and to develop methods for incorporating the mechanisms of natural adaptation into computer systems.[17]

The genetic algorithm (FIGURE 1) is a computational approach inspired by the process of biological evolution. It is a search and optimization method based on the principles of natural selection and genetics. Genetic algorithms are widely applied to solve complex problems in various fields, including engineering, optimization, artificial intelligence, and bioinformatics.[18,19]

The genetic algorithm operates by simulating an artificial evolution process, in which an initial population of individuals (often represented by bit strings) is randomly generated. Each individual in the population is evaluated based on its performance relative to a specific goal defined by an evaluation function.[20]

The crucial step in the genetic algorithm is selection. The fittest individuals, i.e., those with the best performance, are chosen to reproduce and produce offspring. This selection is typically based on a method called "fitness-proportional selection", in which the probability of selection is proportional to the fitness value of each individual.[17,21,22]

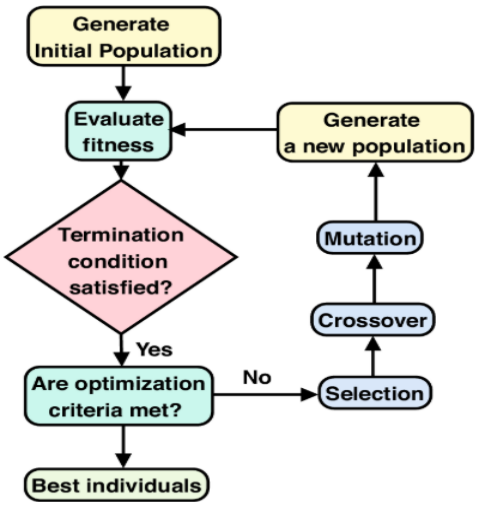

FIGURE 1. General workflow of a canonical genetic algorithm.[23]

Once selection is complete, genetic operations are applied to the offspring. These operations include recombination (crossover) and mutation. Recombination involves combining the genetic information of two selected individuals to create new individuals, while mutation introduces random changes in individuals to explore new potential solutions.[17,21,22] This process of selection, recombination, and mutation is repeated over several generations, allowing the population to gradually converge toward increasingly optimal solutions. The genetic algorithm may also incorporate techniques such as elitism, which involves retaining the best individuals from one generation to the next to ensure faster convergence.[17,21,22]

MATERIALS AND METHODS

Materials

We utilized the Human Metabolome Database (HMDB) to obtain detailed information on small-molecule metabolites present in the human body. The objective was to apply this information for biomarker discovery applications.[24,25]

Additionally, we relied on the work of reference[26], which cataloged over 1,800 volatile organic compounds emitted by the body of a healthy individual. We also consulted the Cancer Odor Database (COD), an online resource documenting known volatile organic metabolites of cancer (VOMC), commonly referred to as "cancer odors".[27]

Finally, Broza et al. [28] highlights the increasing importance of developing new diagnostic and detection technologies to address growing clinical challenges. It emphasizes a new diagnostic frontier based on detecting disease-associated volatile organic compounds (VOCs) using sensors that employ nanomaterials.

Population Dataset Construction

To construct the initial population used in our simulations, we compiled a comprehensive dataset of 2,571 volatile organic compounds (VOCs) from authoritative sources, including the Human Metabolome Database (HMDB), the Cancer Odor Database (COD), and peer-reviewed literature, such as the catalog published by.[26] Each VOC was annotated with a unique CAS number and labeled according to its known association with physiological or pathological states, including various cancer types and healthy conditions.

This dataset served as the basis for generating 25 distinct binary vectors, each representing a specific simulated odor signature associated with a defined condition. The encoding process involved mapping the presence (1) or absence (0) of each of the 2,571 VOCs for every condition, resulting in uniform-length binary chromosomes. These chromosomes were stored and processed as the initial population from which the algorithm searched for the best match to a given target.

The structured nature and dimensional richness of this population enabled meaningful comparison and pattern recognition through Hamming distance evaluation. Importantly, the dataset was constructed to balance diversity (in terms of represented conditions) and consistency (in binary structure), ensuring that the algorithm operated within a representative yet tractable search space.

Methods

The method employed for disease detection is the simplified binary matching algorithm, which encompasses five phases.

Phase 1: Individual Representation

Each individual, denoted by Equation 1, is symbolically characterized by a chromosome—a structured sequence of fixed-length binary digits that corresponds to the quantity of volatile organic compounds (VOCs) defining the olfactory profile. The chromosome is mathematically expressed as:

$$Chromosome_i = [v_{i1}, v_{i2}, \ldots, v_{in}] \quad (1)$$

Within the confines of this representation (Equation 1), each element v_{ij} (Equation 2) is discretized into a binary bit, serving as an indicator of the presence or absence of a specific VOC. This binary encoding is represented by the formula:

$$v_{ij} = \begin{cases} 0, If\ the\ VOC\ is\ not\ present \\ 1, If\ the\ VOC\ is\ present \end{cases} \quad (2)$$

where $v_{i1}, v_{i2}, \ldots, v_{in}$, represent the elements of the chromosome for sample i, v_{ij} denotes the presence (1) or absence (0) of the j_th VOC, n is the total number of VOCs considered, and $i=1,2, \ldots, N$ indexes the sample.

Consequently, the collective exposition of equations (Equation 1) and (Equation 2) coherently explicates the chromosome's nature as a combination of binary units, delineating the presence or absence of VOCs within the context of individual representation. v_{ij} is the binary variable indicating the state of the j_th VOC in the i_th chromosome.

Phase 2: Evaluation Function

An evaluation function assigns a value, or fitness score, to each chromosome based on its ability to solve the given problem. In this study, the Hamming function serves as the objective function (Equation 3), calculating the distance between the desired solution and the candidate solution within the population.

$$f\left(Chromosome_i, Chromosome_s\right) = -\sum_{j=0}^{N-1} Abs(Chromosome_{ij} - Chromosome_{sj}) \quad (3)$$

where $Chromosome_s$ denotes the binary vector representing the i_th individual (candidate solution) in the population, $Chromosome_s$ the target chromosome corresponding to the reference (disease) profile, and f ($Chromosome_s$, $Chromosome_s$) the fitness function measuring their similarity. The term Abs($Chromosome_{ij}$, $Chromosome_{sj}$)defines the absolute difference between the candidate and the target at the position j , while the summation counts $\sum_{j=0}^{N-1} Abs(Chromosome_{ij} - Chromosome_{sj})$ the total number of mismatches between the two binary vectors.

In our implementation, the fitness score is defined as the negative Hamming distance between the target profile and each candidate in the population. This transformation (multiplication by −1) enables the interpretation of higher scores—values closer to zero—as better matches, while preserving the relative ranking of similarity. A score of 0 represents a perfect match, whereas increasingly negative scores indicate greater dissimilarity.

Phase 3: Population Initialization

We initialized the population with binary data imported from a specially prepared Excel file, following the methodology described in previous studies.[24–26,28] These data define the search space for disease identification, representing the presence or absence of volatile organic compounds (VOCs) associated with specific conditions

Phase 4: Main Loop of the Algorithm

The main loop of the algorithm concluded when the predefined termination criterion was met, which in our case was a fixed number of iterations equal to the population size.

Phase 5: Results Analysis

This phase involves examining the individuals to identify those that correspond to the best solution found and extracting relevant information from them to address our problem.

FIGURE 2 illustrates the workflow of a simplified pattern-matching algorithm that identifies the binary individual within a given population that best matches a predefined target profile.

The procedure begins by initializing variables to store the best-known match, then iteratively evaluates the Hamming distance between each candidate chromosome and the target. Whenever a closer match is identified, the best candidate is updated. The algorithm concludes by returning the individual with the smallest distance to the target. This approach is deterministic, easily interpretable, and does not employ stochastic genetic operators such as crossover or mutation.

This flowchart (FIGURE 2) illustrates the sequence of steps in the proposed deterministic algorithm:

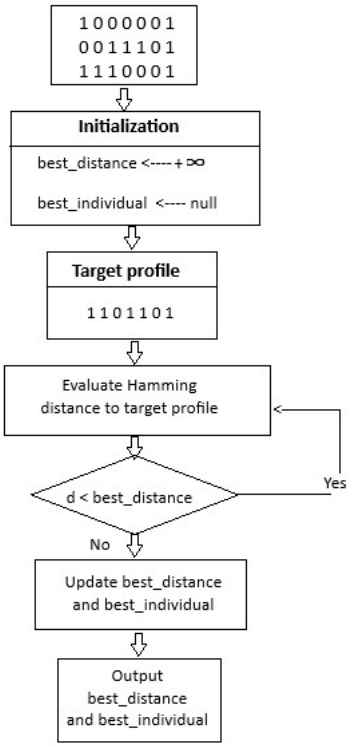

FIGURE 2. Workflow of the simplified binary matching algorithm.

1. Initialization of the binary-encoded population based on VOC presence/absence;

2. Comparison of each individual with a target profile using the Hamming distance;

3. Selection of the profile with the minimum distance as the optimal match.

The algorithm bypasses traditional genetic operations—such as selection, mutation, and crossover—and relies exclusively on distance-based evaluation.

FIGURE 3 presents the pseudocode for a simplified computational procedure designed to identify the individual within a binary population that most closely matches a given target profile. The method iteratively computes the Hamming distance between each chromosome and the target, updating the best match whenever a smaller distance is encountered. This approach enables efficient nearest-neighbor selection in discrete binary spaces while eliminating the need for evolutionary operators such as crossover or mutation.

RESULTS AND DISCUSSION

Results

The simplified binary matching algorithm, applied to early disease detection through body odor analysis, produced the following results:

Presentation of Data in Binary Form

We obtained data encoded in binary form, as illustrated in Figure 4, representing our search space.

```
Input: Population P = {Chromosome_1, ..., Chromosome_n}, Target_Profile
Best_Distance ← +∞
Best_Individual ← None

for each Chromosome_i in P:
    d ← Hamming_Distance(Chromosome_i, Target_Profile)
    if d < Best_Distance:
        Best_Distance ← d
        Best_Individual ← Chromosome_i

Output: Best_Individual, Best_Distance
```

FIGURE 3. Pseudocode for a simplified matching algorithm based on hamming distance.

	CAS-number	Compound name	Codes	Feaces	Urine	Breath	Skin	Milk	Blood	Saliva	...	Pancreatic_Cancer	Prostate_Cancer	Skin_Cancer	Synovial_Cancer	T
0	75-07-0	acetaldehyde	v1	1	1	1	1	1	1	1	...	0	0	0	0	
1	60-35-5	acetamide	v2	1	0	1	0	0	0	0	...	0	0	0	0	
2	64-19-7	acetic acid	v3	1	1	1	1	1	0	1	...	0	0	0	0	
3	140-11-4	acetic acid, benzyl ester	v4	0	0	0	1	0	0	1	...	0	0	0	0	
4	123-86-4	acetic acid, butyl ester	v5	1	0	1	0	0	0	0	...	0	0	0	0	
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	
2566	64-17-5	ethanol	v2567	0	0	0	0	0	0	0	...	0	0	0	0	
2567	598-58-3	methyl nitrate	v2568	0	0	0	0	0	0	0	...	0	0	0	0	
2568	598-58-3	Methyl nitrate	v2569	0	0	0	0	0	0	0	...	0	0	0	0	
2569	1330-20-7	xylene	v2570	0	0	0	0	0	0	0	...	0	0	0	0	
2570	100-41-4	ethylbenzene	v2571	0	0	0	0	0	0	0	...	0	0	0	0	

2571 rows × 30 columns

FIGURE 4. Binary encoding of VOCs related to body odor.

Best Individual and Fitness Score

The code outputs the best individual identified within the population of potential solutions—namely, the body odor sequence achieving the highest fitness score. This score, derived from the Hamming distance between the individual and the target sequence, facilitates the identification of the most effective profiles for disease detection based on body odor. Execution traces of the algorithm are presented in Figures 5–12.

Processing by our simplified binary matching algorithm on a randomly generated chromosome classified it as healthy, with a fitness score of −1,257 (FIGURE 5), indicating a high similarity to the healthy reference profile. The corresponding fitness scores for this case are shown in FIGURE 6.

Processing by the same algorithm on another randomly generated chromosome classified it as diseased, with a fitness score of −1,241 (FIGURE 7), indicating slightly lower similarity to the healthy reference profile. The corresponding fitness scores are presented in Figure 8. Within our search space, this chromosome is associated with breast cancer.

A diseased chromosome from the search space was processed using our simplified binary matching algorithm, which identified it with a fitness score of 0 (FIGURE 9).

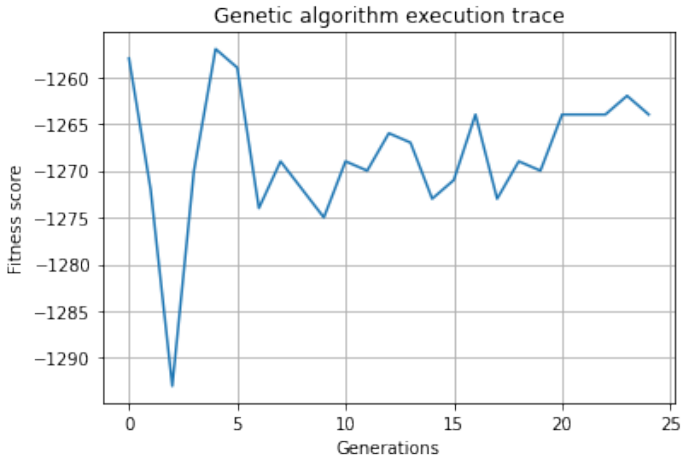

FIGURE 6. Fitness scores generated by a random healthy chromosome.

In our search space, this chromosome corresponds to an individual with neck cancer (FIGURE 10).

Regardless of the target chromosome, the simplified binary matching algorithm converges toward an optimal solution with an associated score. A score of 0 (FIGURE 1) indicates that the target chromosome is present in the solution space; otherwise, the algorithm identifies the chromosome in the space that is closer to the target than any other (FIGURE 2). The chromosome in the

```
target_sequence [0 1 0 ... 1 0 1]
Best individual : [1 0 1 ... 0 0 0]
Fitness score : -1257
Index found : 4
fitness_scores [-1258, -1272, -1293, -1270, -1257, -1259, -1274,
-1269, -1272, -1275, -1269, -1270, -1266, -1267, -1273, -1271,
-1264, -1273, -1269, -1270, -1264, -1264, -1264, -1262, -1264]
The closest line :
CAS-number                  Milk
75-07-0                        1
60-35-5                        0
64-19-7                        1
140-11-4                       0
...
64-17-5.4                      0
598-58-3                       0
598-58-3.1                     0
1330-20-7                      0
100-41-4.2                     0
Name: 6, Length: 2572, dtype: object
```

FIGURE 5. Algorithm trace for a random healthy chromosome.

```
target_sequence [1 0 1 ... 1 0 1]
Best individual : [0 0 0 ... 0 0 0]
Fitness score : -1241
Index found : 7
fitness_scores [-1296, -1284, -1301, -1322, -1291, -1277, -1288,
 -1241, -1284, -1265, 1279, -1274, -1274, -1277, -1269, -1269,
-1274, -1273, -1273, -1282, -1272, -1272, -1272, -1268, -1272]
The closest line :
CAS-number              Breast_Cancer
75-07-0                             0
60-35-5                             0
64-19-7                             0
140-11-4                            0
                                  ...
64-17-5.4                           0
598-58-3                            0
598-58-3.1                          0
1330-20-7                           0
100-41-4.2                          0
Name: 9, Length: 2572, dtype: object
```

FIGURE 7. Algorithm trace for a random diseased chromosome.

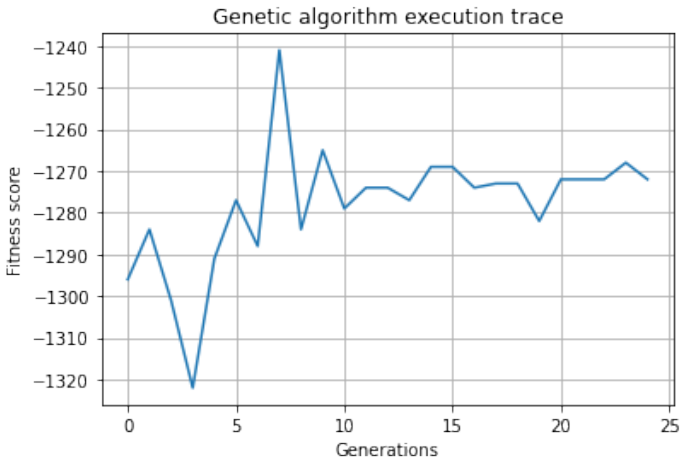

FIGURE 8. Fitness scores generated by a random diseased chromosome.

```
target_sequence [0 0 0 ... 0 0 0]
Best individual : [0 0 0 ... 0 0 0]
Fitness score : 0
Index found : 10
fitness_scores [-393, -291, -886, -543, -268, -168,
 -371, -94, -73, -62, 0, -35, -31, -42, -286, -28,
-17, -18, -20, -69, -23, -31, -45, -23, -15]
The closest line :
CAS-number     Head_Neck_Cancer
75-07-0                       0
60-35-5                       0
64-19-7                       0
140-11-4                      0
                    ...
64-17-5.4                     0
598-58-3                      0
598-58-3.1                    0
1330-20-7                     0
100-41-4.2                    0
Name: 12, Length: 2572, dtype: object
```

FIGURE 9. Algorithm trace for a selected diseased chromosome in the search space.

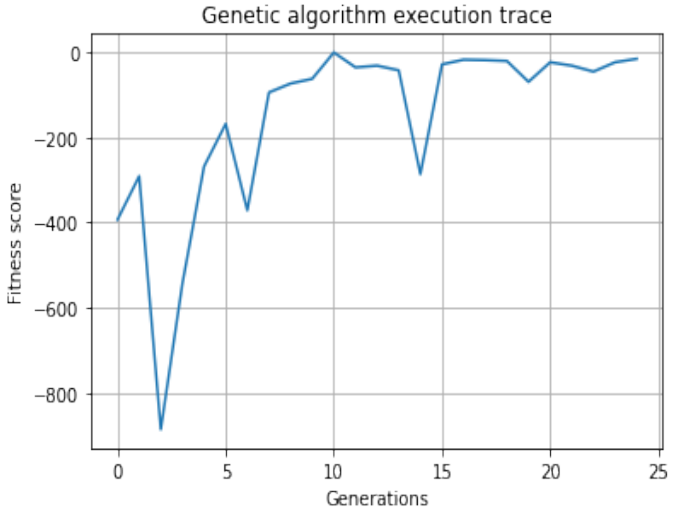

FIGURE 10. Fitness scores generated by a selected diseased chromosome with neck cancer in the search space.

space that is closer to the target than any other (FIGURE 2).Regardless of the target chromosome, the simplified binary matching algorithm converges toward an optimal solution with an associated score. A score of 0 (FIGURE 1) indicates that the target chromosome is present in the solution space; otherwise, the algorithm identifies the chromosome in the space that is closer to the target than any other (FIGURE 2).

Index of the Nearest Data Point

The code identifies the index of the nearest data point in the fitness score sequence. This index is then used to associate the corresponding data with additional information for results analysis. In our case, it links to detailed information about the volatile organic compounds associated with either a diseased or a healthy individual, as determined by their unique CAS identification number.

Fitness Scores

The code outputs the list of fitness scores for each individual in the population at every generation. This enables visualization of score evolution over time and facilitates tracking of the algorithm's progress in identifying the best individual. As the search space becomes more enriched, these scores are expected to improve.

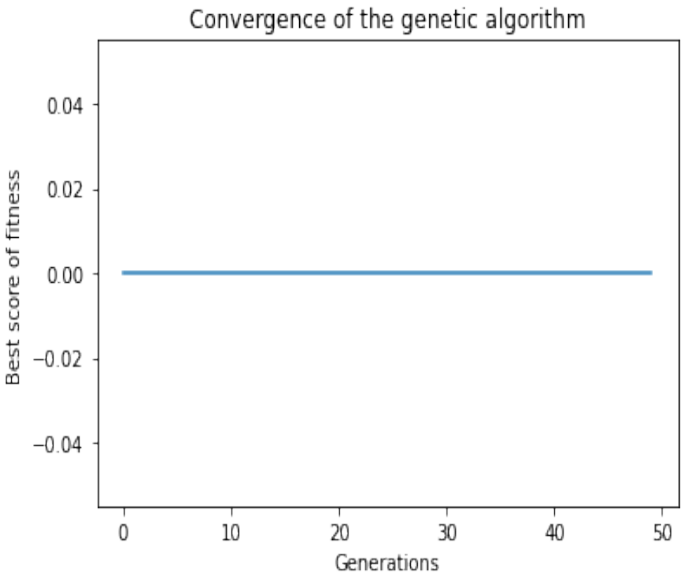

FIGURE 11. Convergence to zero of the algorithm for a target chromosome present in the search space.

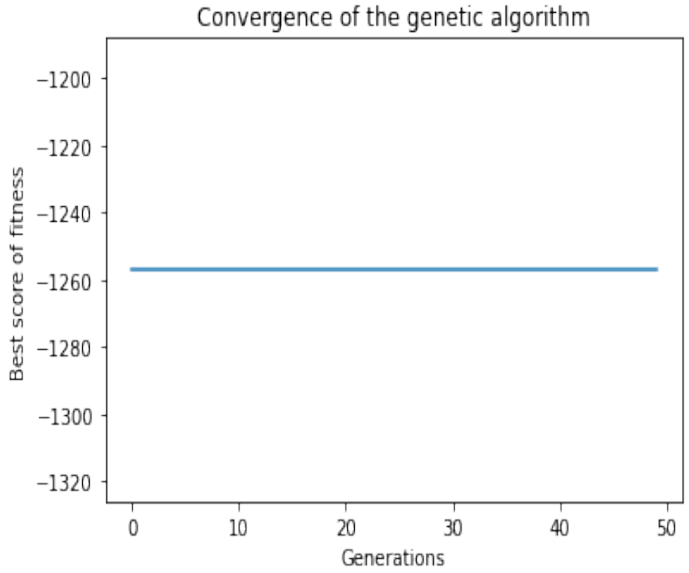

FIGURE 12. Convergence to a finite score of the algorithm for a target chromosome absent in the search space.

Nearest Line

The code retrieves information associated with the nearest data point from the Excel file used to generate the initial population. This allows for examining the specific details of that data and analyzing them in relation to the results of the simplified binary matching algorithm.

Algorithm Convergence

Regardless of the target chromosome, the algorithm converges towards an optimal solution.

DISCUSSION

By deliberately omitting evolutionary components such as selection, crossover, mutation, and replacement, the algorithmic procedure in this study deviates from conventional genetic algorithms, adopting instead a deterministic, pattern-matching framework. The resulting model functions solely through the initialization and evaluation of a predefined population of binary VOC profiles. Each individual in the population represents a potential solution encoded as a fixed-length binary vector, with evaluation performed using the Hamming distance as the fitness metric.

This simplified configuration enhances interpretability and reproducibility by avoiding the stochastic variability and convergence dynamics inherent in evolutionary systems. Although this design sacrifices the exploratory capabilities of classical genetic algorithms, it is well-suited for simulation scenarios in which the search space is predefined and fully enumerable.

To ensure that the dataset retained discriminatory power despite the absence of evolutionary mechanisms, we conducted a distributional analysis using the Hamming distance metric. This analysis assessed profile diversity and spatial separability within the binary encoding space. The results confirmed that the initial population preserved sufficient structural variability to support meaningful pattern recognition.

CONCLUSION

In conclusion, the simplified binary matching algorithm demonstrates significant potential for early disease detection based on body odors within medical diagnostics. Analysis of volatile organic compounds present in body odor offers valuable insights into an individual's health status. The study's results indicate a strong correlation between body odor profiles, volatile organic compounds, and disease presence, thereby opening new avenues for non-invasive and cost-effective diagnostic methods.

However, further studies and the establishment of standardized protocols are essential to validate this approach and ensure its clinical reliability. While the results

demonstrate the feasibility of body odor analysis for early detection of various diseases, additional research is necessary to improve the specificity and sensitivity of the method.

Integrating the simplified binary matching algorithm into body odor analysis offers the potential to optimize early disease detection, enabling faster and more effective medical intervention. Additionally, this non-invasive approach may enhance patient acceptance and participation.

Although inspired by the genetic algorithm paradigm, the implemented model diverges from traditional evolutionary computation by adopting a deterministic, non-stochastic structure. For clarity, the term "simplified binary matching algorithm" is used to reflect both its origins and methodological constraints.

Overall, the use of the simplified binary matching algorithm for early disease detection based on body odors presents promising new prospects in the medical field. This approach has the potential to improve treatment success rates by enabling early and accurate disease diagnosis.

AUTHOR CONTRIBUTIONS

Conceptualization, J.H. and K.A.; Methodology, J.H.; Software, J.H.; Hardware, J.H. and R.H.; Validation, J.H., R.H., and D.M.; Formal Analysis, J.H.; Investigation, J.H.; Resources, J.H.; Data Curation, J.H.; Writing–Original Draft Preparation, J.H.; Writing–Review & Editing, R.H. and D.M.; Visualization, J.H.; Supervision, K.A.; Project Administration, K.A.; Funding Acquisition, D.M.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interest.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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Received April 23, 2024, accepted June 2, 2025, date of publication September 10, 2025.

Review

Catchment of the Test License for the Regulation of Medical Devices in India

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ABSTRACT

The medical device industry in India is gaining momentum and is expected to grow rapidly. Given the significant impact of medical devices (MD) on patient health, a robust regulatory framework that combines policies, laws, regulations, and approvals is necessary to ensure adherence to standards before market entry. To initiate regulatory approval, test license is the preliminary step. It is required to manufacture or import materials in small quantities for specified purposes; for example, testing, training, examination, evaluation, demonstration, and clinical investigation under India's Medical Devices Rules (MDR) 2017. In general, as the associated risk of the device increases, the testing or evaluation parameters required to establish its safety and efficacy also increases. In this regard, test license is introduced so that manufacturers or importers must navigate to ensure compliance for the generation of data, particularly in the context of quality aspects of a MD or *in vitro* diagnostics (IVD), such as its design verification and validation, material of construction, testing, functionality, durability, sterility, biocompatibility, electrical safety, usability, and many more. Therefore, the present paper deals with the basic requirement and the details of the requisite documents for the grant of test license for the aforementioned purposes. It also aims to address the challenges so as to reduce the time-lapsed, effort, and financial burden to the applicant.

Keywords—*Medical device, In vitro diagnostics, Test license, Medical device rules, Testing, Evaluation.*

INTRODUCTION

The medical device sector in India is the fourth largest medical devices (MD) market in Asia after Japan, China, and South Korea, and is among the top twenty globally because of its growth potential driven by the country's increasing healthcare demands, technological advancement, innovations, and government support through various initiatives or incentive opportunities.[1] As MD have a significant potential for hazards, it should be ensured that they are safe and effective before being marketed. Thus, Govt. of India (GOI), Ministry of Health and Family Welfare's Central Drugs Standard Control Organization (CDSCO) headed by the Drug Controller General of India (DCGI), who is the central licensing authority (CLA), has notified Medical Devices Rules (MDR), 2017, vide GSR 78(E), dated 31st January 2017, effective from 1st January, 2018, and its amendment came into effect as Medical Devices (Amendment) Rules, 2020 vide GSR 777(E) dated 14th October, 2022, effective from 14th October, 2022, to have specific requirements for MD that have been framed in conformity with the Global Harmonization Task Force (GHTF) framework in order to align with the best international practices wherein the requirements for import, manufacture, clinical investigation/performance, sale and distribution of MD including *in vitro* diagnostics (IVD) have been prescribed.[2] As India recently joined the International Medical Device Regulators Forum (IMDRF) on 3rd October, 2024, as an affiliate member to accelerate global collaboration, harmonization, and convergence in medical device regulations, the importance of test license significantly helps to protect public health.[3]

At present, 38 categories of MD have been notified and regulated; the current regulatory practices in India are fully geared to meet the requirements to introduce in the country.[4] The present study provides a critical explanation and significance of the regulatory framework's initiation, that is, commencement of test license governing MD, aiming to annotate how such pivotal approvals have shaped the current regulatory landscape and influenced the MD industry in India. It is mandatory that, an applicant shall apply for test license for manufacturing or importing a small quantity of MD/IVD (in case of both availability and unavailability of predicate device in India) to manufacture/import three consecutive test batches accompanied with a fee, as specified in the second schedule of MDR-2017 having a validity of three years. A predicate device is an approved MD (manufacture/import) that may be legally marketed in the country of origin or globally and used as a point of comparison for new IVD/investigational MD seeking approval through CDSCO. An applicant can choose the right predicate device that is similar/ subsequent equivalence to the subject device with regard to indications for use (disease treatment/screening/diagnosis/management), material of construction (MoC), design and technological characteristics/underlying principle, and types of specimen. Any remarkable change in the said features that does not come under the predicate device are supposed to be investigational MD/new IVD. Moreover, if no such predicate device is available in India against the proposed device, meaning that it comes under the scope of investigational MD or new IVD, the applicant must also initiate the regulatory approval by applying for test license.

INITIATION OF TEST LICENSE

A test license is required to ensure that MD/IVD is safe, effective, and meets quality standards before they are sold or used. Test license is a type of approval from CLA that allows an applicant (person/firm/organization/startup/innovator/institute/sole proprietor/limited liability partnership/others) as manufacturer or importer for all risk-based classification to make or import a test device or IVD in a small quantity (Figures 1a and 1b) on the digital platform—a government initiative of National Single Window System (NSWS) for any of the following conditions in Form MD-12 (for manufacture) or Form MD-16 (for import).[5]

- Proof of concept is validated with working prototype, and the design is finalized.
- MD/IVD should be already approved (either manufacture/imported) in India.
- Investigational MD/new IVD in case no such approved devices are available in India.
- For all risk-based classification of MD/IVD (except risk-based class A—non sterile and non measuring).

• Before conducting any preclinical/clinical studies, it is mandatory to obtain the approval for test license. All data obtained prior to granting of test license is not considered for regulatory approval of MD/IVD.

The specific process for obtaining a test license for the proposed MD/IVD in India involves several steps, as outlined in Figure 1c (for manufacture in Form MD-12) and Figure 1d (for import in Form MD-16).

PURPOSE OF TEST LICENSE

Test license is granted (Form MD-13) in order to manufacture and import small quantities of MD or IVD (either earlier approved/investigational medical device/new IVD) for any of the following purposes at a time: testing, evaluation, clinical investigation, examination, demonstration, and training. The purpose of applying for the test license should be very specific in nature, as only one option of purpose is available while filling the Form MD-12 on the NSWS portal. In addition, when a particular purpose of applying the test license is changed, a fresh application must be submitted. A brief illustration of a specific purpose for the grant of test license is given below.

Demonstration

The proposed device (either earlier approved/investigational/new) is manufactured or imported for the purpose of showcasing the said device at a national or international platform/forum.

Training

The proposed device (either earlier approved/investigational/new) is manufactured or imported for the purpose of training for process/method or learning any skills on the said device.

Examination

The proposed device (either earlier approved/investigational/new) is manufactured or imported for the purpose of conducting an examination to understand the technology, familiarity, or proficiency on the said device.

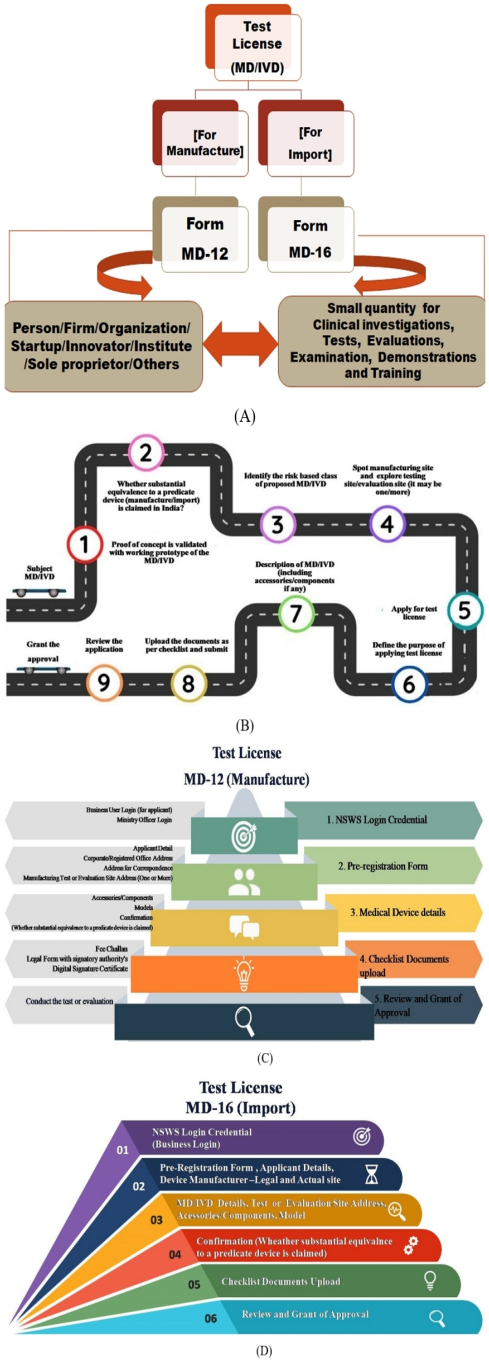

FIGURE 1. (A) An overview to apply for a test license for the manufacture or import of MD/IVD. (B) A process flow to grant a test license. Serial numbers 1 to 4 indicate the prerequisites to apply for test license, and serial numbers 5 to 9 mention the respective steps to grant approval for test license. (C) The process of obtaining manufacture test license (Form MD-12) in India. (D) The process of obtaining import test license (Form MD-16) in India.

Testing

In general, medical device testing is the process of demonstrating that the device will reliably perform safely in use. It is used if the proposed device (either approved/investigational/new) is manufactured or imported for the purpose of assessing various quality aspects of a device, such as its design verification and validation, material testing, mechanical test, reliability test, functionality, durability, sterility, stability, biocompatibility (ISO-International Organization for Standardization 10993 standard for evaluating the biocompatibility of MD), electrical safety and usability, *ex vivo* (animal performance study), and software verification and validation (for any software components).

Evaluation/Performance Evaluation

Predominantly, it is the theoretical assessment of evaluating the safety, effectiveness, and performance of MD that should start even before the product is marketed. If the proposed device (whether approved, investigational, or new) is manufactured or imported for the said purpose that include physical (mechanical, electrical), analytical (sensitivity, specificity, toxicity, stability, linearity, limit of detection, positive predictive value-PPV, negative predictive value-NPV), biological (biocompatibility) and other parameters (sometimes, clinical samples/left over samples are also used) assessment to evaluate its functions as intended use and doesn't provide any faulty information.

Particularly, performance evaluation is carried out specifically for IVD, irrespective of either new or earlier approved devices at CDSCO designated lab under sub-rule (1) of rule 19 of MDR-2017/ National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited lab/Govt. Lab/In-house lab (in case of unavailability of these labs with prior approval from CDSCO).[6] It mainly covers three major parameters, namely, scientific validity, analytical performance, and clinical performance (Figure 2).[7] Scientific validity covers the degree to which a study or test accurately measures what it is intended to measure in a broader population. It is achieved by defining research objectives (to accomplish), choosing appropriate methods (to collect and analyze data), using rigorous methods (to apply strict techniques to ensure the data are accurate), and evaluating the results (to assess the validity of the finding). Analytical performance of an IVD is the ability to measure or detect a specific analyte accurately and reliably. These studies demonstrate the analytical performance of an IVD that includes device specification, accuracy, precision, linearity, detection limit, quantitation limit, cross reactivity, specificity, sensitivity, either qualitative or quantitative, and range. However, clinical performance is the output of a device to yield results that are correlated with a particular clinical condition based on sample size, diagnostic sensitivity, diagnostic accuracy, diagnostic specificity, PPV, NPV, likelihood ratio, and expected values in normal and affected populations.[8] Performance Evaluation Reports (PER), which are essential technical documents for the regulatory approval of the subject IVD, include clinical performance reports as a key component.

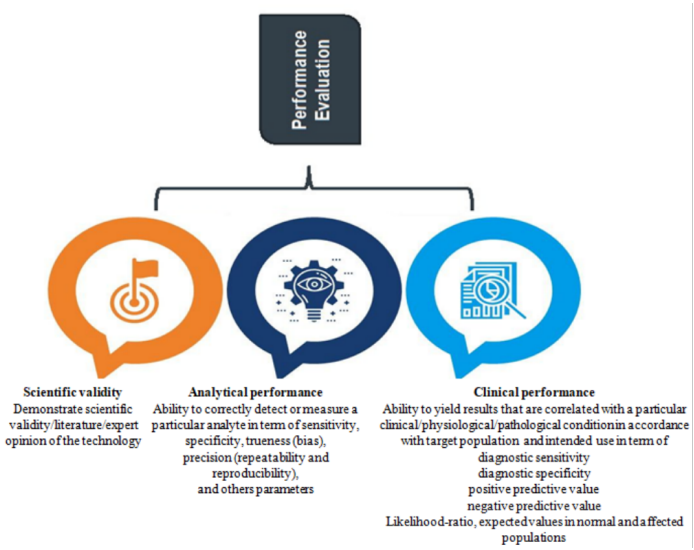

FIGURE 2. Performance evaluation of the IVD with three major parameters.

Clinical Investigation/Clinical Performance Evaluation

Clinical trials using MD are referred as clinical investigations. The purpose of a clinical investigation is to answer important scientific questions. It must follow strict scientific standards (ISO-International Organization for Standardization 14155:2020—clinical investigation of MD for human subjects), which can protect patients and produce reliable scientific outcomes. One of the purposes of a clinical investigation could be to establish and verify clinical safety, meaning to understand how

to prevent and reduce risks, errors, and harm that may happen to patients/end users. Furthermore, the purpose of a clinical investigation is to establish and verify the performance of a device in human subjects. Broadly, it focuses on good clinical practice (GCP) for the design, conduct, recording, and reporting of the adverse events of clinical investigations carried out on human subjects to assess the clinical effectiveness and safety of MD as per the seventh schedule of MDR-2017. This means checking the ability (or capability) of a device to perform as per intended use until the specified period/duration. It needs to be verified whether it enables the manufacturer to achieve the intended purpose of the device leading to clinical benefits for patients.[9]

Moreover, evaluation of clinical performance is the systematic study that can be used to diagnose and treat diseases *in vitro*. Broadly speaking, it is the assessment of an IVD using a specimen taken from humans to evaluate its performance when used as intended by the manufacturer. IVDs are designed to extract information from human samples, such as blood, tissues, and biological fluids that can allow for drawing of conclusions, such as physiological or pathological changes in the body. Clinical performance evaluations may include:

- Testing for sensitivity, specificity, accuracy, precision, and clinical validity.
- Using clinical performance evaluation plan in human specimens.
- Analyzing and summarizing clinical data.
- Demonstrating scientific validity.
- Demonstrating analytical performance.

For applying for a test license (manufacturer) for clinical investigation of MD, a copy of the grant of permission is to be provided (in Form MD-23, whether it is for pilot/pivotal/post-marketing clinical study). Conditional approval of test license may be granted in absentia of Form MD-23. However, for permission to conduct clinical investigation for an earlier approved medical device, valid approval from the ethics committee is required (Table 1).

On the other hand, for applying for a test license (manufacturer) for the evaluation of the clinical performance of a new IVD, a copy of the grant of permission is required (in Form MD-25). Conditional approval of test license may be granted in absentia of Form MD-25 with prior submission of the clinical investigation plan and approval from the institutional ethics committee (IEC).

However, for permission to conduct evaluation of clinical performance of an earlier approved IVD, valid approval from the ethics committee is required (Table 2). In addition, if a certain medical device/IVD is imported for the purpose of clinical investigation/clinical performance evaluation from the USA, Britain, the United Kingdom, Japan, the European Union, Australia, and Canada (with a condition that the product has already been marketed for at least 2 years in these territories, and the CLA is satisfied with the data of safety, performance, and pharmacovigilance of the said device), the requirement to apply for test license to conduct clinical investigation/evaluation of clinical performance is waived off. However, if medical device/IVD is approved and marketed in places other than these territories, proof of grant of permission to conduct clinical investigation/evaluation of clinical performance (Form MD-23/ Form MD-25) is required in accordance with the test license (Table 1).

CONSEQUENT ATTRIBUTES AFTER TEST LICENSE

Once test license has been granted for any of the aforesaid purposes, the applicant may prepare/import at least three test batches of the said device in statistically significant quantities at the manufacturing site (in-house) to generate quality control (QC) data that comply with the essential principles of safety and performance of the proposed device. In addition, these data should also be generated at the testing site that may be comparable enough with the in-house data. However, in the case of manufacture/import of IVD, PER that would be generated at designated labs (specific for a particular IVD) should be compared with the in-house data generated. These data are further used in the next regulatory application in order to get the final approval of the device/IVD for sale and distribution in the market.

TABLE 1. Requirement for the application of test license with the purpose of clinical investigation/evaluation of clinical performance.

Objective		Test License for MD/IVD
Manufacture	Investigational MD/new IVD	Proof of grant of permission to conduct clinical investigation/evaluation of clinical performance (Form MD-23 for MD), (Form MD-25 for IVD).
	Earlier approved in India	Ethics committee (EC) approval
Import	Investigational MD/new IVD in the country of origin	• Waive off if: • Medical device imported from the United States, Britain, the United Kingdom, Japan, the European Union, Australia, and Canada. • Already marketed for at least 2 years in these territories. • CLA is satisfied with the data of safety, performance, and pharmacovigilance of the said device[*,2] However, if medical device/IVD is approved and marketed in places other than these countries, proof of grant of permission to conduct clinical investigation/evaluation of clinical performance (Form MD-23 for MD), (Form MD-25 for IVD) is required.
	Earlier approved in the country of origin	

MD: Medical device, IVD: *In vitro* diagnostics. [*]Subject to approval from the CLA.

Moreover, it has been noticed that at the time of applying for the test license, it is not mandatory that the manufacturing site should comply with the quality management system (QMS) as per the fifth schedule of MDR-2017 and the subject device should adhere with applicable Bureau of Indian Standards (BIS)/ISO/International Electrotechnical Commission (IEC)/pharmacopeial standards). But, while applying for the commercial manufacturing license, the manufacturing facility must comply with QMS or have ISO 13485, which may be audited later by the concern notified body (in the case of risk-based class of A and B by the state licensing authority) or by a medical device officer (in the case of risk-based class of C and D by the CLA), and the proposed device must follow the respective standards.

All the data obtained prior to granting of the test license is not to be considered for regulatory approval of medical device/IVD (Figures 3 and 4). In this regard, it is advisable that the innovator may refer to the regulatory pathway for MD/IVD given on the CDSCO website.[10]

DOCUMENT UNDERLYING FOR APPLYING THE TEST LICENSE

There are a certain set of documents for applying for test license against the proposed device/IVD as per Form MDR-2017.2 A brief overview of each document is herewith discussed and summarized in Table 2.

1. Covering letter mentioning the objective of the test license specifically details the purpose, intended use, justification of quantity, and regulatory status (i.e., availability of predicate device in India and approval status in other countries), and detail of manufacturing and testing/evaluation site.

2. Brief description of applied MD/IVD including intended use, material of construction (MoC, design, label, specimen used for testing (human/animal), type of specimen (blood, serum, plasma, etc.). If a predicate device is available, the applicant needs to submit the substantial equivalence evaluation along with relevant published literature, that is, comparative analysis to prove substantial equivalence to the predicate device(s) as claimed with respect to intended use, MoC, design characteristics, mechanism, principal of operation, etc.

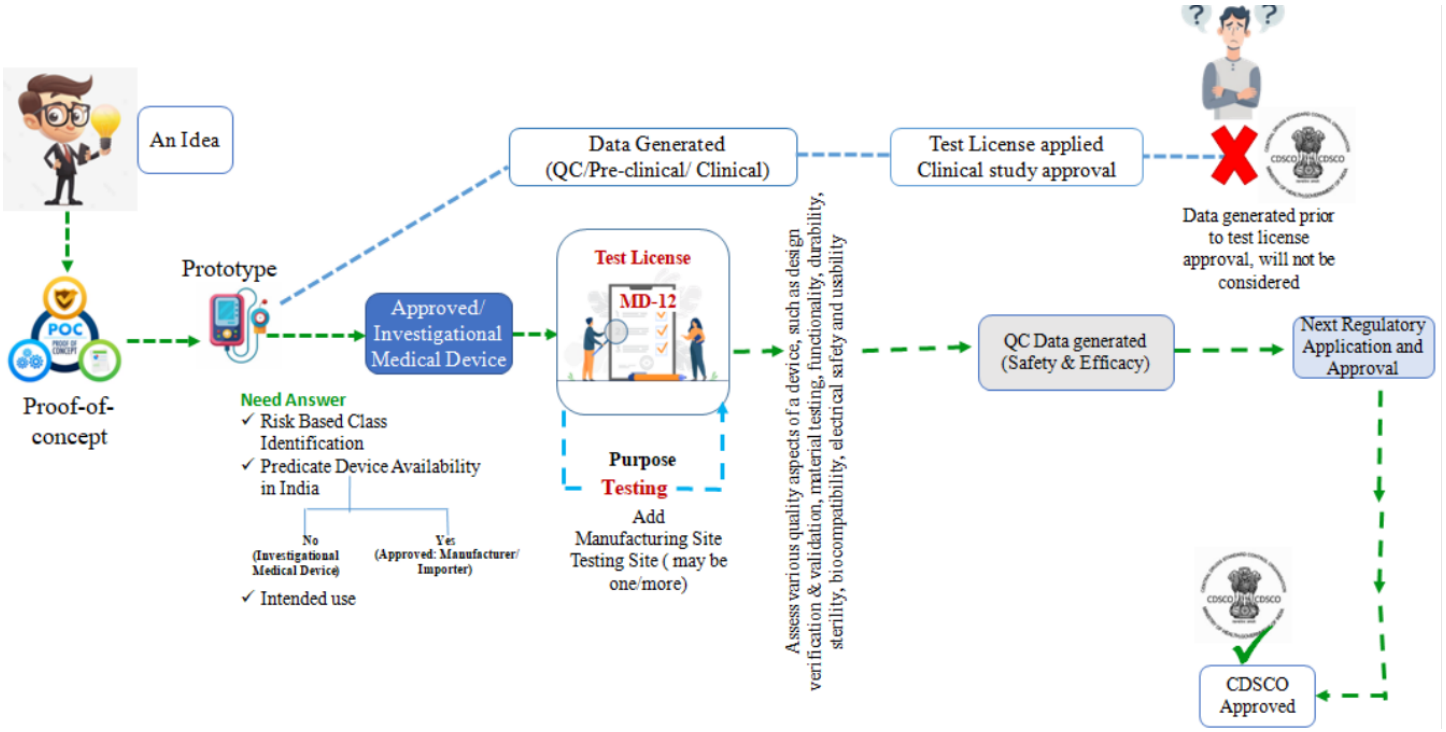

FIGURE 3. Road map to apply test license (Form MD-12) for MD with the purpose of testing.

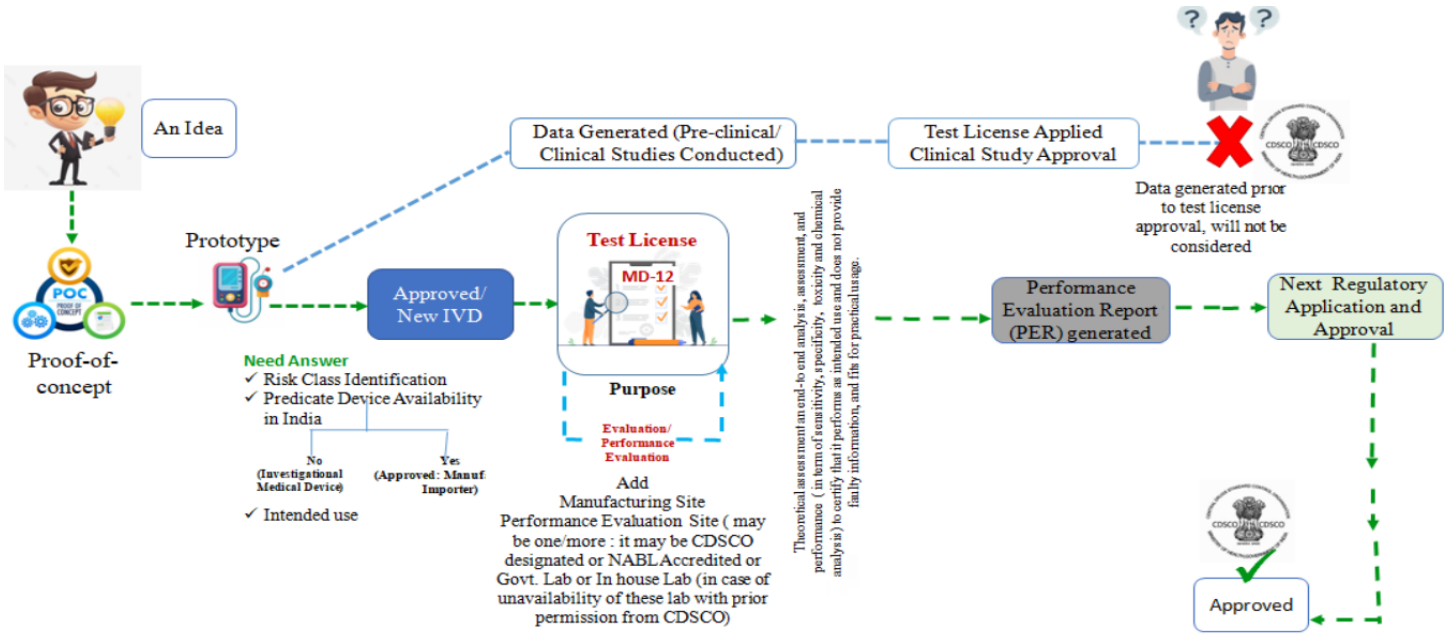

FIGURE 4. Road map to apply test license (Form MD-12) for IVD with the purpose of evaluation/performance evaluation.

3. Undertaking stating that the required facilities including equipment, instruments, and personnel have been provided to manufacture such MD/IVD on the letterhead with a stamp and signed. However, in the case of import of MD/IVD in small quantities, 2 undertakings are required, namely:

• An undertaking stating that the MD/IVD proposed to be imported is to be used exclusively for the specified purpose and not for commercial purpose.

• An undertaking stating that required facilities including equipment, instrument, and personnel will be provided to test or evaluate the medical device.

4. List of equipment, instruments for manufacturing and testing/evaluation of applied MD/IVD (not applicable for the import of MD/IVD).

5. List of qualified personnel for manufacturing and testing of applied MD/IVD in tabular form under whose direction and supervision the test batches' manufacturing activity, testing, and evaluation of a medical device shall be undertaken (not applicable for the import of MD/IVD)

6. Justification of quantity proposed to be manufactured along with its utilization breakup mentioning testing parameters with quantity required for the applied quantity, mentioning both internal and external evaluations (if applicable). Moreover, the same implies for IVD with quantity required for evaluating at both internal and external evaluation sites (if applicable). However, in the case of import of MD/IVD in small quantities, the applicant can give the proper justification of the quantity proposed to be imported with its utilization breakup.

7. Test specification and protocol along with applicable standards that provide the testing protocol or any other protocol specific to the device/IVD. Approved clinical study protocol or approval copy of Form MD-23 or Form MD-25 will be required if the selected purpose of applying for the test license is for clinical investigation or evaluation of clinical performance. It is also applicable for the import of MD/IVD in small quantities.

8. Brief description of the manufacturing and testing process and flowchart that includes each process step of manufacturing of the subject device/IVD.

9. Copy of the manufacturing license of the premises where the development/testing activity is to be carried out, under these rules, if any. It is applicable only to existing manufacturers who have been previously issued a license; otherwise, this does not apply. Please upload a declaration confirming this.

10. Approval letter authorizing to undertake research and development activities issued by a government organization, if any. Any approval from agencies funding research internally or externally

11. Other documents, if any. It may include publication/research paper in support of intended claims, design, principal of operation, MoC, etc.

12. Fee challan that will be paid online via the Bharat Kosh portal (https://bharatkosh.gov.in/) directed through the NSWS portal. The fee amount is subjective and is calculated automatically by the system based on the device applied (as per second schedule of MDR-2017). It is advisable not to pay the respective amount directly through the Bharat Kosh portal.

13. Legal form. It is a system-generated filled form of MD-12 application that should be submitted after being digitally signed with the digital signature certificate (DSC) of an authorized signatory.

In addition, the following documents are used exclusively for the import of MD/IVD in small quantities:

• Quality certificates like QMS, etc., of the manufacturer, if any. Manufacturing site should comply with QMS as per the fifth schedule of MDR-2017 or ISO 13485.

• Labels and instructions for use (IFU), as per Rule 44 of MDR-2017. Labelling of MD needs particulars such as name of the medical device; the details necessary for the user to identify the device and its use; the name of the manufacturer and the address of the manufacturing premises; the correct statement about the net quantity in terms of weight, measure, volume, number of units, as the case may be; and the number of the devices contained in the package expressed in the metric system; the month and year of manufacture and expiry (the label may indicate the product's shelf life. For sterile devices composed of stable materials such as stainless steel or

titanium, and supplied non-sterile, the date of sterilization may be treated as the manufacturing date. In the case of medical equipment, instruments, or apparatus, it may not be necessary to specify an expiry date) on the shelf pack of the MD or on the outer cover of the MD that shall be printed in indelible ink on the label, whereas the intended use of a medical device is clearly communicated in the IFU. The IFU (or electronic IFU) is a set of instructions that are legally required for MD to be sold and are intended to ensure the safe and effective use of the device. It should include:

- Intended use: The specific intended use of the device.
- Precautions: Any precautions or warnings that should be considered while using the device.
- Preparation: How to prepare the device for use, such as sterilization, assembly, or calibration.
- Disposal: How to dispose of the device.
- Other information: The name of the device, manufacturer's address, shelf-life, storage requirements, and technical specifications.

In cases where certain requisite documents are not applicable to a particular device or IVD, the applicant must provide a proper justification and upload the same on the portal.

EXCLUSION OF THE TEST LICENSE

A test license is not required to apply for all MD in India, but it depends on the risk-based class of device, usability, and the purpose in certain conditions as follows:

Manufacture/Import of Class A Nonsterile and Nonmeasuring device

Consequent to the implementation of the notification G.S.R. 102 (E) dated 11th Feb, 2020, all MD are under the licensing regime (except for class A—non-sterile and non-measuring MD), and license is required for the import/manufacture of MD in the country.[11] These devices such as scalpels, scissors, walking sticks, eyeglasses, and wheelchairs do not require a license, but they do need to be registered on "online system for medical devices" established by CDSCO for this purpose.[12] The registration number obtained shall not be considered as a regulatory approval for the manufacture/import of devices.

Import of MD/IVD from the Founding Member Countries of the GHTF

Clinical investigation will be waived off for the subject device if it is imported from the United States, Britain, the United Kingdom, Japan, the European Union, Australia, and Canada and remains marketed for at least 2 years in these territories (Table 1). In addition, the CLA is satisfied with the data of safety, performance and pharmacovigilance of the said device as per rule 63 of MDR-2017.[2] However, it is subject to approval from the CDSCO on a case basis.

Imported for Personal Use

Test license is not required for the import of small quantities of MD/IVD for personal use (by a person or by a government hospital or statutory medical institution for the treatment of a patient), which is otherwise prohibited under Section 10 of the Act. MD/IVD may be imported for personal use subject to prior approval in Form MD-20 as per rule 43 of MDR-2017 accompanied by requisite documents and the fee as specified in the second schedule of MDR-2017 on the cited portal.[12] On the other hand, small quantities of an investigational medical device, the import of which is not allowed, but approved in the country of origin, may be allowed to be imported by the CLA for the treatment of a patient suffering from a life-threatening disease, or disease causing serious permanent disability, or disease requiring therapy for an unmet medical need, on an application made by a medical officer through the medical superintendent of a government hospital or a statutory medical institution in Form MD-18 as per rule 42 of MDR-2017 accompanied by requisite documents required and the fee as specified in the second schedule of MDR-2017 on the cited portal for this purpose.[12]

Manufacturing of Custom-Made Device

MD that are made specifically in accordance with a written prescription of a registered medical practitioner, specialized in the relevant area, under his/her responsibility in accordance with a specific design, characteristics, and

the same is intended for the sole use of a particular patient, and the label mentions "for the sole use of a particular patient," and does not include the mass production of such a device. All provisions of chapter IV (manufacture of MD for sale or for distribution and chapter V (Import of MD) are exempted as per the eighth schedule of MDR-2017.

WITHDRAWAL, REJECTION, AND CANCELLATION OF TEST LICENSE

Once the test license application is submitted successfully, there is no option to withdraw/amend the submitted test license application on the NSWS portal. However, an applicant can request the CLA for cancellation with a proper justification for the same. In addition, after obtaining the test license in Form MD-13, if an applicant fails to comply with relevant provisions of the MDR-2017 against the proposed device/IVD, the CLA may issue a show cause notice for cancellation giving an opportunity to explain in writing the licensee's defense against an order for cancellation. The licensee has the right to appeal to the central government within 45 days from the date of cancellation of the order.[2]

The CLA may reject the grant of a test license in Form MD-17, and the reasons, such as the requirements of these rules are not satisfied by the applicant, are to be recorded in writing within a period of thirty days from the date of the application under sub-rule (2) of rule 40 of MDR-2017.[2]

SIGNIFICANCE OF TEST LICENSE

The importance of test license significantly implies a quality of MD/IVD that should make it worthy of global acceptance. Within a functioning healthcare system, initiating the regulatory application process—beginning with the issuance of a test license—is a crucial first step for any subject device intended for widespread use in the prevention, diagnosis, treatment, monitoring, and rehabilitation of a broad range of diseases and medical conditions. In addition, it can also be used to monitor vital signs, deliver medications, remove biological waste, and support or replace damaged body parts. The important aspects of test license are herewith outlined below:

• Role in regulatory compliance: Obtaining test license is an important step which helps in ensuring adherence with the existing regulatory framework so that it can be of help to protect public health. It also ensures that products that are manufactured/imported in small quantities after obtaining test license shall be used only for specified purposes and not for commercial purposes.

• Safety measures: Test license granted against manufacturing/importing the MD/IVD for the purpose of testing/evaluation ensures that testing/evaluation carried out with respect to applicable gold standards will establish that the products are safe and effective for human use.

• Commercial manufacturing preparedness: The grant of a test license is the preliminary step for the preparedness of commercial manufacturing license for sale and distribution of MD/IVD in the Indian market, as it helps to prevent the marketing of unsafe or ineffective devices. Usually, it is applied for once the working prototype is ready, and its design is finalized in the case of investigational MD/new IVD.

• Build trust: The end user can build trust in the company's various products of MD/IVD for which the license has been granted.

• Adverse event surveillance: Test license encompasses the compliance of regulatory approval, identification of all quality-related issues, investigation of the root cause, and implementation of necessary legal actions in case of adverse events reported (if any) of the subject device. This ensures that such problems do not arise again and develops the confidence of users on device potentially, safety, and effectiveness of use in humans.

KEY CHALLENGES AND SUGGESTIONS FOR AMELIORATION

Test license permits the manufacturer/importer to make/import a limited quantity of MD/IVD falling within class A (except non-sterile and non-measuring)/B/C/D for any of the aforesaid purposes before being put into commercial use. There are certain challenges with regard to applying the test license and possible suggestions, which are summarized below.

Challenges Faced

The dynamic and complexity of regulatory compliance:

With ongoing amendments and regular updates to MDR-2017 in India, usually the applicants often face the following challenges in fully understanding the nuances related to device/IVD:

• Class of MD/IVD: Correct identification of a risk-based class of the device.

• Laboratory for conducting performance evaluation: Availability and identification of CDSCO designated labs under sub-rule (1) of rule 19 of MDR-2017 for IVD.

• Identification of predicate device: It is essential for confirmation that it either falls under investigational MD or New IVD or subsequent equivalent of the approved device/IVD.

• Understanding of different components/accessories/consumables: It includes a basic overview of the device and its parts, whether or not consumable items are included—along with their respective risk-based classification and intended use, is not clearly explained in the remarks. Justification of quantity to be manufactured/imported for different purposes and their breakups utilization.

• Clarity on grouping of MD/IVD; either it falls under the category of single, system, group, family, or cluster.

• Identification of test batch manufacturing sites/testing sites.

Technical Barriers on the NSWS Portal

The NSWS platform, while designed to simplify regulatory processes, can present technical barriers, such as slow response times, connectivity issues, or errors in uploading required documents along with login credential requirements of mandatory DSC, which is linked to the permanent account number (PAN) of the business entity or signatory authority for its validation to submit the application as well as approval.

Extended application review period

In general, 30 working days are allocated to review the application and grant approval. However, long extended time has been utilized to review the application because of a large volume of applications or insufficient information/incorrect documents submitted by the applicants.

POSSIBLE SUGGESTIONS

Inconsistent Testing Standards

There may be inconsistencies in how different laboratories apply the standards, leading to variability in testing/performance outcomes. There is no harmonization of the analytical parameter, which is established to conduct the performance evaluation of the subject IVD that varies across designated labs. Aligning the harmonized results with MDR-2017 is critical for approval.

Emergence of New Technologies:

Emergence of new technologies for health solutions require new risk-based classification under either software integrated medical device (SiMD) or software as medical device (SaMD) for addressing efficacy/intended use in ways that are not previously covered.

An Awareness-Strengthening Regulation

Since, there is an overall trend to cover all MD/IVD under the license regime, it is primarily recommended as safety concern grows, to be aware about increased regulation over previously non-notified category of MD/IVD.

CONCLUSION

MedTech industry is not just a component of healthcare but is the catalyst that links patients, payors, service providers, and regulators to create a stronger and more equitable system in a fast-paced environment globally. In this regard, MD/IVD is the unique positioning of the MedTech sector that holds the promise of revolutionizing healthcare delivery and outcomes, both in India and globally. The wide spectrum MD/IVD, from simple technologies to complex high-throughput systems, presents varying degrees of risk that may directly influence patient health

and safety. On the other end, the regulatory compliances in accordance of risk-based classification of MD/IVD vary. However, test license is an important principal requirement to get the necessary approval for manufacture/import of a small quantity of MD/IVD for the purpose of clinical investigation, testing, evaluation, examination, demonstration, or training. The process of obtaining test license under the MDR-2017 in India via the NSWS portal involves navigating complex regulations and ensuring compliance with testing standards. The objective of the current study is to provide a significant overview of the regulatory framework that brings test license approval of the MD in India. These approvals facilitate ease of doing business, remove regulatory bottlenecks to make in India, while ensuring availability of better MD for patient care and safety. Conversely, there are certain challenges that significantly present opportunities for improvement in regulatory frameworks and quality standards, potentially leading to a more robust medical device market in India. These insights may be relevant when considering the broader context of MD/IVD testing and licensing under MDR-2017.

AUTHOR CONTRIBUTIONS

Conceptualization and Writing– Review & Editing, R.K.; Methodology, D.K.G.; Visualization, J.B.; Resources, A.S.; Supervision, S.M.

ACKNOWLEDGMENTS

I greatly acknowledge ICMR for providing the necessary infrastructure, computing resources, study materials, circulars, and documents to prepare the manuscript.

FUNDING

This study received no funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

We have no conflicts of interest to disclose.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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Received September 18, 2024, accepted June 23, 2025, date of publication September 16, 2025.

Review

Application of Usability Techniques in Medical Devices in Health Technology Management: A Rapid Review

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ABSTRACT

The role of clinical engineering in health technology management (HTM), incorporating human factors engineering tools, such as usability techniques, allow for improvements in the development of safer, more effective, and quality use of technological solutions. This work resulted in a rapid review of the application of usability techniques to contribute to the development and use of technological solutions for health, so that the occurrence of adverse events can be mitigated. As a consequence, information can be provided for improvements in health technology processes, in order to stimulate and highlight the importance of human factors in health. In order to understand the application of usability techniques in clinical engineering throughout the life cycle of HTM, an exploratory study was done on the literature involving medical devices. This work reinforces the importance of applying techniques to identify the problems faced in the use of technologies and thereby contribute to the activities of clinical engineering so as to reduce errors and failures. The integration and consideration of human factors in the life cycle of HTM is essential for the further advancement of clinical engineering in technology management throughout the healthcare ecosystem, and also in the discussion, construction, and validation of strategies that will help in preventing adverse events.

Keywords—*Clinical engineering, Human factors engineering, Usability techniques, Health technology management, Health technology assessment.*

INTRODUCTION

Technological advances have enabled a rapid increase in the use of medical equipment in healthcare facilities.[1] As a result of this growth in the frequency of use of health technologies, it has become necessary to incorporate processes that help with technological management throughout the life cycle, from the development and manufacturing stages to incorporation and use in health services. Health technology management (HTM), in order to make patient care more effective and with greater safety and quality, must encompass and consider the entire context in which the technology is incorporated, and is essential to make its use more appropriate and reliable. The Institute of Biomedical Engineering at the Federal University of Santa Catarina (IEB-UFSC) has a management model based on three main pillars: infrastructure, human resources, and technology, thus providing a systemic assessment of the technological resource[2].

Health technologies are essential for monitoring, therapy, and diagnosis of diseases, but their use can cause adverse events for users. The main problems that could lead to adverse events are differences in functionality between technologies from different manufacturers; lack of standardization[3]; inefficient maintenance services; inadequate planning for incorporation; inefficient technology design; problems arising from hidden flaws; inadequate use; failure to take human factors and user ergonomics principles into account when developing technological solutions[4]; unsatisfactory instructions or training; improper storage and/or improper use; inadequately structured management procedures[5,6]; incorrectly used accessories; displays showing results that are difficult to read; and incorrectly changed alarm settings.[7]

Studies that address technology–user interaction often neglect the human factors' perspective, but because of an increase in technological complexity in healthcare, the need to implement research in this area has also grown proportionally.[8] Usability and user experience is essential in healthcare[8], and can solve usage problems, increase safety, reduce incidents that cause harm to patients, and provide greater reliability in the use of technology in healthcare environments.[7,9] Applying usability techniques at different stages of the life cycle makes it possible to contribute to technological development more safely. In addition, they can be applied to different types of technology and help to improve use and mitigate likely risks to users in HTM.[10]

One of the requirements to be considered in the process of evaluating and developing new technological solutions in healthcare is usability, which establishes a relationship between the characteristics of human factors with ease of use, efficiency, and user satisfaction during the use of technology.[8,11,12] When considering human factors in clinical engineering, the ability of users to use technological resources in a safer and more effective way is considered, according to the real contexts of healthcare environments.[13] The area of study of human interaction with other elements of a system to achieve adequate usability is called human factors engineering (HFE), which is fundamental for analyzing human behavior in the face of new technologies and establishing improvements in protocols for use in health services.[7,11,14] Investigating human behavior, considering their limitations, abilities, and interactions with the environment, helps to improve safety, efficacy, and quality in HTM.[9,15]

HFE

The area responsible for applying knowledge about the characteristics and limitations of people with technologies, processes, and environments is called HFE.[7,9] The focus of HFE is to understand how people interact with technology and to study how design affects the interactions that people have with technology.[9] It is therefore a strategic tool to be incorporated into the activities of clinical engineering in HTM. The tool used to evaluate human interaction with a product is usability, and its consideration in healthcare is fundamental.[8] Most researchers agree that usability is a useful tool for evaluating the user experience,[8] which consists of an approach that goes beyond the design of the interface, and encompasses the system, the user and their characteristics, and the context of use of the technologies or system.[16]

Usability, as defined by the NBR ISO 9241-11:2011 and NBR IEC 62366:2016 standards, is a metric used to measure how well a product can be used by certain users and achieve specific objectives, by considering parameters such as effectiveness, efficiency, and satisfaction in a given context of use.[11,12] The interaction between the

components involved in establishing a usability metric describes the integration between the user, task, and equipment to achieve a common goal, by measuring the metrics of effectiveness, efficiency, and satisfaction.[12] There are five attributes that are involved: learnability, efficiency of use, ease of memorization, low error rate, and user satisfaction.[17] Usability is attributed to effectiveness, efficiency, satisfaction, usefulness, learnability, and accessibility.[18] The different usability attributes are described on Table 1.

There are several international standards and regulations, presented in Table 2, which can be used to initiate a usability approach in HTM,[5,8,9] and are important for demonstrating compliance with safety requirements.[5] HFE has a series of techniques that aim to study the interactions between devices and their users, facilitating identification of problems and dangers related to use.[9,10] By incorporating usability evaluation methods into cyclical human-centered design processes in an iterative way, it is possible to develop designs that involve users, making products, systems, and/or services more usable.[17] In this way, usability techniques enable users to understand the problems they face and thus contribute to the development of technological solutions.

Usability Techniques

In order to assess usability, qualitative and/or quantitative techniques can be applied,[8] in the pre-commercialization stages, in the processes of innovation, exploration, experimentation, and evaluation of prototypes,[20] as well as in post-commercialization, when technologies are already incorporated in their environment of use. Therefore, taking usability into account beyond development and use is essential for safety and reliability,[21] which is why the methods can be applied throughout the life cycle.[22] Usability techniques aim to assist in testing and evaluation with users,[7] enabling the construction of a collaborative and interdisciplinary ecosystem, in which the actors involved with technological health resources interact with each other, enhancing the implementation of solutions and user-centered technological incorporation.[23]

The application of usability techniques is an additional tool for analyzing human factors in HTM.[10] There are various ways of obtaining information regarding technology–user interaction: information and opinions related to usability can be collected with the aim of understanding users and the environment of use; observing people performing certain tasks associated with the product; discussing aspects of the project in user groups with the aim of obtaining new ideas; conducting structured studies with users using the technology in their own real environment or in simulated locations; including in a risk management plan for hazard identification; as well as using tools to model interfaces at different levels of reliability in the course of developing healthcare solutions.[7,11]

TABLE 1. Description of usability attributes.

Usability attributes	Description
Effectiveness	Accuracy with which users have achieved certain established objectives,[12] and thus consists of an important metric for measuring the risk of error during use and ensuring patient safety.[19]
Efficiency	Accuracy in relation to the resources spent by users to achieve a given objective.[12] The system must be efficient and have the lowest possible error rate.[17]
Satisfaction	Absence of discomfort and positive attitudes toward the use of a product[12] refer to perceptions, feelings, and opinions.[17] The system must be pleasant from the user's perspective.[19]
Usefulness	Checks whether the product or service achieves its use objectives.[17]
Learning	Learning measures the ability of users to recall the system after a period of training or time without performing a particular task.[17] The system must be easy to use from the user's perspective.[19]
Accessibility	Easy access to the products needed to complete the objective by people with the widest range of abilities.[12,17] Considering accessibility enables clarity and simplicity in design for people who may temporarily have some limitation or those who have it permanently.[17]

TABLE 2. Standards involving in the usability of medical devices.

Standard	Title	Main objective
ABNT NBR IEC 62366:2016	Healthcare products—Application of usability engineering to healthcare products.	To specify the process for analysis, specification, development, verification, and validation of the safety-related usability of healthcare products.
ABNT NBR ISO 14971:2020	Medical devices—Application of risk management to medical devices.	To specify the principles of the process for risk management of health products, including aspects of usability.
ABNT ISO/TR 16982:2014	Ergonomics of human-system interaction—Usability methods that support user-centered design.	To provide information about usability methods, advantages, disadvantages, and other factors relevant to the use of each usability method.
ABNT NBR IEC 60601-1-6:2020	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability	To specify the minimum usability requirements for medical electrical equipment.
ABNT NBR IEC 60601-1-11:2012	Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance. Requirements for medical electrical equipment and medical electrical systems used in domestic health care environments.	Specifies requirements for electromedical equipment used in domestic environments, including usability aspects.
ABNT NBR ISO 13485:2016	Health products Quality management systems Requirements for regulatory purposes	Specifies minimum requirements for quality management systems in healthcare products, considers usability aspects.
ABNT NBR ISO 9241-210:2011	Ergonomics of human–system interaction Part 210: Human-centered design for interactive systems.	Specifying requirements and recommendations for human-centered design for the entire life cycle.
ABNT NBR ISO 9241-11:2011	Ergonomic requirements for working with visual interaction devices. Part 11: Usability guidelines	Specifies minimum requirements to identify the necessary information to be considered in the specification or evaluation of usability.
AAMI/ANSI HE75	Human factors engineering—Design of medical devices.	Reference covering general principles, managing the risk of use errors, design elements.

Each technique has specific principles and characteristics that need to be known to ensure that the analysis of medical technologies is objective and with valid results.[7,10] No technique is best in all situations.[11,24] Usability techniques can be divided according to the type of data to be extracted from the research: quantitative, when the evaluation of parameters has a numerical perspective; qualitative, to extract choices and feelings from the user's point of view[8]; as well as mixed methods, containing qualitative and quantitative data.

There are various techniques specified in regulations,[11,24] international guidelines and guidance materials,[5,9] and books and scientific publications, some of the main ones being, but not limited to, observational analysis, interviews, focus groups, task analysis, questionnaires, the Delphi method, heuristic evaluation, usability testing, and user error analysis. Figure 1 shows a comparative illustrative proposal for usability techniques, based on the classification between qualitative, quantitative, and mixed-method analysis, whether the application of the technique depends on direct contact with the technology,

and whether the user's perspective on the product or the researcher's view when observing the technology–user interaction is considered predominantly.

Usability techniques have been used at various stages of the life cycle of health technologies, from pre-commercialization to post-commercialization processes,[10] and are strategic HFE tools to support HTM. The choice of the usability technique depends on the information you want to extract.[8] In addition, its results are only reliable when the participants are people who are representative of the population and who perform a certain task of interest.[11] Primary knowledge of usability techniques, including an understanding of the differences and basic principles of application, is essential to choose the one that best meets the needs.[24]

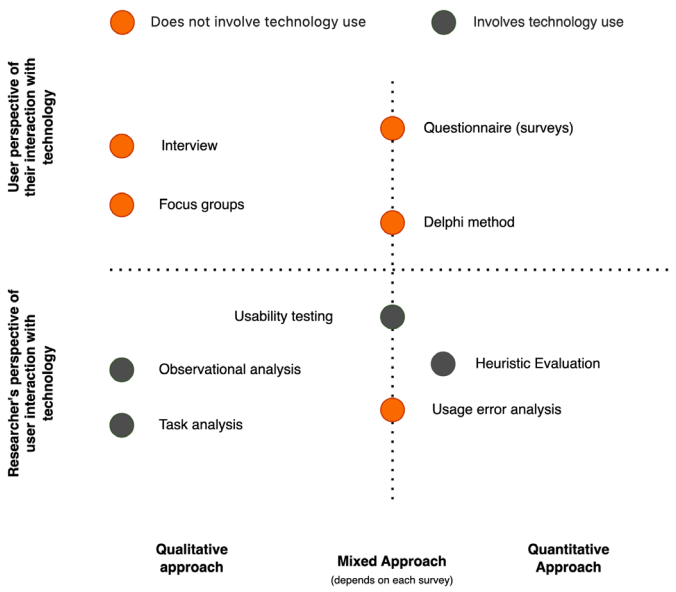

FIGURE 1. Comparison of the usability technique.

In order to understand the application of usability techniques in clinical engineering throughout the life cycle of HTM, an exploratory study was done on the literature involving medical devices.

MATERIALS AND METHODS

This research was conducted through a rapid review, which consists of a reliable and systematized methodology for synthesizing knowledge. This approach is used when steps in the process of a systematic review are simplified, or omitted, to produce information from the selection of research that is available in the literature, and that is of relevance to a topic of study.[25] The rapid review was developed to ensure that decisions influencing the application of usability techniques in medical equipment can be informed by an up-to-date and reliable account of the scientific evidence that is relevant in the context of the research.

This rapid review research was based on the Ministry of Health's Methodological Guideline for the preparation of systematic reviews[26] as well as the University of Oxford's PRISMA methodology, which consists of a set of evidence-based items that aim to assist in the presentation of research results.[27] The guiding question of the rapid review research proposed for this case study was:

"What are the usability techniques that are applied to medical equipment over the course of the technological life cycle?"

To determine the choice of articles, inclusion and exclusion criteria were established, which included population parameters of the desired technology, the type of intervention used, the availability of the work, the date of publication, and the type of evaluation of the results, as presented in Table 3. To answer this question, a search strategy used was to define keywords to identify publications that respond to this theme: Usability; Human Factor; Medical Device; and Medical Equipment. The search was carried out in the following electronic databases: IEEE, Pubmed, and Scielo, which were used systematically, and Scopus, Scielo, Lilacs, Sage, and JMIR, in which searches were carried out independently. In order to determine the choice of articles, inclusion and exclusion criteria were established, which included the population parameters of the intended technology, the type of intervention used, the availability of the work, the date of publication, and the type of evaluation of the results. The use of the logical operators "AND" and "OR" helped in the literature search. The databases were searched using a combination of keywords: (Usability OR "human factor*") AND ("Medical Equipment*" OR "Medical device*").

TABLE 3. Rapid review inclusion and exclusion criteria.

Parameters	1. Exclusion Criteria	2. Inclusion Criteria
Population	1.1 Equipment/devices other than medical devices. Accessories and isolated parts will not be considered. Screening applications, medical records, and medical software will also not be considered. Studies that do not specify the technology will be disregarded.	2.1 Medical equipment used for diagnosis, monitoring, and/or therapy of diseases.
Intervention	1.2 Does not apply usability engineering techniques and/or does not describe the technique.	2.2 Studies that show results of the application of usability engineering techniques.
Availability of the work	1.3 Incomplete and/or unavailable texts.	2.3 Full texts available
Publication date	1.4 Works more than 10 years old from the date of publication.	2.4 Works up to 10 years old from the date of publication.
Assessment	1.5 They do not present results of the application of usability techniques in medical equipment. They do not show the assessment of usability and the interference of human factors with technology.	2.5 They present results of the application of usability techniques in medical equipment to evaluate the usability of technology and the interference of human factors.
Type of work	1.6 Nonprimary studies (such as reviews, meta-analyses) and/or works from the same research project.	2.6 Primary studies and works not part of the same research project.

After the initial search, a publication date filter was applied, excluding articles with a publication date greater than 10 years ago. The titles and abstracts were read, and a total of 189 publications were selected. Reading these studies in full resulted in the exclusion of 124 articles that did not meet the established inclusion criteria. Thus, 65 articles were eligible to compose the rapid review, which present the application of usability techniques in medical equipment. The studies were classified according to the techniques used, the type of medical equipment in which the evaluation was carried out, the stage of the technology life cycle in which the methods were applied, and whether or not there was a conflict of interest in the research. The usability techniques presented in the articles were applied by the researchers to observe user interaction with the medical equipment or to identify problems by observing and transcribing the opinions of the users of the technologies.

RESULTS

The results of the review showed a variety of possibilities for applying usability techniques to medical equipment, from higher risk class devices, such as computed tomography,[28] to even less complex equipment for home use.[29] Of the 65 studies, the medical equipment with the most research was the infusion pump, with sixteen in total,[30–35] followed by pulmonary ventilator with five,[36,37] defibrillator with five,[38,39] and vital signs monitor, referenced in five studies.[40–43] In addition to those already mentioned, usability techniques have also been applied to: glucometer,[44–46] pulse oximeter,[29] anesthesia machine,[47,48] electrosurgical unit,[49] endoscope,[50] insulin infusion pump,[51] operating table,[52] ultrasound,[53] among others, demonstrating the diversity in the application of usability techniques. In some selected studies, human factors methods were applied to more than one piece of

equipment, who applied the methodology to blood pressure monitors and pulse oximeters.[38]

The results show that usability techniques are being used for a variety of purposes, from design validation in the early stages of product development, to assisting in the processes of incorporating technology into a facility; to assessing the ergonomics of medical equipment; to analyzing usability problems through adverse event analysis; investigating product design problems; analyzing the instructions for use of a piece of equipment; and assisting in identifying hazards and minimizing risks to the patient, even at the level of comparing usability between different types of make/model of a technology.

An analysis of the selected papers showed that usability techniques are being applied at different stages of the technology life cycle, from pre-commercialization to post-commercialization. Usability techniques were applied both individually and integrated with one or more other methods, with the integration of techniques being the most widely used methodology in the selected studies. The studies that applied more than one technique reinforce the importance of integrating different methods to extract information from different perspectives, as each technique has its advantages and limitations. An example of the presence of integrating techniques is the usability test, which was the method with the highest number of applications among the selected works, and which was generally accompanied by the implementation of questionnaires in the pre-test, to analyze the profile of the participants, and in the post-test, to quantify user satisfaction regarding the usability of the technology. In the post-test questionnaire, most of the time, the SUS Scale, a tool used to extract relevant information about how satisfied the user feels when interacting with the technology, was applied.

A complementary tool, also applied in some of the selected studies, was the use of eye tracking used to analyze the user's eye movement when interacting with the product interface, to help assess the usability of users when using technologies.[47,54] Another validated tool used in the selected studies was the NASA-TLX Scale, used to measure people's mental workload. This scale was applied in all the studies in which this usability technique was used, and was applied through integration with other methods.[28,36,37] Reducing the physical and mental workload is one of the recommendations, in which the authors cite the importance of manufacturers considering these scenarios for users and providing customizable options to meet the needs of the end operator.[28]

DISCUSSION

Human factors in health must be involved throughout the entire life cycle of the technology in the technology management processes of clinical engineering activities, from the pre-commercialization stages, based on a user-oriented development of health technologies, to the post-commercialization stages, involving the clinical staff in the processes of technological incorporation, investigation of problems in the use of technology to minimize harm to the patient, among many other activities that involve clinical engineering.[7,10,13]

Interdisciplinary interaction in health technology processes is essential for identifying potential problems in the use of medical equipment in establishments, and thus establishing and implementing improvement actions. The implementation of a collaborative and interdisciplinary living lab ecosystem has the potential to contribute to HTM, through the application of usability techniques with different actors involved with medical devices, including clinical engineering, end users, health professionals, industry, and government, among others. Usability techniques can be applied at different stages of the life cycle of health technologies, helping to identify user needs in order to develop and/or improve technological solutions. A program proposal was developed to cover the main activities considering human factors, as shown in Table 3. The objective to apply usability techniques for the consideration of the human factor in each life cycle stage is presented in Table 4.

TABLE 4. Objective to apply usability techniques for the consideration of the human factor in each life cycle stage.

Life Cycle Stage	Main Activities	Objective to Apply Usability Techniques for The Consideration of The Human Factor
Design and development	- Innovation ideation. - Design, prototyping, and development. - Compliance with regulations. - Regulations, good manufacturing practices, and certification. - Production, distribution, storage, and marketing.	- Establishing project goals and requirements based on the problems identified by users when using the technologies. - Collecting data on user needs. - Developing solutions centered on user needs. - Testing solutions with the user for validation, risk, usability analysis, and project adjustments.
Planning and selection	- Market analysis - Health technology assessment (HTA) - Sizing up the establishment's profile by analyzing the technologies, infrastructure, and human resources to understand the need for incorporation. - Checking that the technology has been regularized with the health agency and complies with regulations, ordinances... - Carrying out economic analyses of the total cost of ownership. - Specifying and selecting the technology. - Purchasing process (bidding if necessary)	- Meeting user needs, combining clinical interest with the technologies available on the market. - Consider usability aspects when specifying technology, check that technological development is user-centered and based on standards. - Consider usability in technology selection. - Consider human factors engineering principles and usability techniques to incorporate into HTA.
Receipt, verification, and acceptance	- Ensure that all equipment incorporated complies with what has been requested. - Ensure that they are evaluated before first use through acceptance tests that attest the safety and performance of the technology. - Document and implement criteria for supplier qualification.	- Test the incorporated technologies with users for final acceptability, checking that they meet the need.
Inventory	- Carry out the inventory (survey, registration, and identification) of the entire technology park with all the necessary information to ensure the accuracy and traceability of the data. - The entire inventory process must be documented and conducted periodically.	- Involve the user who operates the technology in the inventory of the technology park, to understand the importance of identification and traceability for management. - Identify possible flaws in the processes of incorrect and/or incomplete identification of the inventory, thereby hindering traceability.
Installation	- Install the equipment in compliance with the manufacturer's regulations and recommendations.	- Show users the impact of the infrastructure on performance and security with the technology. - Evaluate the infrastructure to check the implications for users' use of the technologies. - Understand the difficulties faced by users when interacting with the infrastructure.
Training	- Ongoing and periodic training program to ensure that operators are able to carry out their activities. - Drawing up and implementing good practice guidelines for the proper use of health technologies.	- Train users to operate the technology properly. Carry this out immediately after installation and inventory and periodically on an ongoing basis with the entire team. - Develop training focused on solving problems faced by users. - Develop good practice materials for proper use.

Life Cycle Stage	Main Activities	Objective to Apply Usability Techniques for The Consideration of The Human Factor
Use	- Risk management - Draw up and implement standardized procedures and protocols for the use of technologies. - Develop methodologies to ensure technological traceability. - Analyze the history of failures and analyze the probable causes. - Investigate the adverse events involved.	- Understand the problems of using the technology and understand the impact of human factors on the occurrence of failures and adverse events. - Analyze the cause of failures incorporated into risk management in order to establish improvement strategies. - Analyze usability problems in order to establish specific strategies and improvements in new technological solutions.
Technical interventions	- Define and implement procedures to ensure the metrological traceability and safety of technologies. - Develop and implement procedures for inspection, testing, calibration, preventive and corrective maintenance, electrical safety tests, and qualification.	- Involve the user in the importance of carrying out calibration, maintenance, and other technical interventions for the safety and performance of the technologies. - Analyze the impact of human factors on technical interventions in technologies.
Obsolescence, decommissioning, and final disposal	- Developing and implementing procedures describing the criteria for decommissioning technology, taking into account the technical, operational, financial, or strategic aspects of the establishment. - Execution of the activity by issuing a decommissioning report.	- Analyze the effectiveness of using the technology. - Evaluate the needs of the clinical staff to ascertain the need for technological replacement. - Researching technological advances that consider human-centered aspects for technologies with better usability.

Analysis of the Application of Usability Techniques in Pre-Commercialization

In processes involving the development of technological solutions, it is essential to include the user in the gathering of data on the need and validation of the product, enabling the prior identification of usability problems that the technology may pose.[10] Therefore, user-centered design encompasses the active involvement of people during technological development, with a clear understanding between user requirements and tasks, providing solutions through continuous interactions with users in an interdisciplinary team.[15]

The pre-commercialization stage is the time when the technology is under development, and it is essential to include the user in gathering data on the need and validating the idea or product. This stage makes it possible to reduce future complications by anticipating possible usability problems that the technology may pose.

The studies in which usability techniques were applied in the pre-commercialization stages demonstrate the need to include users throughout the technological development process to ensure better usability results and greater patient safety,[55,56] as well as making it possible to reduce costs.[57] The application of usability techniques in the technological development process reduces the need for design modifications and more costly upgrades post-market introduction, which becomes a competitive advantage. In addition, there are considerable improvements in safety, which minimize the likelihood of medical device recalls. When HFE approaches are used during the technology–user interface development process, especially taking into account the user's perspective, there are considerable improvements in ease of use.[9]

Analysis of the Application of Post-Marketing Usability Techniques

Usability techniques applied in post-marketing demonstrate the relevance of studies considering human factors during the use of technologies, and thus assist manufacturers, researchers, among other actors, who wish to explore ergonomic studies after incorporation of technology into the market.[58]

The application of usability techniques in the process of incorporation in health establishments can obtain

satisfactory results, as the use of technologies in environments directly impacts the experience of staff and patients, and the selected equipment will normally be used for several years.[59] Inadequate incorporation that does not meet local and operator needs can lead to disuse of the technology, as well as operating errors, resulting in problems for patient safety. In addition to the impacts on the establishment, considering usability in the process of incorporation also provides manufacturers with information on users' needs, and thus helps with feedback for the development of new products.[59] Liu et al. also presented a usability evaluation methodology through the integration of techniques that can provide evidence to support the selection of more appropriate equipment, by considering the context of use of the technology.[60]

By applying usability methods, it is possible to recommend improvements to the technology–user interface and increase safety[61;] identify how the context of use can affect the usability of technology[55]; as well as understand educational needs60 and improve training strategies[39] and instructions for use.[19]

Studies have shown that the application of usability techniques through the analysis of adverse events makes it possible to identify sources of hazards and investigate the causes of these incidents associated with the use of medical devices,[62] and thus assist in both the pre-marketing and post-marketing of technologies. Through the evaluation and analysis of adverse events in databases, it is possible to optimize risk control solutions in the use of medical equipment and achieve satisfactory results in usability to contribute to the development of public health and better user experiences.[32]

Another approach, little explored in other studies, is the use of technology by individuals with physical/sensory disabilities, demonstrating in their research that medical devices are often not designed to meet the needs of specific users.[63] Clinical engineering needs to work toward managing health technologies that are more accessible to everyone.

Usability techniques can also be applied in the design and implementation of training programs, which are a stage in the technology's life cycle, and should be carried out periodically and continuously. Training should include the difficulties faced by users in order to mitigate the occurrence of user errors. Therefore, a continuing education program should consider the problems faced by users in their day-to-day use of the technology, both when it is first introduced and throughout its life cycle. Usability techniques can be applied to analyze the impact of training to investigate its effectiveness and thus establish actions that can improve the use of the technology.

Throughout the use of technology in healthcare environments, usability techniques can be applied continuously to analyze the users' perspective on interaction with the technological resource. In this way, it is a strategy for identifying possible problems and planning preventative actions. Drawing up and monitoring indicators involving technologies is a clinical engineering activity that must also take human factors into account when critically analyzing the results of the metrics. Incorporating user evaluations of user satisfaction, error rate, effectiveness, and efficiency in performing certain tasks are important usability metrics to be considered in clinical engineering.

Clinical engineering must incorporate the monitoring and analysis of adverse events in its activities. Analysis of failures and adverse events also requires attention to probable human errors, and applying usability techniques can help to investigate the probable causes, and thus establish strategies more assertively. Clinical engineering should also stimulate the environment for reporting adverse events, by implementing actions that minimize the main barriers that influence the deficiency in the reporting process by operators, which are fear of guilt, lack of time, nonperception of effectiveness when reporting, lack of knowledge of the reporting system, lack of feedback, and a complicated and time-consuming platform for reporting. Metrology in health is a strategic tool for identifying adverse events and hidden failures involving health technologies. Metrological problems can be associated with inaccurate diagnoses and inadequate treatment, as these factors are directly related to the prevalence of adverse events.

When assessing obsolescence, applying usability techniques can provide data to help clinical engineering make decisions on whether or not to discard technology, by understanding the problems faced and clinical needs,

as well as assessing the availability of new technologies on the market. Human factors must also be taken into account in the stages of technological substitution, so that the transition and incorporation of a new technology has minimal impact on the healthcare environment.

CONCLUSION

This work demonstrated that the application of usability techniques can assist clinical engineering in the development and use of technological solutions that integrate the user in the processes throughout the life cycle, and that provide data with a more systemic view of the problem. Some of the actions of clinical engineering highlighted and discussed in these usability techniques consist of: development of technologies with better usability for users; process of incorporation of new technologies in establishments that meet clinical needs; preparation and implementation of training and qualifications in technologies; development of good practice materials for appropriate use; identification and monitoring of the occurrence of failures and adverse events to propose improvement actions; and performance evaluation as a metrological tool to preventively identify adverse events and hidden failures, as well as in the evaluation of technological obsolescence considering the users in these processes. Therefore, human factors must be considered throughout the life cycle, integrating a feedback system of information for continuous improvements.

The integration and consideration of human factors must be encouraged for the further advancement of clinical engineering throughout the healthcare ecosystem, in the discussion, construction, and validation of strategies that may assist in the prevention of adverse events. Incorporating usability techniques must be a tool applied throughout the life cycle of technologies as a strategic methodology to ensure safety, regulatory compliance, and cost reduction in healthcare environments. With these integrated and collaborative actions, the aim is to achieve an increasingly humanized, inclusive, collaborative, sustainable management of health technologies, focused on the best user experience and focused on quality and safety for all people involved in the technological processes in health.

AUTHOR CONTRIBUTIONS

Conceptualization, M.B. and R.G.; Methodology, M.B. and R.G.; Formal Analysis, M.B.; Writing–Original Draft Preparation, M.B.; Writing–Review & Editing, M.B. and R.G.; Supervision, R.G.

ACKNOWLEDGMENTS

Not applicable.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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Received January 23 2025, accepted July 12 2025, date of publication September 22 2025.

Original Research Article

Influence of Airflow on Dispersion of COVID-19 Droplets in Classrooms Using Computational Fluid Dynamics

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ABSTRACT

COVID-19, caused by the 2019-nCoV coronavirus, is a global pandemic that spreads through respiratory droplets that are transmitted by inhalation or contact with droplet nuclei produced during sneezing, coughing, and speaking by infected people. COVID-19 can also be spread by air in the infected person's close-by surroundings. In this study, computational fluid dynamics (CFD) was employed to analyze the airborne transport of virus-laden droplets generated by a coughing event in a typical classroom environment. Simulations were conducted for three ventilation airflow velocities—3, 5, and 7 m/s—under both side and top wall configurations. The results showed that higher airflow velocities significantly reduced the residence time of airborne particles, with the 7 m/s case clearing over 90% of droplets within 60 seconds. Top wall ventilation led to early dispersion near the front rows, while side wall ventilation carried droplets to the rear seats over time. In addition, smaller aerosols (< 1 μm) remained suspended for a significantly longer duration than larger droplets (> 100 μm), indicating higher long-range transmission risk. These findings underscore the importance of optimizing airflow velocity and vent placement to reduce airborne exposure and support safer classroom ventilation design.

Keywords—*COVID-19, Classroom, CFD, Airborne transmission, Ventilation.*

INTRODUCTION

COVID-19 is a highly contagious respiratory illness caused by the 2019-nCoV coronavirus, which belongs to the destructive coronavirus family that has rapidly spread worldwide, resulting in a pandemic.[1–3] Airborne transmission involves inhaling virus-laden aerosols, which are smaller than 5 μm. These aerosols can travel in airflows and infect individuals at short and long distances from the source.[4–6] These droplet nuclei are created when infected individuals sneeze, cough, or talk. Individuals' social, cognitive, and intellectual development is greatly enhanced by classrooms.[7] However, because of many uncertainties about the transmission routes of COVID-19, there are ongoing worries about creating safe and supportive educational settings. Environmental factors such as temperature, humidity, and ventilation significantly affect the transmission of aerosols. Poorly ventilated indoor spaces increase the risk of airborne transmission.[4,5,8] One crucial question that requires attention is how the ventilation systems in the classroom impact the ability of the virus to spread. Computational fluid dynamics (CFD) can simulate the propagation of virus-laden droplets from an infected student's sneezing or coughing to avoid experimental complications.[9–11] Statistical investigations showed that COVID-19 dispersed by aerosols, droplets, fomites, and human waste affected human health.[12,13] Asadi et al. investigated the spread of COVID-19 by direct or indirect contact, including transmission through the air when sneezing or coughing and through physical contact with contaminated objects.[14] Diwan et al. investigated the airflow produced by sneezing and coughing in dry and wet circumstances.[15] They also considered the evaporation of droplets using direct numerical simulations (DNS). The researchers replicated the act of coughing by modelling it as a turbulent jet/puff phenomenon. Kotb and Khalil used ANSYS-Fluent 18.0 to mimic COVID-19 transmission by sick passengers sneezing and coughing in an aircraft cabin.[16] They found that sneeze droplets were more harmful than cough droplets, yet both could travel long distances in the aircraft. As speed rises, more droplets are distributed. Wang et al. calculated the distribution of COVID-19-contaminated particles from sneezing in a three-bed hospital unit.[17] Particle path and residency period were simulated using ANSYS Fluent 19.0 to assess cross-infection risk.

Common ventilation systems change indoor air concentration, temperature, and humidity.[18,19] The influence of displacement and mixed ventilation systems on interior air quality affects human health and comfort.[20,21] Multiple studies show that poor ventilation increases disease transmission in confined settings. Several researchers have studied indoor airflow, room pressurization, and filtration in infectious illness hospitals and chemical labs.[22,23] The goal was to find low-risk situations. Ren et al. numerically modelled three typical breathing strategies in a hospital's prefabricated COVID-19 inpatient room.[24] The study examined various droplet sizes. Main currents transport small particles across significant distances. Portions of droplets are expelled via outlet ventilation. However, streams cannot carry large particles. They land on solid objects because of gravity. Different ventilation methods cause sedimentation in different parts of the ward.

Because of the lack of empirical data on COVID-19-infected droplet fluid dynamics, models of droplet transmission by sneezing or coughing are useful.[25,26] This analysis improves our understanding of the COVID-19 simulation. Gupta et al. experimentally studied coughing airflow dynamics.[27] Researchers used gamma functions to track coughing rates throughout time. The researchers found no association between cough direction, mouth opening size, and physiological parameters, including height, weight, and gender. Many studies show how human-breathed air affects respiratory infections in ventilated environments to minimize breathing-related infections.[28,29] Big droplets settle swiftly over a short distance and are hardly affected by air temperature changes. However, personal contact with an infected person might spread droplet-borne diseases to susceptible others. Educational researchers have examined COVID-19 transmission among pupils. Abuhegazy et al. studied COVID-19 aerosol mobility and deposition on classroom surfaces.[30] They found that particle size, aerosol source location, glass barriers, and windows affected their numerical results. The researchers found that gravitational sedimentation deposits bigger particles on the ground, tables, and other surfaces in the room, whereas the air conditioning system expels most small particles. Researchers have studied seat placement in different rooms and regions using equilateral triangle seat designs.[31] Their COVID-19 study may benefit schools, universities, restaurants, libraries, and other indoor areas

where seat availability is crucial. This method boosts seats by 13% on average and 25% to 50% sometimes.

The review of the existing sources and the consistency of concerns and uncertainties regarding the COVID-19 spread demonstrate the necessity for further studies on the distribution of the virus in the classroom. It is important to develop suitable design methods to reduce the risk of air transmission within these environments. This paper has applied CFD to study the geographical and time dispersion of virus-laden droplets emitted by a coughing individual in a typical classroom. The paper examines how the velocities of airflow ventilation and droplet sizes affect the dispersion of infectious particles and how sitting positions are more vulnerable to infection. The originality of this study lies in the extensive modelling of aerosol-sized and large ballistic droplet behavior within an authentic classroom layout under the various ventilation types, which helps in gaining useful information on how to improve airflow and counter the issues of transmission indoors.

MATHEMATICAL MODEL

In this investigation, numerical modelling of the flow dynamics of the transmission of the COVID-19 virus was done using the RNG k-e model in Ansys Fluent 19.0. The Eulerian–Lagrangian approach was used to monitor the water droplets of different sizes released from the mouth of the diseased individual standing in front of the classroom because of coughing.

Ventilation Airflow Modelling

The equations (1–3) that describe the preservation of mass, momentum, and energy for a steady airflow that does not change in volume are as follows:

$$\frac{\partial \rho}{\partial t} + \nabla \cdot \left(\rho \vec{V}\right) = 0 \tag{1}$$

$$\rho\left(\frac{\partial \vec{V}}{\partial t} + \vec{V} \cdot \nabla \vec{V}\right) = -\nabla P + \mu \nabla^2 \vec{V} + \vec{S} \tag{2}$$

$$\rho \frac{\partial T}{\partial t} + \rho \vec{\nabla} \cdot \left(T\vec{V}\right) = \nabla \cdot \left(\frac{K}{C_p} \nabla T\right) + S_T \tag{3}$$

where, ρ is the Fluid density (kg/m^3), t is the time (s), $\vec{V}$ is the Velocity vector field (m/s), and $\nabla \cdot (\rho \vec{V})$ is the divergence of mass flux. In equation (2), the P denotes the pressure (Pa), μ denotes the dynamic viscosity (Pa·s), $\nabla^2 \vec{V}$ denotes the Laplacian of velocity (diffusion of momentum), and $\vec{S}$ denotes the external source term (e.g., body forces like gravity or electromagnetic forces). In equation (3), T is the temperature (K), K is the thermal conductivity (W/m·K), C_p is the specific heat capacity at constant pressure (J/kg·K), and the $\nabla \cdot \left(\frac{K}{C_p} \nabla T\right)$ is the heat diffusion term, and S_T is the volumetric heat source (e.g., radiation, chemical reaction, Joule heating).

Turbulence Modelling

According to Tsan–Hsung, the RNG k-ε turbulence model is a reasonable choice for modelling airflow in interior conditions.[32] The dissipation rate ε and turbulent kinetic energy k have matching transport equations, which are given as:

$$\frac{\partial}{\partial t}(\rho k) + \frac{\partial}{\partial x_i}(\rho k u_i) = \frac{\partial}{\partial x_j}\left[\alpha_k \quad \mu_{eff} \quad \frac{\partial k}{\partial x_j}\right] + G_k - \rho\varepsilon + S_k \tag{4}$$

$$\frac{\partial}{\partial t}(\rho \varepsilon) + \frac{\partial}{\partial x_i}(\rho \varepsilon u_i) = \frac{\partial}{\partial x_j}\left[\alpha_\varepsilon \quad \mu_{eff} \quad \frac{\partial \varepsilon}{\partial x_j}\right] + C_{1\varepsilon}\frac{\varepsilon}{k}(G_k) - C_{2\varepsilon}\rho\frac{\varepsilon^2}{k} - R_\varepsilon + S_\varepsilon \tag{5}$$

where, G_k represents the turbulent kinetic energy output resulting from the average velocity gradients. In this context, S_ε and S_k represent source terms that are defined by the user, while refers to the source term derived by renormalization. The x_i and x_j represent the i^{th} and j^{th} spatial coordinates, respectively. The Equations (4) and (5) define α_k and α_ε as the effective inverse Prandtl numbers for the turbulent kinetic energy and its dissipation, respectively. The symbol ε represents the turbulence dissipation rate ($m2/s3$), μ_{eff} is the effective viscosity, and u_i is the velocity component in x_i-direction. The product $\rho\varepsilon$ represents the dissipation of turbulent kinetic energy (k) into heat. The model constants $C_{1\varepsilon}$ and $C_{2\varepsilon}$ are assigned the values of 1.42 and 1.68, respectively.

Discrete Phase Modelling

In this study, the airflow was initially assessed for a sparse concentration of droplets before analyzing the trajectory of particles. The movement of droplets carrying viruses was examined employing Newton's second law within a Lagrangian framework,[33–35] with the associated equation of motion expressed as:

$$\frac{dV_d}{dt} = F_D\left(\vec{V} - \vec{V}_d\right) + \frac{\vec{g}\left(\rho_d - \rho\right)}{\rho_d} + F_L + F_B \quad (6)$$

In Equation (6), F_L represents the Saffman lift force, and F_B denotes the Brownian force[36]. The given equation is the Lagrangian particle force balance used in multiphase flow modeling, where $\frac{dV_d}{dt}$ denotes the acceleration of the dispersed particle with $\vec{V}_d$ as its velocity. The term $F_D\left(\vec{V} - \vec{V}_d\right)$represents the drag force per unit particle mass, where $\vec{V}$ is the fluid velocity and F_D is the drag coefficient depends on Reynolds number and drag law. The term $\frac{\vec{g}\left(\rho_d - \rho\right)}{\rho_d}$ accounts for gravitational and buoyancy effects, with $\vec{g}$ being gravitational acceleration, ρ_d the particle density, and ρ the fluid density; this drives particles to settle if $\rho_d > \rho$ or rise if $\rho_d < \rho$. While F_D represents the coefficient of drag force, given as (Equations 7 and 8):

$$F_D = \frac{18\mu}{d^2 \rho_d C_C} \quad (7)$$

$$C_C = 1 + \frac{2K}{d}\left(1.257 + 0.4e^{-\left(\frac{1.1d}{2K}\right)}\right) \quad (8)$$

where, μ is the fluid's dynamic viscosity, d is the particle diameter, ρ_d is the particle density, and C_C is the Cunningham correction factor that corrects drag at very small particles.[37,38] Within the Cunningham coefficient, the ratio $2\lambda/d$ appears, where λ is the mean free path of gas molecules, which introduces a slip correction when particles are comparable in size to the molecular spacing. The mass flow rate of particles is expressed as (Equation 9):

$$\dot{m} = \frac{\left(\frac{4}{3}\pi r^3\right) \times \rho_d \times n}{t} \quad (9)$$

where, the symbol $\dot{m}$ denotes the particle mass flow rate, representing the mass of particles transported per unit time. Symbols n and ρ represent the number and density of particles, respectively. The ρ_d is the particle material density used in determining individual particle mass and flow contributions

In Equation 10, F_L represents the Saffman lift force, given as:

$$F_L = 6.46\mu_f \left(\frac{d_p}{2}\right)^2 .V_s \left(\frac{\rho_f G}{\mu_f}\right)^{1/2} \quad (10)$$

where, d_p represents the mean diameter of particles, μ_f is the dynamic viscosity of the fluid, and V_s is the slip velocity defined as the relative velocity between the fluid and the particle. The term ρ_f represents the fluid density, while G denotes the velocity gradient in the surrounding fluid.

Geometry

This study has examined the movement and scattering of droplets that carry the COVID-19 virus produced by coughing in a classroom with under-ventilated or non-ventilated circumstances. The dimensions and specifications of the classroom and chairs are depicted in Figure 1 (a) and Figure 1 (b) from both a top perspective and a side view.

The classroom floor under study dimensions is 6 m in width and 8 m in length. The height of the classroom is 4.5 m. The floor area per student is consistent with a value of 0.36 square m. The class's student seating is arranged with a precise distance of 0.5 m. Figure 2 displays a comprehensive 3D representation of the simulated classroom, including all relevant details.

This study examines the scenario where an individual infected with COVID-19, measuring 1.8 m in height and with a mouth area of 4 cm^2, coughs abruptly and releases virus-infested droplets into the surrounding environment. The ventilation air is drawn in from a wall intake located behind and on top of the individual and is expelled via the open door. The door dimension is 1 × 2.1 m^2.

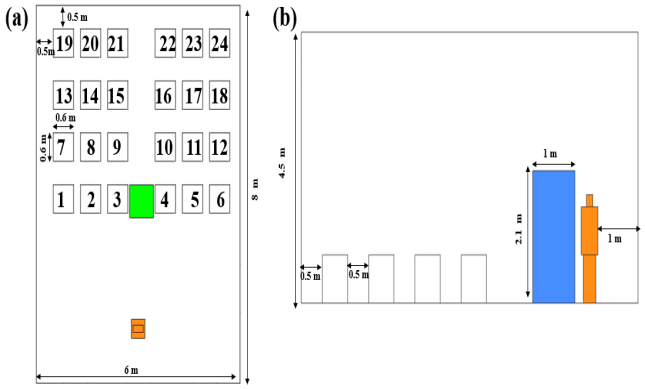

FIGURE 1. Classroom geometry and schematics. (a) Top view. (b) Side view.

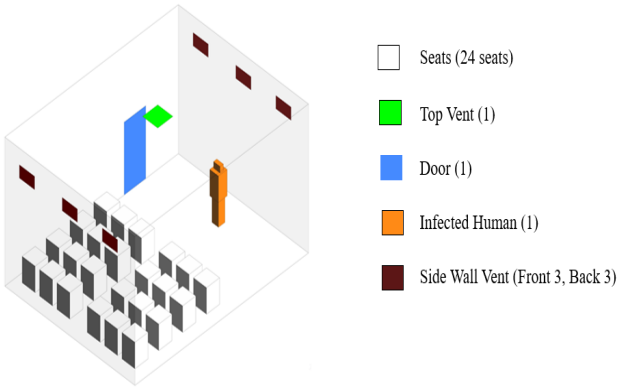

FIGURE 2. 3D model of the classroom with all the details.

Meshing

All simulations use an unstructured tetrahedral mesh created with ANSYS-Fluent, as shown in Figure 3. Meshing details are provided in Table 1.

Boundary Conditions and Solution Process

The simulations are conducted for both scenarios: one without and one with ventilation. The ventilation was positioned in several locations, including top ventilation, side wall ventilation with either one or three ventilation apertures, and the classroom door was used as the exit for the ventilation. Water droplets of different sizes are analyzed to represent the current conditions accurately. A coughing velocity of 10 m/s sustained for 0.75 seconds was applied, in alignment with measured human coughing dynamics reported by Gupta et al.[27] The injected droplet diameters ranged from 0.15 μm to 150 μm, consistent with experimental respiratory emission size distributions.[30] Inlet velocities of 3, 5, and 7 m/s and the corresponding outlet placements were selected based on airflow conditions investigated in previous classroom ventilation studies.[16] The specific details of the droplets are provided in Table 2.

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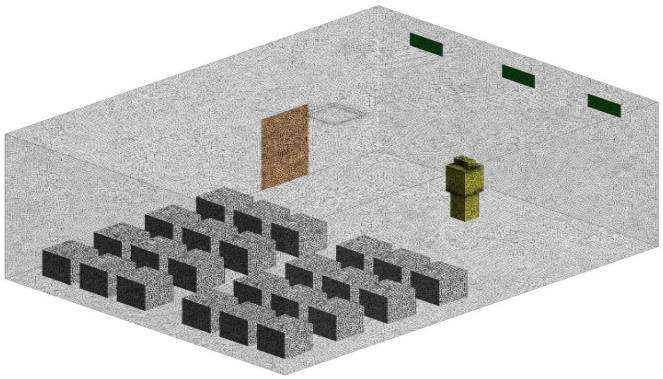

FIGURE 3. Meshing of the flow domain.

TABLE 1. Meshing details.

Parameter	Value
Cell type	Tetrahedrons
Maximum face size	50 mm
Nodes	672,869
Elements	3,679,749
Skewness	0.21935
Orthogonal quality	0.77935
Aspect ratio	1.8284

TABLE 2. Injection conditions for droplets carrying COVID-19 viruses.

Diameter (µm)	Velocity (m/s)	Number of Particles	Injection Time (Sec)	Mass Flow Rate (kg/sec)
0.15	10	1,800	0.75	4.2413E-15
1	10	1,800	0.75	1.2566E-12
10	10	1,800	0.75	1.2566E-09
50	10	1,800	0.75	1.5706E-07
100	10	1,800	0.75	1.2566E-06
150	10	1,800	0.75	4.2413E-06

The trap condition is used for the solid walls to govern the interactions between droplets and various surfaces, while the escape condition is utilized for the inlet and exit. The simulation utilizes three velocities within this range and subsequently compares the outcomes. The additional boundary conditions employed include a velocity input and a pressure exit. The temperature is set as a starting value for the outlet. In addition, a turbulence intensity of 5% is assumed at the inlet.

RESULT

This section delineates the numerical validation and results derived from CFD simulations, emphasizing airflow dynamics, turbulence intensity, and particle dispersion across varying droplet sizes and airflow velocities under distinct ventilation setups.

Validation

Prior to analyzing the fluid dynamics and flow patterns within the classroom geometry, the current numerical model for simulating particle motion was validated against the results of Jacob et al.[39] Figure 4(a) illustrates the computational domain, while Figure 4(b) presents the velocity profiles at various locations within the designed room. In addition, Figure 4(c) compares the velocity distributions at different locations, demonstrating a strong agreement with the findings from the previous study.

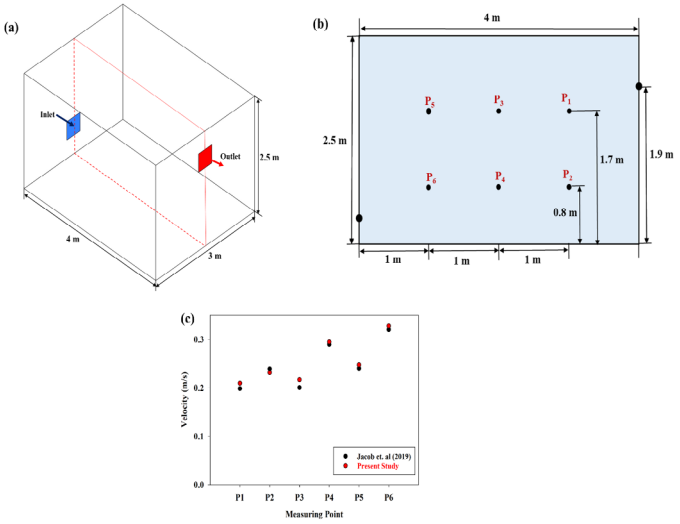

FIGURE 4. (a) Computational domain for validation, (b) measured location inside the test chamber, and (c) velocity distribution at various positions.

Airflow Characteristics

The airflow distribution within the classroom was simulated under different ventilation configurations (top and side walls) and inlet velocities (3 m/s, 5 m/s, and 7 m/s). The velocity distribution analysis within the classroom was carried out concerning different airflow velocities (3, 5, and 7 m/s) and two ventilation patterns: side wall and top wall ventilation. Figure 5 demonstrates that side wall ventilation creates a horizontal jet that becomes deeper and larger in circulation as velocity augments and circulation zones influence particle movement and dispersion. The recirculation zone is clear-cut and increases with the inlet velocities. As velocity increases, the graph in Figure 6 demonstrates a rise throughout the room. Contrarily, Figure 7 presents velocity vector fields at the mid-plane for top wall ventilation across three inletvelocities—3, 5, and 7 m/s—demonstrating the formation of

a downward airflow jet from the ceiling. Figure 8 shows the corresponding velocity magnitude contours near the floor, indicating that at the highest velocity of 7 m/s, the airflow penetrates more deeply into the student seating area, thereby increasing airflow coverage near occupant breathing zones.

Turbulence Intensity Distribution

An analysis of turbulence kinetic energy (TKE) was conducted to examine the influence of airflow velocity on turbulent mixing in the classroom. TKE contours illustrate the impact of ventilation airspeed on turbulent mixing. The results demonstrate a clear association between input airspeed and the magnitude and intensity of turbulent regions. In side ventilation (Figure 9), an increase in inflow velocity results in a wider and more violent turbulence zone. The top wall ventilation (Figure 10) demonstrates elevated turbulent kinetic energy (TKE) next to the first row of students and the droplet source, indicating enhanced mixing in the anterior area.

Droplet Size and Settling Behavior

Figure 11 illustrates the dynamic behavior of droplets of varying diameters 1 s after a coughing event simulated with a velocity of 10 m/s sustained for 0.75 s. Larger and heavier droplets, such as those measuring 100 µm and 150 µm, exhibit rapid gravitational settling as expected, while smaller droplets measuring less than 1 µm remain suspended in the air for a prolonged duration. This persistence highlights their potential role as aerosol carriers, contributing to airborne transmission risk within the classroom environment.

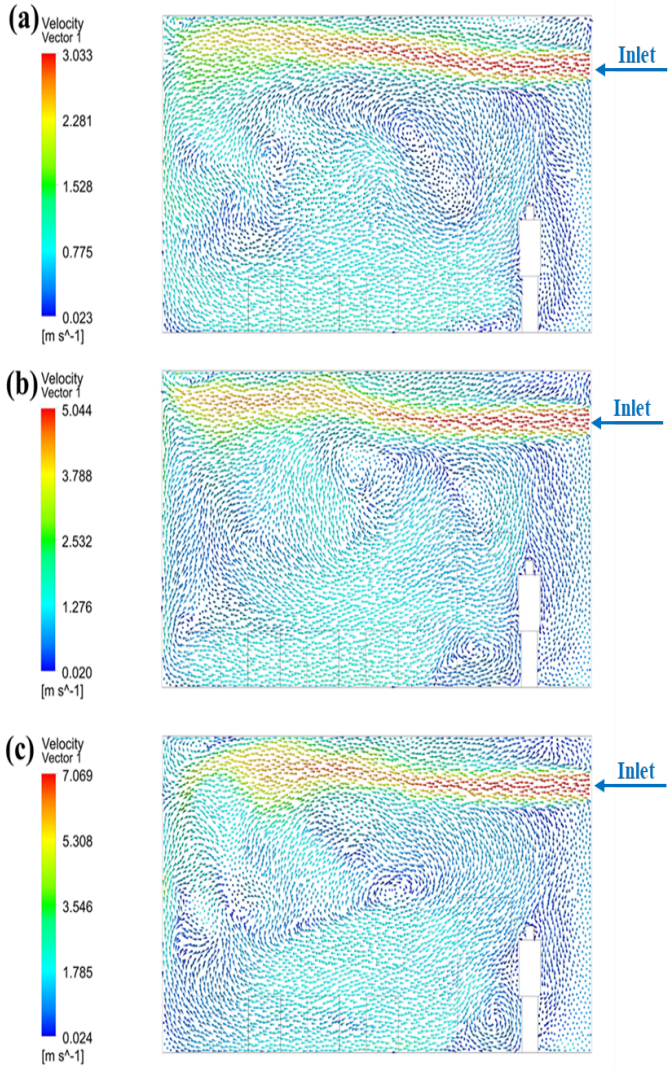

FIGURE 5. Velocity vector fields at mid-plane for side wall ventilation at different inlet velocities: (a) 3 m/s, (b) 5 m/s, and (c) 7 m/s.

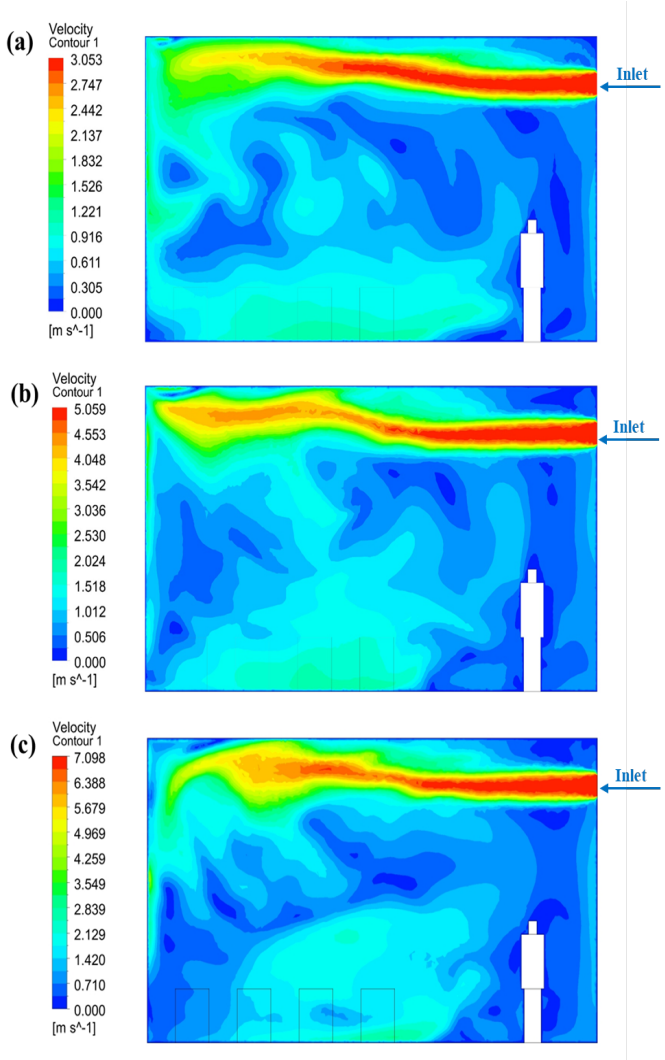

FIGURE 6. Velocity magnitude contours (in m/s) at classroom mid-plane for side wall ventilation: (a) 3 m/s, (b) 5 m/s, and (c) 7 m/s.

Particle Dispersion Under Different Ventilation Scenarios

The spatiotemporal evolution of particle distribution was evaluated under three conditions: no ventilation, top wall ventilation, and side wall ventilation. Droplet trajectories were recorded at various intervals to analyze which seating zones were most affected over time. In the absence of ventilation (Figure 12), droplets accumulate near the first row, especially in seat 3. With top ventilation, initial dispersion is limited (Figure 13); however, by 10 seconds, some particles reach seats 1–6 (Figure 14). Side ventilation shows a greater concentration near the source at 10 s (Figure 15), expanding to the rear seats, such as 22–24, after 20 s (Figure 16). After 60 s, most particles exit the classroom, but some remain near the last row (Figure 17).

DISCUSSION

This section interprets the results regarding ventilation design, airflow behavior, particle dynamics, and implications for infection risk.

Influence of Airflow Velocity on Turbulence and Jet Formation

The simulations validate the sensitivity of the velocity of the airflow against the configuration of the ventilation jet, the generation of the turbulence, and the transport of the droplets in the classroom environment. With a higher inlet velocity (7 m/s) compared to the previous velocity (3 m/s), the ventilation jets are more energetic and deeper, forming a larger and more stable circulation zone (Figures 5–8). This accelerated jet stream promotes air mixing and particles suspended, particularly along the flow axis in ventilation. In parallel, the kinetic energy of turbulence (TKE) increases significantly as the speed of airflow increases (Figures 9 and 10). It spreads the areas of turbulent mixing and promotes the wider dispersion of droplets. These findings agree with already-known principles of jet behavior in closed environments and support the existing literature by Tan and Glenn[11], Liu et al.,[9] and Kotb and Khalil,[16] who identified increased turbulent transport and possible cross-contamination with higher airspeeds in their CFD-based studies. Significantly, high turbulence not only enhances particle mixing but also causes a shorter residence time of the airborne droplets, which increases the possibility of evacuating infectious aerosols promptly. This highlights that ventilation velocity is the most crucial factor in managing the risk of air distribution within an indoor environment.

Ventilation Configuration and Spatial Exposure Risk

The spatial distribution of suspended droplets because of the ventilation layout is greatly influenced; this is the difference that is most exposed in a classroom. The top wall ventilation scheme delivers air to the ceiling and directs it downward, making the jets of air so strong at the frontmost rows of learners. In this setup, as seen in Figures 13 and 14, droplet concentration will be around seats 1–6 shortly after a coughing session.

On the other hand, the side wall ventilation type causes air to travel laterally along the room, and the direction of air moves the particles toward the back of the room as time goes on. As seen in Figures 16 and 17, the peak in the concentration of particles can be observed when it is already 20–60 s after an emission occurs, with the most in and around the last row.22–24 This redistribution effect has proved that although the top ventilation can enhance the occupants' exposure in the front row, the side ventilation can cause delayed but more extensive exposure at the back of the classroom. The results aligned with those of Abuhegazy et al.[30] who identified that ventilation's directionality significantly affects particle transport and particle deposition on a surface. The findings indicate how ventilation should be designed to be context-sensitive, with consideration to the geometrical nature of the rooms, room occupancy, floor plans, and the temporal exposure patterns.

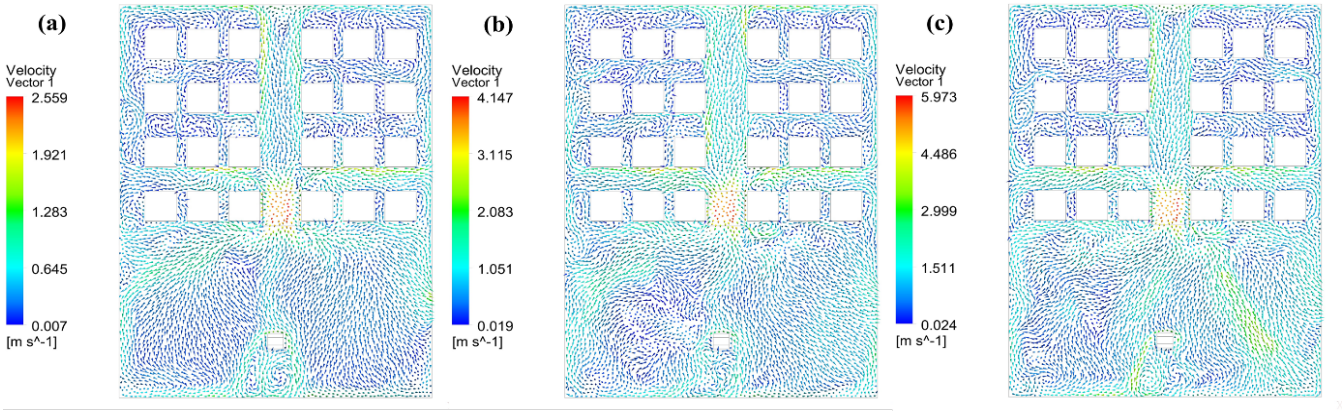

FIGURE 7. Velocity vector fields at mid-plane for top wall ventilation at inlet velocities of: (a) 3 m/s, (b) 5 m/s, and (c) 7 m/s.

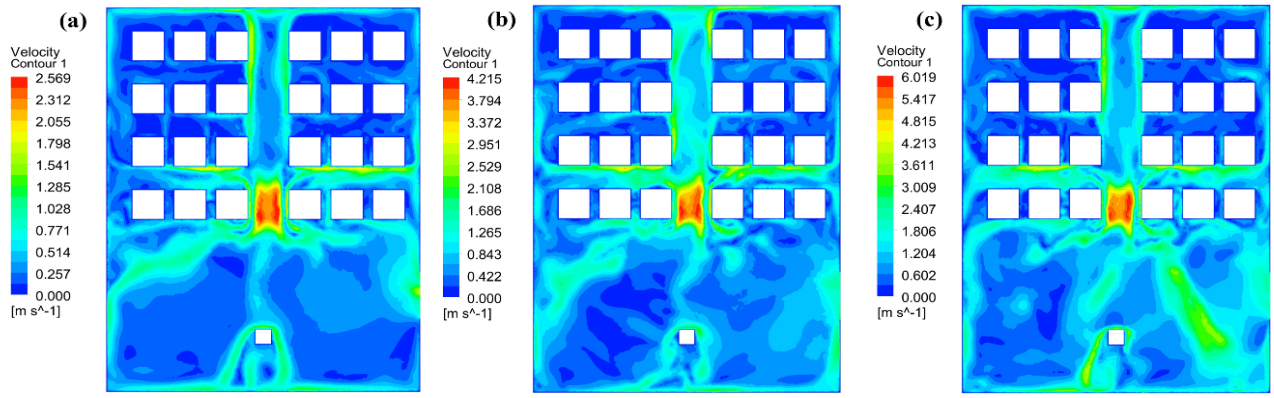

FIGURE 8. Velocity magnitude contours (in m/s) near floor level for top wall ventilation: (a) 3 m/s, (b) 5 m/s, and (c) 7 m/s.

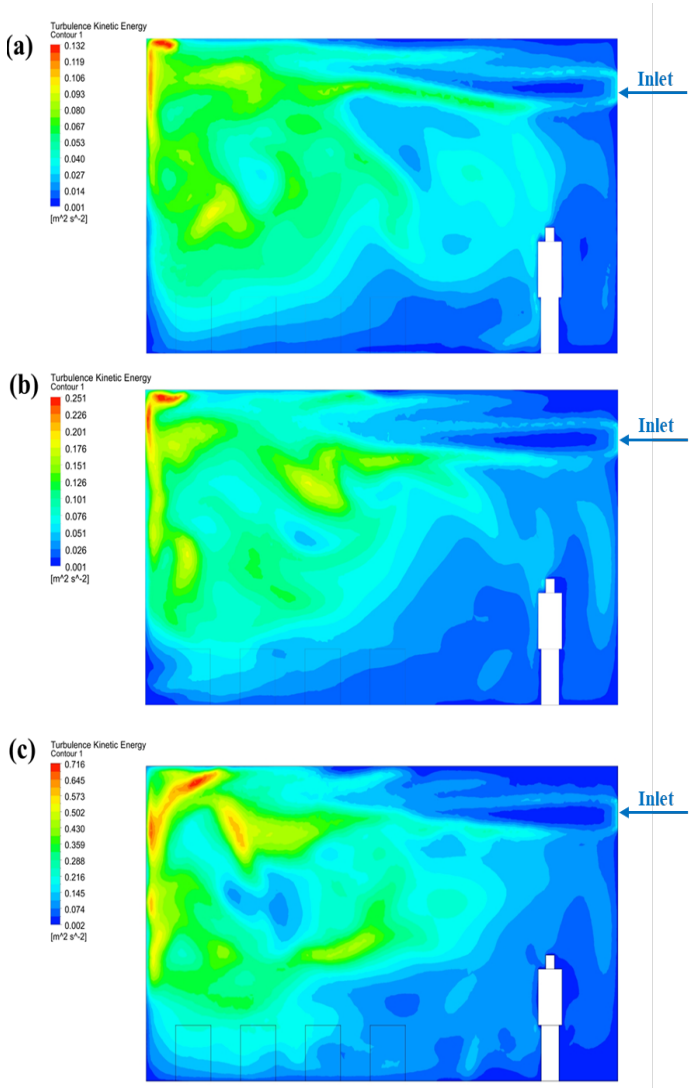

FIGURE 9. Turbulence kinetic energy (TKE) contours (in m^2/s^2) for side wall ventilation: (a) 3 m/s, (b) 5 m/s, and (c) 7 m/s.

Effect of Droplet Size on Suspension and Deposition

The size of virus-laden droplets plays a huge part in how they behave. Simulation results indicate that large droplets (100–150 µm) fall fast within a few seconds because of gravitational settling (Figure 11). These droplets are usually related to close contact and contamination of surfaces. Smaller droplets, especially those less than 1 µm across, on the contrary, can stay in the air current much longer. These particles sink to the ground a little and are more prone to be carried by wind and turbulence. This is in line with what Morawska and Milton[6] suggest in their findings, as they pointed out that aerosols are the most prominent route of transporting the transmission over long-range airborne transmission indoors. This size-dependent activity explains the significance of ventilation measures that can efficiently eliminate or dilute small particles instead of focusing on surface cleaning and spatial distancing.

Implications for Classroom Ventilation Design

Considering airflow velocity, droplet size distribution, and ventilation geometry provides interesting suggestions for improving classroom design to reduce air provision. First, it was found that the higher the ventilation velocity, the better the particle clearance, and the shorter their mean residence time (meaning that it was shortened more in the case of aerosols of small size). But this advantage should be weighed against the possibility of redistribution of particles by high-speed air to broader areas.

Secondly, the air in/out location should be well thought over. Top ventilation could quickly clear an area of particles in the breathing zone behind them, but might also cause a rise in exposure in the front seat areas. Side ventilation, however, will provide a more homogeneous air distribution in case of slow clearance or would lead to accumulation in downstream areas. This evidence confirms the approach suggested by Bazant and Bush,[8] that directional high-efficiency ventilation and an occupancy-sensitive design layout should be used. This might include not placing high-risk individuals (e.g., teachers or symptomatic students) in the direct flow path, opening air exchange rates in classrooms, and using specific filtration or air disinfection technologies.

CONCLUSION

The study examined the flow dynamics and dispersions of droplets of various sizes produced by a COVID-19-infected person coughing in a classroom with varying ventilation systems. 3D simulations were performed for various ventilation airflow velocities entering the intake

duct and exiting the open classroom door. Based on the reported findings, the following conclusions are drawn:

- Seat number 3 is the most impacted by contaminated human coughing in the absence of ventilation.
- Coughing affects the first row of students because of inadequate top ventilation. Sidewall ventilation affects the final row of students the most because of reduced airflow in that area.
- The turbulence rate rises with higher airflow velocity, increasing the dissemination of contaminated particles.
- The number of suspended droplets typically decreases as the ventilation velocity increases at a given period after injection.
- In all types of ventilation, the average concentration of droplets in the room decreases as time increases.

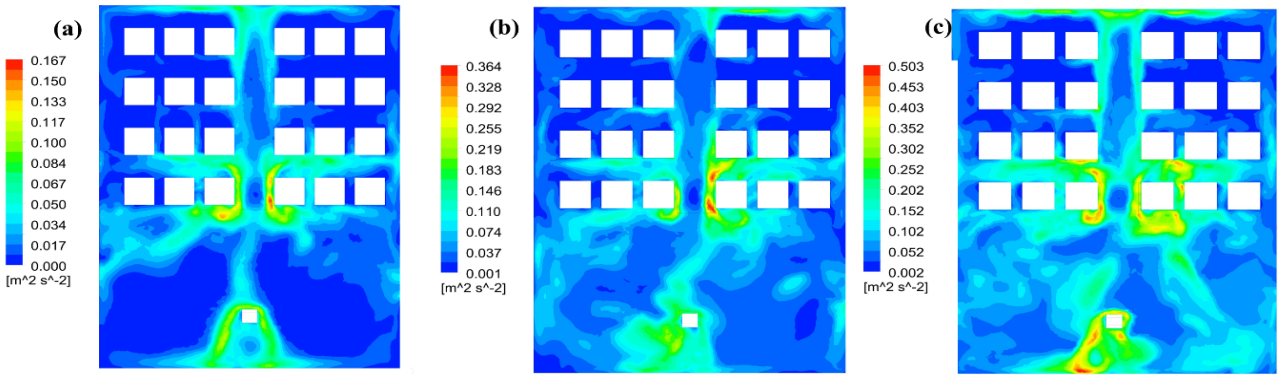

FIGURE 10. Turbulence kinetic energy (in m^2/s^2) contours for top wall ventilation: (a) 3 m/s, (b) 5 m/s, and (c) 7 m/s.

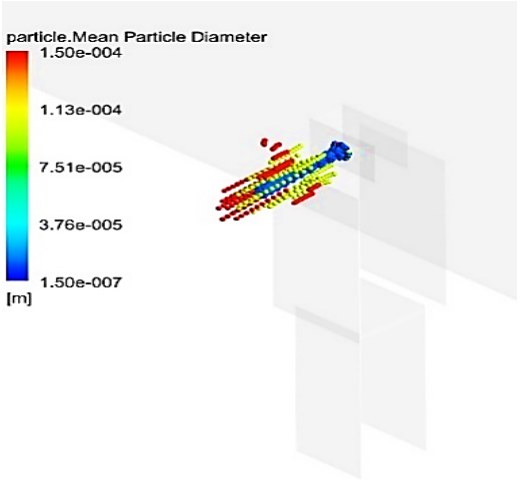

FIGURE 11. Initial droplet distribution 1 s after coughing (velocity = 10 m/s for 0.75 s): Droplets of varying diameters (0.15–150 μm).

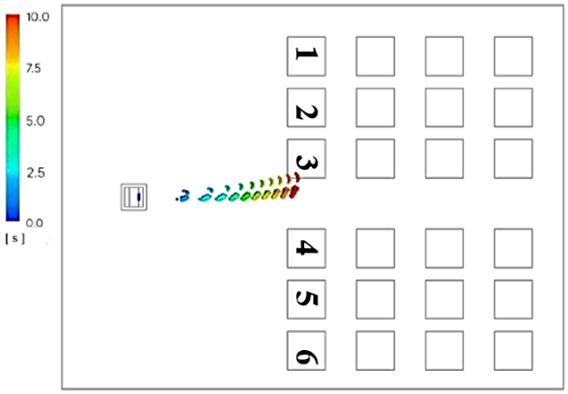

FIGURE 12. Droplet dispersion 10 s after coughing with no ventilation.

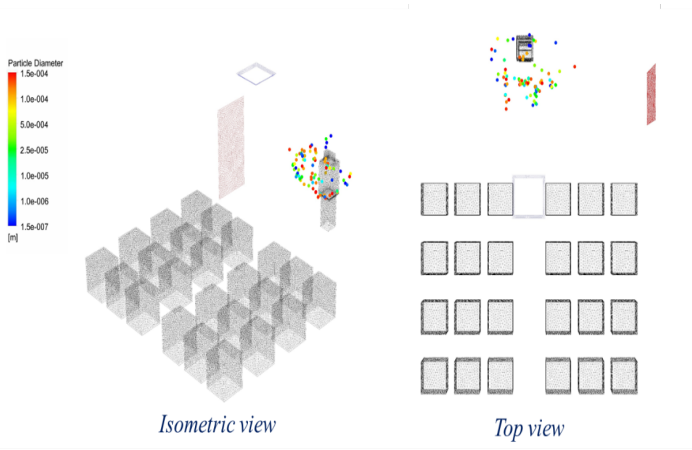

FIGURE 13. Droplet distribution 5 s after coughing with top ventilation at 5 m/s.

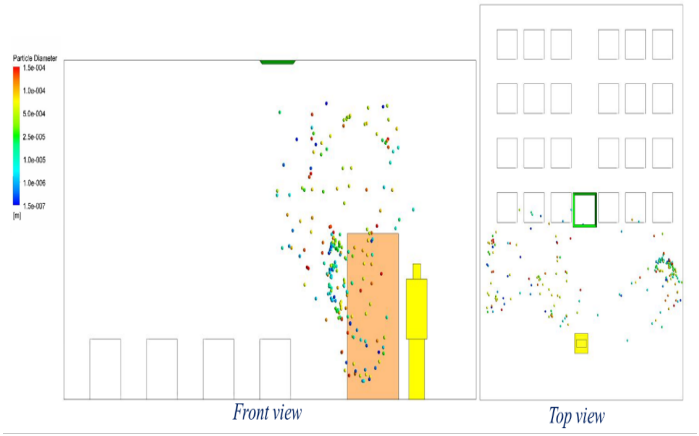

FIGURE 14. Droplet spread 10 s after coughing with top wall ventilation at 5 m/s.

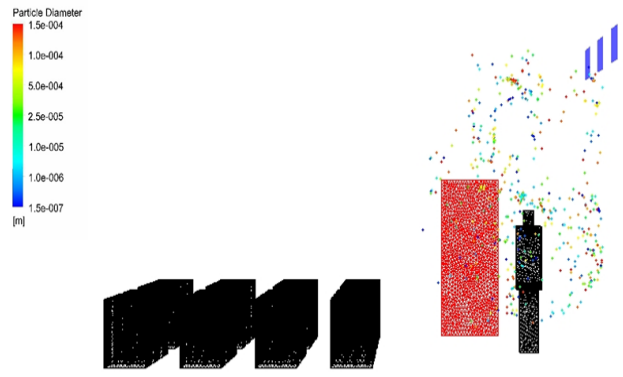

FIGURE 15. Particle distribution 10 s after coughing with side wall ventilation at 5 m/s.

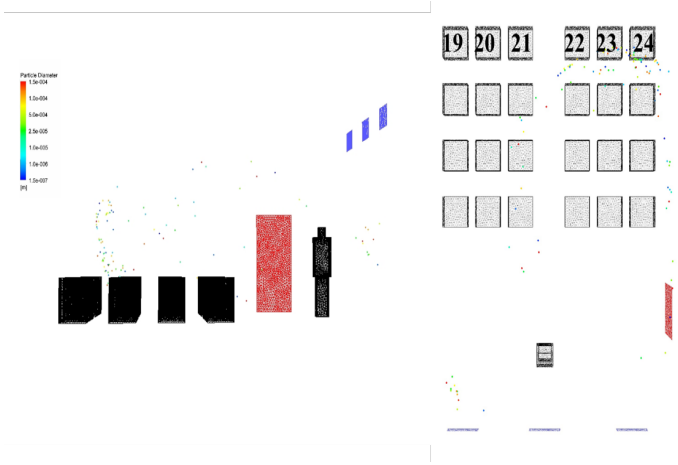

FIGURE 16. Particle distribution 20 s after coughing under side wall ventilation (5 m/s).

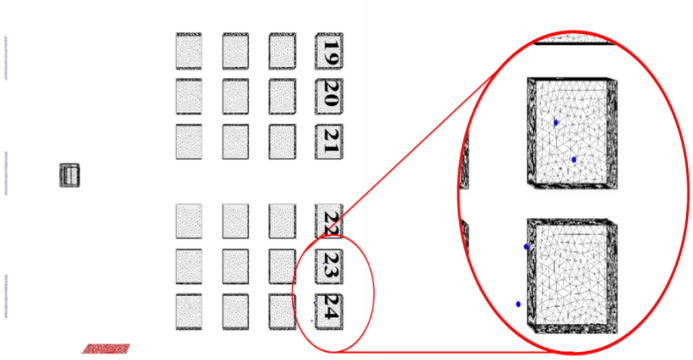

FIGURE 17. Droplet distribution 5 s after coughing with top ventilation at 5 m/s.

AUTHOR CONTRIBUTIONS

Conceptualization and methodology: A.R.P., S.K., and S.K.; Literature review: A.R.P.; Formal analysis: A.R.P. and S.K.; Writing–original draft preparation: A.R.P. and J.S.; Software: A.R.P. and S.K.; Writing–review & editing: A.R.P. and J.S.; Visualization: S.K.; Supervision: A.S., P.K., J.S., S.K.

ACKNOWLEDGMENTS

Not applicable.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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Received September 18, 2024, accepted June 23, 2025, date of publication September 30, 2025.

Original Research Article

Training of Surgical Skills by a 3D Augmented Liver Model Response During Instrument Interactions Simulation

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ABSTRACT

Background and Objective: In recent years, interest in surgical robotics simulation has grown significantly, particularly among trainee surgeons. This trend is driven by the demand for cost-effective training solutions, improved surgical outcomes, and reduced training times. Simulations also play a vital role in the design and testing of surgical instruments, enabling analysis of static and dynamic loads and optimization of tool–tissue interactions. However, because of the complex nature of soft tissue deformation during surgical procedures, developing realistic and effective simulations remains a challenge. This study focuses on modeling liver responses during tool–tissue interactions in laparoscopic surgery. Building on prior research in surgical robotics, the goal is to develop a personalized training platform that enhances the skills of surgical personnel without the need for live human or animal subjects.

Materials and Methods: The study begins by analyzing the motion of a tactile surgical instrument interacting with tissue. Direct kinematics is used to enable remote control of surgical robots by the lead surgeon. To improve control accuracy, systematic positional errors are introduced into the control links. A simulation program is developed to define the operational workspace and potential tool actions. Movement within this space is controlled by four motors connected to transmission mechanisms. Analytical models of these mechanisms are used to optimize performance under defined constraints. In addition, a training simulation program (TSP) is created to model liver responses during tool–tissue interactions. This program visualizes the 3D behavior of organs using physical material properties and simulates collisions between solids. The Unity Game Engine is used to generate animations compatible with both standard and VR/AR environments.

Results: Experimental data involving various laparoscopic instrument tips and biological tissues are stored in a MySQL database. These data can be accessed via local workstations, institutional servers, or cloud-based platforms. Users can also store their simulation data on mobile devices or processor cards.

Conclusion: This study presents a comprehensive approach to developing a surgical training system that simulates realistic tool–tissue interactions. The findings contribute to the advancement of minimally invasive surgical education by enabling personalized, data-driven training experiences. The proposed system offers a scalable and ethical alternative to traditional training methods, with potential applications in both academic and clinical settings. The simulation programs effectively transferred acquired skills to real-world scenarios, demonstrating the system's potential for enhancing surgical training.

Keywords—*Augmented reality, Training program simulation (TPS), Software applications, Surgical robotics, Surgical training.*

INTRODUCTION

Software applications offer innovative solutions in Medicine. In surgery, this progress allows the development of surgical simulators that reach the maximum level of realism and emulate complex procedures, taking into account the specificity and anatomical requirements of individual patients. Also, the simulation is a suitable method for training surgeons in complex movements and operations because it reduces the duration of the surgeon's training in minimally invasive surgery (MIS). The methodology for developing a web-based laparoscopy e-training system is particularly important.[1] Software applications can provide a surgical environment with its physical properties, texture, and complexity. Computer-based methods can be the main part of surgical tool design. To solve new problems that continue to arise in real surgical procedures, new tools are created every day. An important step in the creation of surgical instruments is the development and application of a virtual environment and near-real models to simulate the response of the organ when interacting with an instrument. Simulation methods can provide different scenarios for the operation to take into account different anatomies, pathologies, and working areas. Training modes include tabletop models, virtual reality (VR), augmented reality (AR), animals, and cadavers. There are claims that the haptic interface, along with the visual simulation, aids the student or young surgeon to get a virtual experience of the surgical procedure as in a real patient operation. However, a number of studies prove that a combination of models is more effective than model-based learning alone.

The main ways to accomplish the simulation task are: a model, a detailed description of the real-world application of the model, and the applied forces/moments. Different medical procedures require different organ models.

The basic approaches for model response during instrument interactions are Mass-Spring System (MSS)[2] and Finite-Element Method (FEM).[3] In the first approach, the geometric model of an organ is represented as particles with their own positions, velocities, and accelerations, which are connected by springs and dampers. The particles move under the influence of the forces of the surgical instruments. In FEM, each element of an organ model is calculated to obtain the deformation of the model under the applied forces.

Real-time surgical simulation requires computing the deformation of viscoelastic human tissue and generating both graphic and haptic feedback. Deformation simulation is based on a sequential calculation of the tissues' shape. The reaction forces result from the tool–tissue model interactions, where the virtual tools are controlled by the smart tools. Tissue models must look and behave realistically and be based on the physical laws related to human organ behavior.

Models used for simulation are mainly based on geometry or mechanics. Geometric models are not accurate enough because they only simulate relative visual displacements. Mechanical models are accurate, but for a VR simulation, they can change continuously until they reach an equilibrium state, which makes them difficult for the operator to manipulate.

Sorkine and Alexa4 propose a method for surface modelling, where the object changes the shape of a mesh while preserving the details. It is characteristic that the peaks of the original grid must be specified. Then, the boundary is determined for new positions, so that the rest of the mesh vertices adapt to the new shape. The original geometric size of the mesh should preserve as much of the deformation as possible.

Some authors show a virtual simulator for pre-rolled soft tissue suturing without showing the making of knots, which is a basic moment in suturing.[2]

Telesurgery is evolving thanks to AR and wireless technology. Lead surgeons can train students and young surgeons in complex surgical procedures. Surgery is also aided by 3D printing technology. Tumor data can be extracted from CT or MRI scans and converted into a digital 3D model, which can then be 3D printed. From this model, the surgeon can see the relationship between the tumors and the surrounding tissue, which aids in planning the surgery.

The student or young surgeon can virtually experience all the essential aspects of a procedure through visual simulation and haptic technology, which otherwise would involve invasive techniques on a real patient or a corpse.

Great computing power and accuracy of haptic devices are only part of the advantages characteristic of modern laparoscopic simulations, which create favorable conditions for the process of preoperative planning and the training of surgeons. One such development is the EU PASSPORT for the simulation of laparoscopic liver resection, which uses many modern methods and the capabilities of the GPU to simulate various deformable organs in real time."[5] The work of Acharya, where the kinematics of the surrounding organs are studied, is also intended for simulation training and access (geometry) to the liver.[6] In this research, diaphragm movement patterns are also presented for use in simulators for preoperative planning and training. An advancement in the field of organ modelling is also the work of Villard,[7] where respiratory movements of the chest and soft tissue behavior of organs of a group of patients segmented by computed tomography in a liver biopsy simulator are modelled. A nonlinear liver model to measure organ response to force, accounting for organ deformation and boundary conditions, is presented by Lister.[8] The accuracy of the model is assessed by drilling simulation.

There has also been progress in the modelling of surgical procedures. A team of scientists presented a real-time electrosurgical simulation virtual tool where the relationship between heat generated in the tissue and applied electrical potential was explored.[9] All this finds good application in virtual surgical ablation. Over the years, 3D organ models have moved from linear[10] to nonlinear,[11] Moreover, simulations are increasingly complex and realistic, making them accessible and attractive for applications.

Force feedback simulators are a more intuitive means of providing haptic information to the surgeon, while visual force feedback provides information about instrument contact with tissue under certain conditions. That is why haptic devices with touch simulation are increasingly being used. They are used in medicine for training and planning operations.[12] One of the first palpation developments is a 3D visual and haptic liver diagnostic simulator with open-source software.[13] SimSuiteTM System by Medical Simulation Corporation is one of the representatives of haptics devices, with a realistic simulated clinical environment.[14] It offers haptic systems with real scenarios and images together. The force feedback is transmitted by an endoscope to give the real feeling. The system includes personal or team training with varying levels of complexity. Its possibilities are the patient history, diagnosis, risk assessment, and intervention preparation.

The training program proposed in this publication, referred to as the training program simulating (TPS), facilitates the observation of three-dimensional (3D) augmented model responses during tactile instrument interactions within the context of surgical education. This program was developed to enhance the training of students and improve the qualifications of surgical personnel in the use of laparoscopic instruments. The application presented herein represents an advancement of an existing mechatronic system designed for laparoscopic surgical training, aimed at both student education and the professional development of surgeons. The system is constructed on a modular framework, reflecting the principles underlying the program's implementation. This training platform was developed so that students and surgeons can improve their qualifications without using living organisms—humans and animals.

VIRTUAL AND AR SIMULATORS AND THEIR PART IN SURGICAL EDUCATION

One of the first VR simulators is the Satava, proposed in 1993. It used a computerized 3D model of the abdominal cavity and a head-mounted display (HMD).[15] Satava is also

targeting the military and aerospace industries, which rely on VR for training, to apply this training to teach skills in operating rooms.[16] This simulator sets the stage for VR training in surgery for many types of procedures, from elementary tasks such as suturing and knotting to mimicking entire surgical procedures.

Virtual-based simulators can use an application that allows interactive exploration of 3D anatomical models and animations. VR makes it possible, through developed mobile applications, to explore different surgical approaches using a smartphone or tablet. Each virtual study uses 3D anatomical models and animations. A learning system aimed at understanding the patient's positioning according to specific anatomy and specific purpose. The study of each approach in 3D mode can be divided into phases too.

VR simulators allow trainees to practice individual movements or entire procedures in a near-real environment. Modern VR simulators can reproduce complex MIS by measuring various parameters of the procedure, including movement efficiency and node reliability, time to perform the operation, and even remote performance evaluation. The price of simulators is quite high, and they do not have tactile feedback and lack realism.[17–19] Because of the lack of realism, the models of corpses and animals in VR simulators should be added to get optimal training. Despite these disadvantages, the number of VR training simulators is growing. VR simulators, such as LapSimTM (Surgical Science, Gothenburg, Sweden),[20] were used for training basic laparoscopic surgery skills, and LapMentorTM (Simbionix Corporation, Cleveland, OH, USA),[21] was used for comprehensive training in laparoscopic sigmoidoscopy. Wynn et al. evaluated the effectiveness of this training in terms of the completion time of the process, the number of right and left tool movements, and the total route length of the right and left tool movements.[22] The research indicates high efficiency. Surgical simulation combined with virtual, mixed, and AR has become increasingly popular in recent years. AR is a technology where digital information does not interact with the real environment but is superimposed on the user's view of the external environment as graphics, audio, or video information.[23]

Telesurgery is a good aid for experienced surgeons teaching young surgeons in complex operations. Thanks to AR and wireless devices, AR simulators take advantage of VR and physical materials, tools, and tactile feedback. The 3D virtual model is a static preoperative photo of a certain part of the body, where even respiratory movements and manipulation of the organ are taken into account. These kinds of simulators are useful for simulation immediately before performing complex surgical operations.[24,25] The high simulation accuracy of the simulator allows visualization of different tissues, tumors, arteries, and veins.

AR in medicine dates back to 1988. One of the first medical AR systems was designed to display individual ultrasound slices of a fetus on a pregnant patient.[26,27] AR aids MIS by enhancing reality in the operating room, expanding the internal view of the patient based on preoperative or intraoperative data, and presenting the surgeon with detailed information about the operative field. Integrating pictures of virtual objects into real scenes is a major tool used in AR systems in medicine. While the surgeon's working area is synthesized in the virtual environment, AR superimposes computer-generated images on the actual view oriented to the direction of vision of the surgeon, who usually wears a suitable HMD or similar instruments. MEDICAL AR for Patient Workstation (MEDARPA) has recently been developed[28] which uses AR without HMD. The surgeon can see the exact location of the damage on the patient while being observed without making a single incision. It is possible to design invisible blood vessels, reducing the risk of accidental damage. The improved visualization from this technology can benefit a variety of clinical procedures. AR serves as a guide for planning practical surgical actions. The patient is positioned in AR: with the help of AR, it is possible to view the entire anatomy and change the position of the body along the three axes. AR visualizes the target of the operation before it is visualized on the simulator. Some of their weaknesses are related to the correct alignment of the position and orientation of the surgeon's eyes with a virtual coordinate system of the augmented images, the spatial tracking systems, and the virtual environment peripherals used.

Simulators combining haptic interfaces with AR tools can be used to detect deviations between the real position

and the preoperative plan and to generate guiding forces for the surgeon. Robot-guided instruments follow the movement of the surgeon, who senses forces interacting with the tissue through the haptic device. The haptic device includes preoperative planning based on medical images and AR to guide the surgeon's movements; AR models also provide visual feedback to the surgeon.

The advantage given by the simulation is that different parameters can be optimized, which gives good results in different areas of application.[29]

From the foregoing, it is clear that the high level of technical complexity of advanced laparoscopic procedures and the lengthy training pose many challenges to surgeons. This makes simulation an important tool in the training of complex laparoscopic surgery. That is why our efforts are directed in this direction.

This paper is organized into the following sections: Section 2 is referred to as the Investigation of Instrument Moving. Section 3 marks Architectures of Control Program Algorithms. Section 4 refers to A Simulating Approach of Liver Model Response during Tactile Instrument Interactions and Its Results. At the end, there are sections on Future Challenges and Conclusions.

Software applications offer innovative solutions in all spheres of human life,[30,31] the most significant of which are in medicine. For this work, some calculating methods[32] for identifying both tool tissue force and maximum local strength are touched upon. Authors will specifically try to investigate these in the future.

A contemporary strategy yielding favorable outcomes involves the enhancement of existing systems across various domains and purposes, thereby conserving both financial and temporal resources in the research and development of new systems. An illustrative example is provided in reference,[33] which outlines the primary procedures for upgrading existing systems for the automation and control of industrial and manufacturing processes. In alignment with this approach, it proposes to upgrade a laparoscopic execution tool system for robotic applications, incorporating functionalities that leverage AR and simulation technologies to facilitate the training of surgeons.

INVESTIGATION OF INSTRUMENT MOVING

The action control in telecontrol (by the leading physician of the operation) is realized by the direct kinematic task. Moreover, to refine the action, the systematic positional error in the working position can be introduced into the control links. Solving the straight kinematic problem is a standard procedure.[34] It is possible to develop a simulation program to outline the workspace and possible actions in it. For an instrument with four independent movements, these movements are obtained by four motors and the corresponding transmission mechanisms between the motors and the executive links in this space. Figure 1 shows the possible instrument workspace and the instrument motions in this workspace. The relation can be written in Equation 1:

$$\begin{vmatrix} \varphi_1 \\ \cdot \\ \varphi_2 \\ \cdot \\ \varphi_3 \\ \cdot \\ \varphi_4 \end{vmatrix} = \begin{bmatrix} \frac{\partial \varphi_1}{\partial q_1} & 0 & 0 & 0 \\ 0 & \frac{\partial \varphi_2}{\partial q_2} & \frac{\partial \varphi_2}{\partial q_3} & \frac{\partial \varphi_2}{\partial q_4} \\ 0 & 0 & \frac{\partial \varphi_3}{\partial q_3} & 0 \\ 0 & 0 & 0 & \frac{\partial \varphi_4}{\partial q_4} \end{bmatrix} * \begin{bmatrix} \cdot \\ q_1 \\ \cdot \\ q_2 \\ \cdot \\ q_3 \\ \cdot \\ q_4 \end{bmatrix} \quad (1)$$

where $\varphi = [\varphi_1, \varphi_2, \varphi_3]^T$ is a vector of angular velocities of the executive link

$$J = \begin{bmatrix} \frac{\partial \varphi_1}{\partial q_1} & 0 & 0 & 0 \\ 0 & \frac{\partial \varphi_2}{\partial q_2} & \frac{\partial \varphi_2}{\partial q_3} & \frac{\partial \varphi_2}{\partial q_4} \\ 0 & 0 & \frac{\partial \varphi_3}{\partial q_3} & 0 \\ 0 & 0 & 0 & \frac{\partial \varphi_4}{\partial q_4} \end{bmatrix}$$

where J is the Jacobian matrix, which reflects the value of the transfer functions, including dependent movements; $q = [q_1, q_2, q_3]^T$ is the vector of angular velocities at the robot's joints.

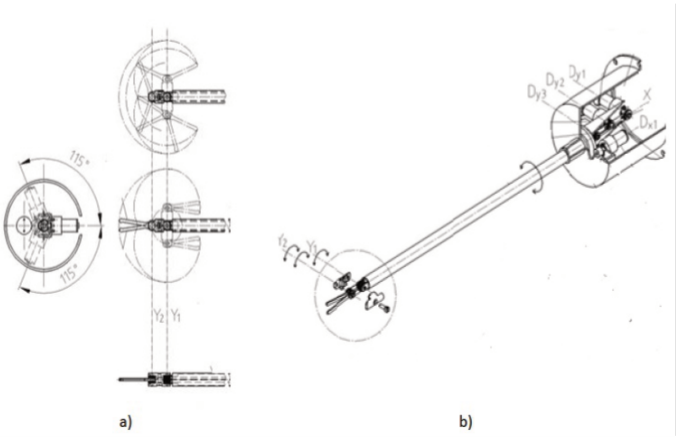

FIGURE 1. Possible instrument workspace and instrument monuments.

There is a need to determine the optimal area for the movement of the tool, using qualitative indicators. These indicators are based precisely on the Jacobian matrix. As a result, the geometry of the tool is optimized so that in a certain area, the configurations will provide optimal movement from the point of view of kinematics. This is important when scaling movements, that is, with a larger "size" of movement by the operator (master), minimal movements of the robotic tool are ensured. In an optimal configuration (a good quality indicator), these optimal configurations facilitate the control system.

The transmission functions $\frac{\partial \varphi_i}{\partial q_i}$ (i = 1, 2, 3, 4) along the main diagonal have the same structure:

$$\frac{\partial \phi_i}{\partial q_i} = i_{pi} \times i_{ni}, (i = 1,2,3,4) \quad (2)$$

where $i_{pi}(i = 1,2,3,4)$ is the value of the gear ratio of the reducer of the corresponding circuit (most often and in this case are equal); $i_{ni}(i = 1,2,3,4)$ is the value of the gear ratio of the wires. For the determination of i_{ni}, kinematic chains of links 2 and 3 are used, as the kinematic chain of link 4 is similar to link 3.

Transmitting functions at the major diagonal $\frac{\partial \varphi_i}{\partial q_i}$, where $i_{pi}(i = 1,2,3,4)$ possesses a similar structure.

$$\frac{\partial \phi_i}{\partial q_i} = i_{pi} \times i_{ini}, (i = 1,2,3,4) \quad (3)$$

where $i_{pi}(i = 1,2,3,4)$ is the value of the gear reduction ratio of the respective chain (often and in this case they are identical) and $i_{ni}(i = 1,2,3,4)$ is the value of the gear transmission ratio of the wire.

The derived analytical dependencies of the transmission functions make it possible to carry out calculation procedures for the optimization of dimensions under the existing limiting conditions and also to be implemented in the software for controlling the movement of the tool, which is explained in the next section.

A SIMULATIING APPROACH OF LIVER MODEL RESPONSE DURING INSTRUMENT INTERACTIONS

Tasks and Motions in Surgical Operation

The actions that are referred to in the performance of laparoscopic operations are numerous, and their priorities are defined and strictly performed by the medical teams. In this case, when they are referring to actions that require manipulative movements through specialized tools, they include:

Visualization (illumination and movement of a mini video camera into the body of patients) of the manipulated objects at the place where the controlled action is performed:

- Gripping with positional fixation of the object in order to be manipulated, without being uncontrolled;
- Gripping (clamping) in order to isolate and temporarily disconnect the object during manipulation with it;
- Clamping blood vessels to hold up bleeding damage.

Elementary actions such as touching and grasping are basic tool manipulations and are relatively easy to

perform. More complicated actions are (1) dissections and (2) working with robotic suturing instruments, which require a lot of knowledge and skills from the surgeons, and they are more difficult to simulate too. However, some of them, such as robotic needle driving and grasping, which are easy in open surgery, are found to be more difficult to perform during laparoscopy.

A surgical task such as suturing includes a needle acting with one rotation and one translation.[35] The surgeon's hand is close to the surface being sutured while rotating the needle so that the needle moves in a circular path without damaging the tissue. In robotic surgery, it can be reduced to one movement—rotating around the axis of the instrument, bending the short part of the needle near the blunt end, and just in front of where it is held by the slave instrument, so that the needle moves in a circular arc, while the tool rotates about its axis.[36] Some authors have been focusing on knitting manipulation by robots. Some researchers have performed in vivo tests with different types of needles and tissues, showing that the required range of force and resolution is 2.5 N and 0.01 N, respectively.[37,38] The results in Table 1 are obtained with the designed laparoscopic executive instrument for robots (Figure 2).

TABLE 1. Description of usability attributes.

Samples	Min. force (N)	Max. force (N)	Average value (N)	Amplitude (N)
Styrofoam sample	0.1	1.67	0.83	1.57
Styrofoam rubber sample	0.785	2.26	1.13	1.47
Muscle tissue sample	0.45	2.4	1.21	1.94
Sample liver, pork	0.05	1.96	0.93	1.9

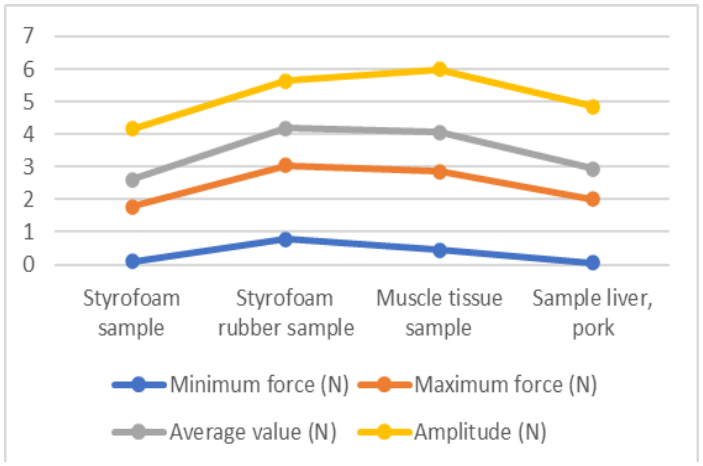

FIGURE 2. Force measurements for different samples.

The research shows the following results. The required force for soft tissues is about 0.2 N, the applied gripping force for soft tissues is 0.5 N, and it is 0.9 N for hard tissues. The required force is different for different cases. It depends on the patient's age, health, gender, and other factors. In general, the maximum force is from 1.5 to 3 N. In isolated cases, the required force is from 6 to 12.5 N. These cases occur when the instrument is used for tissue lifting. So, the instrument force is combined with the forces because of the properties of the fabric and those of gravity. However, the simulation program does not take gravity into account. The maximum cutting and spreading force is from 3 N to 6 N. Suture tasks force measurements show liver puncture up to 5 N, and the required gripping force is 3.45 N. [39–41]

This information is useful for realizing a 3D augmented model.

A SIMULATING APPROACH OF LIVER MODEL RESPONSE DURING INSTRUMENT INTERACTIONS AND ITS RESULT

A training simulation program (TSP) has been developed wherein the 3D extended model response of a human organ upon impact with external objects. The behavior of the model is represented by the collision of

two solid objects with different physical characteristics. The physical properties of the solids are transposed to "physical material" properties that enable the behavior of the object in the TSP. The Unity Game Engine is used for the TSP, which is intended for developing graphical animations for conventional or VR/AR artificial representations.

TSP includes surface manipulation libraries such as the mesh class. Meshes contain vertices and multiple triangle arrays with corresponding vertices. All vertex information is stored in separate arrays of the same size. The mesh class, along with its vertices, vectors, triangles, and normal, can be used to deform a mesh grid on a 3D object. An example of using the mesh class to deform a 3D object in Unity (see Figure 3) is given with the script below:

```
using UnityEngine;

public class Example: MonoBehaviour

{

    void Update()

    {

Mesh = GetComponent<MeshFilter>().mesh;

Vector3[] vertices = mesh.vertices;

for (int i = 0; i < vertices.Length; i++)

{

//Some conditional transformation for example

                    vertices[i] += Vector3.up * Time.
deltaTime;

}

mesh.vertices = vertices;

mesh.RecalculateNormals();

mesh.UploadMeshData(false);

}

}
```

If the mesh surface deformation has to be executed on some event, the void method Start() should be invoked.

```
void Start()

{

Mesh = GetComponent<MeshFilter>().mesh;

mesh.Clear(); //preserves the existing mesh vertex positions

    //Do some calculations with the mesh.vertices and mesh triangles

}
```

Figure 3 shows an example of the usage of the mesh class for deformation of a 3D object in Unity.

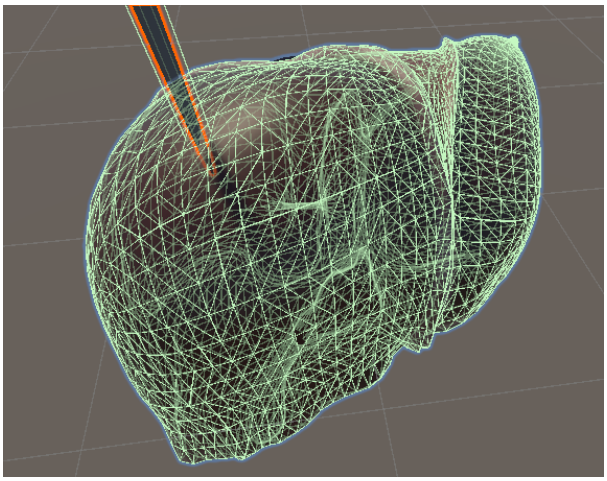

FIGURE 3. A 3D augmented model with mesh collider in Unity.

SOFTWARE ARCHITECTURE

The information from the experiments performed with different tips of the laparoscopic instrument and different biological tissues is recorded in a database that has a connection with the database of the application (developed on the basis of MySQL). The databases are structured as a collection of directories, one for each student (surgeon), with each directory carrying its own ID number (for students, this may be a faculty number). Each of the directories is a collection of subdirectories as follows:

• Personal data for the student/surgeon (three names, social security number, etc.). Only the learner and the teacher can access this subdirectory;

• Subdirectory with information about conducted experiments and their results in text and graphic forms;

• Evaluation of the achieved results and attestation of the student/surgeon;

• Other information required by the relevant university or medical facility.

At the discretion of the institution/clinic concerned, subdirectories of experimental results may be made publicly available to allow for comparisons and solutions for further simulations.

It is planned that the information accumulated in the relevant databases will be stored on a local operator station, a server of the relevant university/clinic, or a cloud medical server, on which more important results of conducted experiments will be published.

Each student/surgeon can save their information on their mobile phone or on a processor card. By their nature, processor cards have the same appearance as telephone cards. However, phone cards only have memory, while electronic chip cards contain a processor. The reprogrammable memory acts as a hard disk for the card—the data stored in this memory retains its values after the supply voltage is turned off.[42] The introduction of processor cards in the educational system in Bulgaria will allow the replacement of existing paper student books with electronic ones, which will guarantee greater reliability, security of information, and access to student data at all levels of educational institutions. Data change is associated with different priority levels. Each teacher will have a unique number/password to change the data in the cards of students/surgeons.

The solution assumes that each classroom is equipped with a personal computer with a minimum configuration that allows work in the Windows operating system. The database will be installed on the teacher's personal computer, as well as the terminal program allowing working with the processor cards. Each student/surgeon must be provided with a Basic Card ZC2.3 processor card (or similar) upon commencement of training by the instructor. The teacher or another person authorized for this activity personalizes the card using the personal computer and the included reading device.[42]

Various means of controlling access to the information are provided, such as the use of passwords, QR codes (for mobile phones),[43] ECG,[44] or an identification chip of the company Dallas Semiconductor/Maxim-DS9490B45 (for access to the software installed on the teacher's personal computer/laptop). The ECG device as a means of access control is proposed because one has already been developed for the modular laparoscopic system described above. At this stage, access control and information protection tools are based on the team's accumulated experience in this area. Information encryption tools are an important element in building a medical security system. This fact is a consequence of the requirements that personal data be protected, both at the local operator stations and on the way to another destination. As a means of access control, the wireless ECG device developed for the mechatronic system can be used.

As the system is built on a modular principle, it will be further updated in the future, both in terms of hardware and in terms of developing new applications based on VR and AR, with the aim of improving the quality of training of medical students and improving the qualification of surgical personnel, which allows various skills and capabilities of the instruments to be acquired and tested before their application in real laparoscopic operations. In the area of information protection and access control means, the possibilities of using other means will be explored, which will be applied at all levels of usability of the accumulated information, which will be effectively used in improving the work with laparoscopic instruments. The possibilities and combinations of means of access control and protection of information in the developed mechatronic training laparoscopic system and the applications developed for it will be studied, as discussed in the present publication. A secure transfer of the information to central servers (of the educational or medical institution) or to specialized cloud medical servers is also planned.

Unity's physics engine is used to simulate the behaviors of objects in the scene and create realistic interactions between them, through physics-based behaviors applied to GameObjects (Rigidbodies and Colliders). Each of the objects should contain a Rigidbody component in order to be affected by the physics engine. The configuration of the Rigidbody component is made by adjusting the properties in the Rigidbody component's inspector. Some of the properties include:

- Mass: The mass of the object, which affects how it will be affected by forces;
- Drag: The amount of air resistance the object will experience;
- Angular Drag: The amount of resistance the object will experience when rotating;
- Use Gravity: Enables or disables the effect of gravity on the object;
- Is Kinematic: This checkbox makes the object not affected by forces, but it will be affected by collisions;
- Forces can be applied to objects by using the "AddForce() function" of the Rigidbody component.

Using Unity's physics engine enables tool–tissue model interactions to be reduced to setting parameter values, without the need to write complex programs with physics dependencies. The correct settings give a realistic concept of the interaction pattern between the two objects, which depends greatly on the level of detailing of the mesh.[46] The coding is reduced to a basic script that initiates the interaction between collider objects and the deformation of the rigid bodies. The script has to be attached to the corresponding object. The result from a 3D augmented model response because of the impact with external objects is shown in Figure 4.

Figure 5 shows screenshots of the MySQL-based database in the developed application. Figure 6 shows the 3D augmented model response during tactile instrument interactions simulating in surgical education.

Figure 7 shows a photograph of the laparoscopic instrument included in the system (Figure 6). The tool

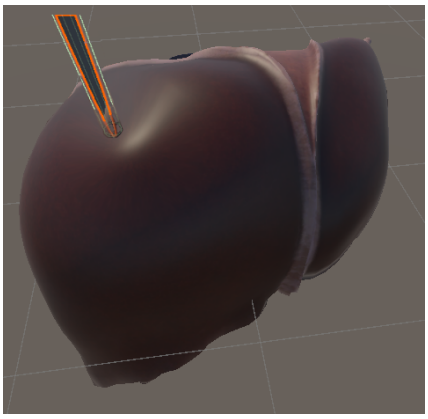

FIGURE 4. A 3D augmented model responds because of the impact with external objects.

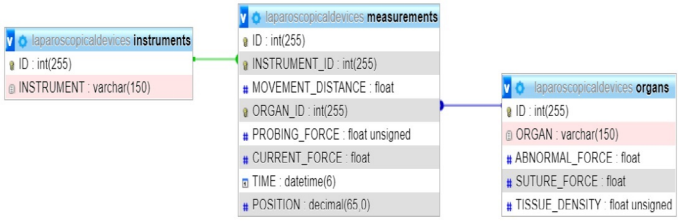

FIGURE 5. MySQL database.

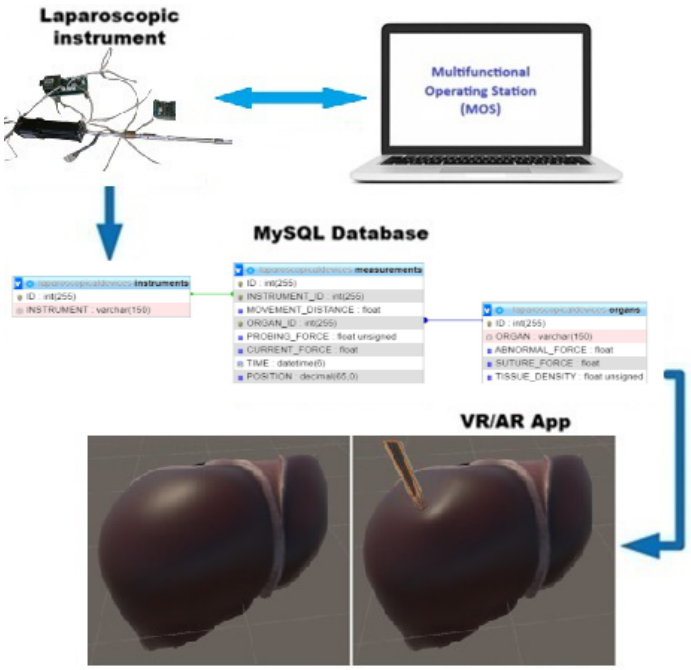

FIGURE 6. The 3D augmented model response during tactile instrument interactions simulation in surgical training.

was developed as part of the "System for analysis and control of mechanical properties of biological tissues," and is protected by a utility model.

Figure 8 shows four tips, called end effectors, that were designed for contact of the tool with a given surface.

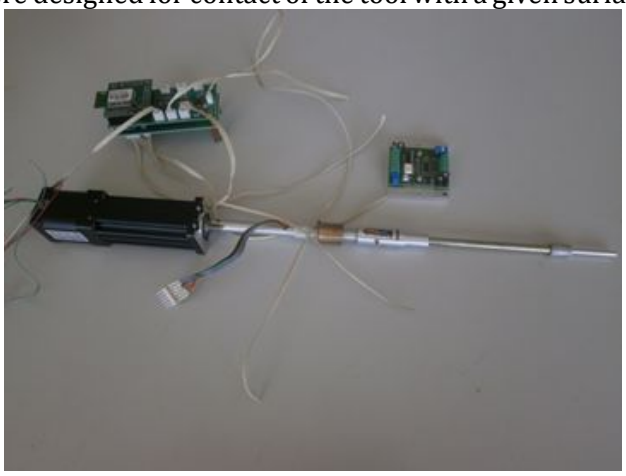

FIGURE 7. An experimental module with force capabilities.

Several experiments were performed with the developed experimental model of a laparoscopic executive instrument.

Figure 9 shows the frame of the AR video stream. The program could be installed on smart devices such

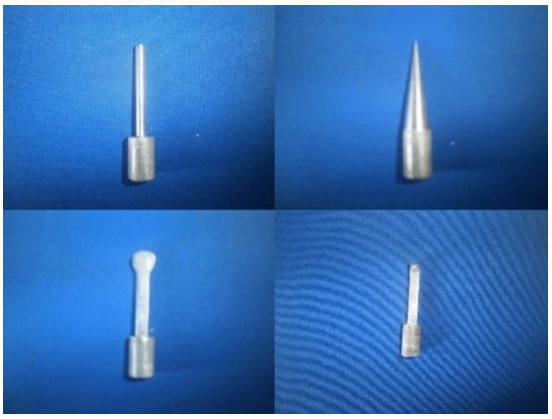

FIGURE 8. End effectors for an experimental module.

as smartphones or smart glasses and exploit built-in microelectromechanical system (MEMS) sensors (accelerometer, gyroscope, camera, solid state compass, GPS, etc.) to evaluate objects and positions situated in the surrounding world.

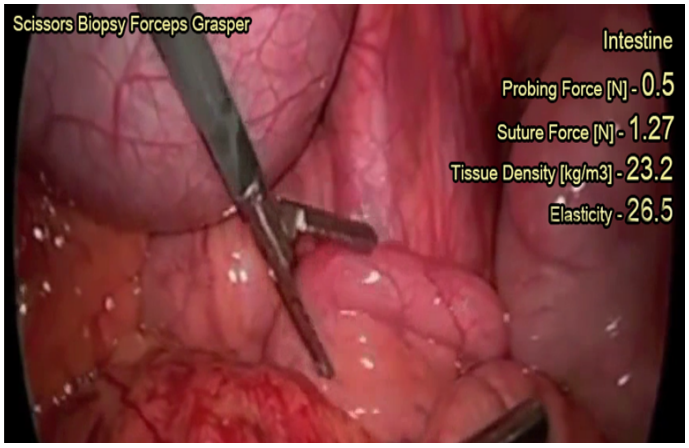

FIGURE 9. The frame of the AR video stream. The visual interface contains only essential information in order to allow the surgeon to concentrate on the medical task.

EVALUATION OF ACQUIRED SKILLS

The review of the literature revealed two approaches to evaluate the skills of medical students and staff: (1) the objective structured assessment of technical skills checklists and (2) the GOALS.[47,48] Methods using AR have been developed to overcome some of the shortcomings of working with laparoscopic instruments, and basic assessment methods have been identified. More information on the topic is given by Roberto et al.[49] These approaches help with the objective assessment of surgical competencies before performing an MIS.[50]

CONCLUSION

The simulation of realistic interactions has become a tangible reality, despite existing challenges such as modeling realistic behavior during user interactions, fluid dynamics, and force feedback mechanisms. The application of computer graphics techniques in medical contexts is increasingly prevalent; however, numerous research challenges persist. These include the need for enhanced realism, a broader array of solution approaches, and improved computational methods for applications. The optimization of training simulators and the effective utilization of computer graphics methods remain critical areas for development.

This article presents a simulation approach that examines the response of a liver model during tactile

interactions with surgical instruments. Initially, the investigation focuses on the movement of instruments, utilizing a direct kinematic task to control actions in teleoperated environments. The derived analytical dependencies of the transmission functions enable the execution of computational procedures aimed at optimizing dimensions within specified constraints, which can subsequently be integrated into software for controlling tool movements. The architecture of the control program algorithms is reviewed, highlighting the simulation module's relevance to this research. This training platform was developed so that students and surgeons can improve their qualifications without using living organisms— humans and animals

Subsequently, a 3D augmented model simulating a human organ's response to external impacts is developed using Unity 3D modeling capabilities. The model's behavior is illustrated through the collision of two rigid objects exhibiting different physical properties. The application of the mesh class for deforming a 3D object within Unity is implemented via scripting. Results depicting the 3D augmented model's response to external impacts are presented, with the coding distilled into a fundamental script that initiates interactions between collider objects and the deformation of rigid bodies. This script must be attached to the corresponding object, with an example provided utilizing the Unity Engine.

Future investigations will specifically focus on computational methods and animation projections to quantify both tool–tissue forces and maximum local strength. The outcomes of this research are deemed applicable to surgical education, allowing for the development of training tasks aimed at cultivating skills necessary for minimally invasive surgical procedures.

AUTHOR CONTRIBUTIONS

Conceptualization, V.I., P.V.V. and A.T.B.; Methodology, V.I., P.V.V. and A.T.B.; Software, P.V.V. and A.T.B.; Hardware, V.I.; Validation, V.I, P.V.V. and A.T.B.; Formal Analysis, V.I and P.V.V.; Investigation V.I., P.V.V., and A.T.B.; Re-sources, V.I. and P.V.V.; Data Curation, V.I.; Writing–Original Draft Preparation, V.I., P.V.V. and A.T.B.; Writing–Review & Editing, V.I., P.V.V. and A.T.B.; Visualization, P.V.V. and A.T.B.; Supervision, V.I. and P.V.V.; Project Administration, V.I.

ACKNOWLEDGMENTS

This work is developed as part of contract №: BG16RFPR002-1.002-0009-C01, project name: 'Regional Center for Digital Solutions and Innovation NCIZ', under Procedure BG16RFPR002-1.002-Funding of selected by the European Commission European Digital Innovation Hubs awarded with Seal of Excellence, funded by Operational Programme 'Research, Innovation and Digitalization for Smart Transformation'.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

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