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Traceability System Analysis for Medical Device Management

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Abstract—Effective management of medical devices is essential to ensure quality and safety in hospital care. In Honduras, the lack of an integrated traceability system limits timely control and maintenance of these devices, affecting the efficiency of health services. This study compares two digital platforms, MaintainX and Airtable, evaluating their applicability for traceability and lifecycle management of medical devices in public hospitals. Aspects such as ease of use, efficiency, interdepartmental communication, and technical feasibility were analyzed through pilot tests and surveys of healthcare personnel. The results show that implementing digital systems significantly improves the monitoring and maintenance of equipment, optimizing resources and enhancing the quality of medical services. This work provides recommendations for adopting technologies that strengthen biomedical management in hospital settings in developing countries.

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Keywords - Clinical engineering, Digital health systems, Medical device, Technovigilance, Traceability.

I. INTRODUCTION

Medical device management in healthcare systems is a critical priority to ensure quality care and patient safety[1]. Traceability, understood as the ability to monitor the status, location, maintenance, and lifecycle of medical equipment, is essential for optimizing resources and operational efficiency within hospitals [2]. In developing countries like Honduras, the lack of an integrated traceability system represents one of the major challenges, as medical devices are essential for accurate diagnoses and effective treatments [3].

The lifecycle of medical devices spans several stages, including acquisition, clinical use, preventive and corrective maintenance, and eventual decommissioning. Each phase requires careful management to avoid unexpected failures that may compromise patient health [4]. Emerging technologies such as QR code identification systems have enabled real-time access to device status and have shown promise in improving traceability and streamlining management processes [5].

In hospitals with traditional management systems, the absence of digital tools and the reliance on manual data entry continue to be recurring issues. This not only hinders proper equipment monitoring but also increases operational costs and reduces the effectiveness of maintenance procedures [6]. Studies show that integrating digital systems leads to better equipment control and faster emergency response, directly contributing to improved healthcare quality [7].

In the Honduran context, medical equipment management is affected by limited resources, fragmented data records, and a lack of technological infrastructure [2]. The Ministry of Health of Honduras has acknowledged these weaknesses, highlighting the urgent need for technological solutions that enhance

traceability and support the effective management of device lifecycles in public health institutions [8], [9].

This study addresses the pressing need to strengthen traceability systems for medical equipment in hospitals, focusing particularly on Biomedical Engineering departments. It evaluates the applicability of two digital traceability systems: MaintainX, oriented toward preventive and corrective maintenance, and Airtable, which provides a versatile platform for data centralization, inventory control, and real-time device monitoring [10]. The goal was to identify the best practices and improvement opportunities that can be applied to similar healthcare settings in developing countries.

In the context of increasing digitalization and the demand for higher standards in healthcare management, ensuring the operational continuity of medical equipment is essential to guarantee patient safety and service quality. Traditional paper-based maintenance records and manual tracking methods are no longer sufficient to meet the complexity and volume of clinical assets in modern hospitals.

As part of the global shift towards digital health systems, Computerized Maintenance Management Systems (CMMS) have emerged as standardized tools that streamline the planning, execution, and documentation of maintenance activities through an integrated digital platform [11]. A CMMS allows hospitals to move beyond fragmented or reactive approaches by enabling structured scheduling of preventive maintenance, real-time incident tracking, inventory control, and automated reporting. These systems offer traceability throughout the lifecycle of medical devices, supporting better decision-making regarding replacements, repairs, and regulatory compliance.

Medical Device Vigilance refers to the systematic monitoring, evaluation, and management of adverse events and quality issues related to medical devices, ensuring that they remain safe, effective, and compliant throughout their lifecycle. As defined by regulatory authorities, medical device vigilance aims to guarantee that each device is used according to its intended purpose, meets established quality standards, and, when risks or failures are identified, undergoes timely risk assessment and corrective actions to prevent recurrence [12], [13].

This vigilance process plays a critical role in healthcare systems by fostering a culture of reporting among users, including clinicians, technicians, and patients. Active participation enables continuous assessment of the risk-benefit profile of medical devices and enhances regulatory oversight of devices in real-world clinical settings [14]. Therefore, medical device vigilance is essential not only for regulatory compliance but also for improving patient safety and operational efficiency in hospitals [15].

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In low- and middle-income countries such as Honduras, where digital reporting systems are still emerging, strengthening the infrastructure for medical device vigilance is crucial. Traditional manual incident reporting methods—often relying on paper forms or verbal communication—limit traceability, delay response times, and hinder data analysis needed for preventive action. Integration of digital tools into biomedical workflows can significantly enhance the accuracy, traceability, and timeliness of incident management.

Modern medical device vigilance frameworks now incorporate cybersecurity as a fundamental pillar. With the growing use of connected and networked medical devices, new challenges related to data privacy, system vulnerabilities, and cloud infrastructure have emerged. Effective vigilance must therefore include proactive monitoring of digital threats to ensure the safety not only of the physical device but also of the digital environments where they operate [16].

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Ultimately, medical device vigilance systems support better decision-making regarding device maintenance, replacement, and post-market surveillance. Their implementation, particularly when supported by CMMS, enables hospitals to strengthen the traceability of clinical assets and uphold safety standards aligned with international health regulations. Effective vigilance must therefore include proactive monitoring of digital threats to ensure safety not only of the physical device but also of the digital environments where they operate.

Medical device vigilance systems support better decision-making regarding device maintenance, replacement, and post-market surveillance. Their implementation, particularly when supported by computerized maintenance management systems (CMMS), enables hospitals to strengthen the traceability of clinical assets and uphold safety standards aligned with international health regulations.

Quick Response (QR) codes have emerged as a practical and scalable technological solution to enhance the management and traceability of clinical assets in healthcare settings [17]. Their ability to store and transmit structured data such as device identification, location, maintenance history, or reporting links makes them especially valuable for biomedical workflows [18].

In the context of medical device vigilance, QR codes enable rapid access to real-time information by simply scanning a label with a mobile device, reducing the reliance on paper-based systems and minimizing human error. This technology not only streamlines the reporting of incidents and the documentation of maintenance tasks but also improves response times and ensures continuity of information.

Therefore, the integration of QR code technology into hospital workflows marks a pivotal step toward modernizing asset traceability systems [19]. When combined with Computerized Maintenance Management Systems (CMMS), QR codes facilitate seamless access to device-specific data, streamline incident reporting, and support proactive maintenance planning. This synergy strengthens the operational dimension of medical device vigilance by enabling real-time monitoring, faster response to adverse events, and improved data-driven decision-making. Ultimately, these digital tools create a more efficient, transparent, and resilient healthcare

infrastructure, bridging current needs with long-term goals for safety, accountability, and digital health transformation in resource-limited settings.

Incident reporting is essential to properly manage medical technology and ensure patient safety; however, its practice is limited by the perceived ineffectiveness of current methods [20]. In Latin America, device traceability faces challenges such as insufficient digital infrastructure, high implementation costs and incomplete regulatory frameworks, which hinders failure control and preventive maintenance [21], [22]. In addition, economic barriers and dependence on public funds restrict the adoption of sustainable technological solutions in the region [23].

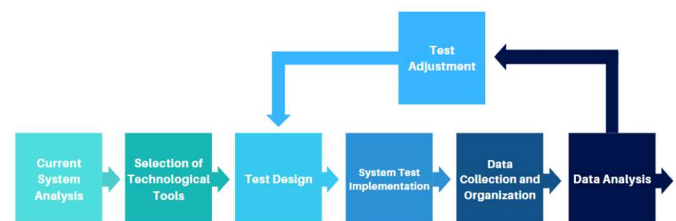
Digital traceability requires stable connectivity and access to centralized databases, conditions that are still limited in public hospitals in the region [24]. Its implementation requires significant investments, which represents a high burden for low- and middle-income countries such as Honduras, where assets and reports are still managed manually or with non-integrated tools [25].

II. METHOD

The methodology used in this research employed a descriptive approach to evaluate the implementation of digital medical device traceability systems in a public hospital in Honduras.

The sample used in this study was non-probabilistic by convenience and intentional. A public hospital in the city of San Pedro Sula was selected, deliberately excluding those health institutions that do not belong to the public sector or that are located outside the city. Within the hospital, a specific room was chosen that has a significant number of medical devices in operation and presents a high frequency of failure reports, which allowed a pertinent evaluation of the performance of the proposed system in a real context and with a constant flow of incidents.

Two independent failure notification systems were developed using the Airtable and MaintainX platforms, with the objective of determining which one was more functional and adequate to optimize the reporting and tracking processes of



technical incidents.

Fig. 1. Study methodology's stages.

The study methodology was designed to evaluate the feasibility and effectiveness of a digital traceability system for medical devices in a public hospital environment in Honduras, through the implementation of identification technologies, such as QR codes, and platforms for maintenance management.

First, a diagnosis of the current failure notification process was carried out. From this analysis, we proceeded with the selection of technological tools, choosing digital platforms according to their capabilities to manage reports and technical data efficiently. Airtable and MaintainX were selected for testing because of their ease of use and accessibility. With the selected platforms, the system design phase focused on creating digital forms and generating QR codes to simplify fault reporting and equipment tracking. Access points were strategically placed in key areas to ensure that personnel could easily use them.

Once the system was designed, tests were conducted under real working conditions. Hospital staff used the QR codes to report incidents, replacing traditional paper-based methods. During implementation, quantitative and qualitative data was collected to document the operational performance of the digital traceability system within the hospital environment. Subsequently, these data were analyzed with the objective of identifying weaknesses and areas for improvement in the developed system. An adjustment phase was contemplated to allow modifications to the system design in case the clinical and technical staff detected inconsistencies in its use, failures in the interoperability of the platforms or operational difficulties during the pilot stage. Fig. 1 shows the general outline of the process conducted in the study methodology.

The validation of both systems was carried out through the implementation of complementary strategies that combined field observation, comparison with the traditional method, expert evaluation and collection of end-users perceptions. This ensured that the system responded to the real needs of the clinical environment, with results that support its possible adoption on a larger scale as a model of digital traceability in the country's public hospitals.

III. RESULTS AND DISCUSSION

The system was implemented based on pilot tests carried out using QR codes on the MaintainX and Airtable platforms. Quantitative and qualitative data were collected to evaluate the performance, functionality and acceptance of the proposed system.

A. Analysis of the Current System

The purpose of this analysis was to identify the processes, tools and formats currently in use, as well as to recognize the limitations present in the process that affect the efficiency and responsiveness of the hospital's technical and clinical staff.

The failure reporting process begins with clinical staff detecting a malfunction and completing a standardized paper-based work order, which is submitted to the Biomedical Engineering Department along with the device. In some cases, informal methods (calls or messages) are used to expedite reporting, but these lack documentation and hinder traceability. The average time to physically deliver a work order is 5.24 minutes, covering a distance of 260 meters. The selected unit reports an average of 13 incidents per month.

Upon receiving the report, technical staff inspect and repair the device if spare parts are available; otherwise, the equipment is temporarily disabled. After maintenance, a physical work

order is completed and signed by the relevant department heads to validate the service.

The manual digitalization of these records requires approximately 28 hours per month representing a significant operational burden. This manual system not only consumes valuable human resources that could be allocated to critical tasks but also increases the risk of transcription errors and compromises the accuracy of maintenance indicators.

The results of this analysis establish a basis for contrasting the operation of the proposed digital traceability system with the operation of the system currently used, allowing to know the areas of improvement and optimization opportunities in the operational processes within the hospital environment.

B. Proposed Operation of the Digital Traceability System

The analysis of the proposed system is based on the objectives of the study, which seek to compare the performance of both tools in terms of ease of use, efficiency and scalability, considering the particular conditions of the hospital. In this way, it is sought to determine whether these digital solutions can contribute to optimize traceability, reduce technical response times and facilitate access to updated information on the status of medical devices. Due to the limited financial resources typically available in the healthcare sector, investment in areas such as digital clinical and maintenance management is often restricted. For this reason, and to assess their applicability under real conditions in the current hospital context, both Airtable and MaintainX were evaluated using their free versions.

For the implementation of Airtable, a reporting system based on digital forms linked to a relational database was designed. A unique QR code was generated, printed and strategically placed in different key areas, including the nursing station of the ward selected for the study, the office of the ward chief and the workshop of the Biomedical Department. In this way, both clinical and technical staff were able to easily access the forms created in Airtable via their mobile devices. Through this access, failure reports were registered, work orders were generated, and the delivery and reception of medical equipment were verified.

The system developed with MaintainX required the use of its mobile application to generate fault reports and work orders. To carry out the tests with this platform, a specific QR code was assigned to each medical device, which was placed directly on the vital signs monitors in the selected room.

Unlike Airtable, MaintainX application had to be installed on the user's mobile device to scan the QR codes. For this reason, the tests were performed using the researchers' cell phones, since the nursing staff did not have the application installed. Through these devices, the QR codes of the equipment were scanned, the corresponding failure report was generated and the Biomedical Department was notified in real time for follow-up and attention.

Airtable stands out for its flexibility and customizable database structure, allowing the configuration of workflows through relational tables, digital forms, and portals accessible via QR codes. However, its application in large-scale hospital environments can be limited due to the data volume restrictions imposed by its free plan, which often requires the creation of multiple databases to manage an extensive inventory of medical

equipment. Furthermore, communication between departments is limited, as once clinical staff submit a report, there is no built-in channel for follow-up or coordination with the technical team. This lack of interoperability can hinder the continuity of information and reduce the operational effectiveness of the system.

MaintainX, on the other hand, presents itself as a more robust and specialized solution for CMMS, integrating features specifically designed to enhance both technical efficiency and user experience. One of its key strengths lies in the generation of unique QR codes for each device, allowing clinical staff to automatically populate equipment data in the incident report upon scanning. This not only streamlines the reporting process but also minimizes human error and ensures accuracy in equipment identification. Additionally, the ability to attach photographs directly within the report enhances the visibility and understanding of the issue. MaintainX also incorporates internal messaging and real-time notifications, enabling effective communication across departments and ensuring that all users remain informed throughout the maintenance cycle. Its role-based user management—comprising requester, full user, and administrator profiles—supports task delegation, access control, and complete traceability of actions. These features make MaintainX a more efficient, interoperable, and context-appropriate tool for the real-world demands of hospital maintenance systems.

C. System Cybersecurity

Cybersecurity in these platforms is essential not only to protect technical data of the assets, but also to ensure the operational integrity of the hospital and the privacy of users interacting with these systems. A vulnerability in these environments could compromise service continuity, generate economic losses and even affect patient safety. Therefore, when evaluating solutions for a traceability system, it is essential to analyze the protection mechanisms implemented to safeguard the confidentiality, integrity and availability of information.

Both MaintainX and Airtable implement essential cybersecurity measures to ensure the protection of information within hospital environments. As shown in Table I, the two platforms offer basic authentication methods and support role-based permissions, allowing for differentiated access depending on the user's responsibilities. These controls are vital to maintain the traceability of operations and prevent unauthorized modifications of technical data related to medical devices.

TABLE I. CYBERSECURITY COMPARISON

Criterion	MaintainX	Airtable
Authentication	✓	✓
Session control	✓	✗
Role-based permissions	✓	✓
Unique user identifiers	✗	✓
Automatic data backup	✓	✓
Digital signature	✗	✗
Cybersecurity compliance	✓	✓

^a. Cybersecurity comparison between Maintainx and Airtable

On the other hand, Airtable includes unique user identifiers and secure authentication through OAuth 2.0, enhancing traceability at the individual level. One of its advantages lies in its modular and customizable database design, which allows users to structure fields and workflows according to institutional needs. However, this flexibility also implies a dependence on manual configuration and the creation of multiple interconnected bases, which may be a limiting factor in environments such as hospitals, where large-scale equipment inventories require centralized and scalable solutions.

D. System Cybersecurity

The validation of MaintainX and Airtable was conducted in a hospital setting to evaluate their actual operation within the dynamics of the clinical area and the biomedical department. This phase evaluated not only technical functionality but also practical applicability, user acceptance, and integration into existing reporting and maintenance processes. The findings provided direct evidence on the feasibility of implementation, highlighting each platform's strengths, limitations, and overall adaptability to hospital conditions.

A two-week pilot study was conducted with four nursing staff members, who were tasked with reporting equipment failures using both platforms. MaintainX enabled individual QR codes to be placed directly on each medical device, allowing staff to scan and initiate reports instantly. This feature was highly valued by the clinical staff, who reported that the process was fast, intuitive, and minimized delays in reporting incidents. In addition, the ability to upload images directly within the report was perceived as a major advantage, as it helped improve the clarity and accuracy of the issue being reported. Table II presents the average completion times and user satisfaction scores, highlighting the positive reception and efficiency of MaintainX during the pilot phase.

TABLE II. MAINTAINX PILOT TESTING RESULTS

Participant	Completion Time (min)	Ease of Use (1-5)
Nurse 1	2.14	4
Nurse 2	1.11	5
Nurse 3	1.28	4
Nurse 4	1.55	5
Average	1.52	4.5

These findings suggest that MaintainX's design particularly its equipment-specific QR scanning and intuitive interface contributed to faster and more seamless reporting. Airtable also performed well and was considered user-friendly, although its dependence on stable connectivity occasionally caused delays in form submission.

During the pilot test conducted with Airtable, the nursing staff quickly adapted to the use of the QR code placed at the nurse station, which provided direct access to the incident reporting form developed in Airtable. Participants found the interface intuitive and easy to navigate, highlighting the system's user-friendly design. However, it became evident that

the performance of the platform was influenced by the quality of the internet connection in the area. In some instances, slower connectivity caused minor delays during the submission of reports. In terms of performance, the form completion times ranged from 1.50 to 3.09 minutes, with an overall average of 2.33 minutes as shown in Table III. Regarding ease of use, Airtable received an average score of 4.0 out of 5, suggesting a generally positive reception among users, despite occasional connectivity limitations.

TABLE III. AIRTABLE PILOT TESTING RESULTS

Participant	Completion Time (min)	Ease of Use (1-5)
Nurse 1	1.50	3
Nurse 2	3.09	5
Nurse 3	2.20	4
Nurse 4	2.53	4
Average	2.33	4

When comparing both platforms under identical hospital conditions, MaintainX outperformed Airtable with faster form completion (1.52 vs. 2.33 minutes) and higher usability scores (4.5 vs. 4.0). Its device-specific QR codes and intuitive interface enhanced efficiency, while Airtable faced minor delays due to centralized QR codes and internet issues. MaintainX proved more adaptable and effective for clinical staff in demanding environments.

E. Comparison with Traditional Reporting Method

To evaluate the system's impact, the traditional failure reporting method was compared with the new digital platforms. The manual process averaged 12.54 minutes per report and involved walking 260 meters, while the digital alternatives Airtable and MaintainX reduced reporting times to 2.33 and 1.52 minutes, respectively, and minimized physical movement to under 6 meters. This efficiency gain is largely due to QR code integration and the elimination of intermediaries.

These improvements translate to a time reduction of 81.95% with Airtable and 88.21% with MaintainX, and a distance reduction of 97.7% and 99.4%, respectively. When projected to the average monthly incident reports in the ward (13 reports), Airtable achieves a monthly time saving of 135.33 minutes (2.26 hours), and 1,624 minutes (27.07 hours) annually. MaintainX generates even greater savings: 145.86 minutes (2.43 hours) per month and 1,750 minutes (29.17 hours) per year.

This comparative analysis underscores the operational advantages of implementing digital traceability tools, both in terms of time efficiency and reduced physical workload, thereby enhancing the responsiveness and overall productivity of hospital staff.

F. Comparison with Traditional Reporting Method

During the pilot phase, the technical staff of the Biomedical Engineering Department reported a generally positive experience with the digital reporting platforms, particularly highlighting improvements in organization, traceability, task clarity, and centralization of data. A notable potential

improvement is the reduction in time required for documentation. Both Airtable and MaintainX enabled faster and more structured report generation in comparison to the manual method, which involves entering information into Excel spreadsheets one by one for each device. This digital approach could allow staff to dedicate more time to technical responsibilities instead of repetitive administrative tasks.

MaintainX stood out for its advanced features tailored to maintenance operations as shown in Fig 2 which reflects technical staff responses collected through a post-use survey.

One of its key strengths was the ability to assign work orders to specific personnel, ensuring better task distribution and accountability. Additionally, MaintainX includes a request validation mechanism that allows the Biomedical Engineering Department to accept or reject incident reports submitted by clinical staff. This feature helps avoid duplicate requests and improves the quality of the data being processed, reinforcing a more reliable and efficient workflow.

Airtable was also recognized for its intuitive interface and efficient handling of incident data. All participants found it easy to navigate and did not encounter issues related to data synchronization or access. However, in comparison to MaintainX, Airtable required more manual configuration to align with maintenance-specific needs and lacked built-in tools for task assignments and approval workflows.

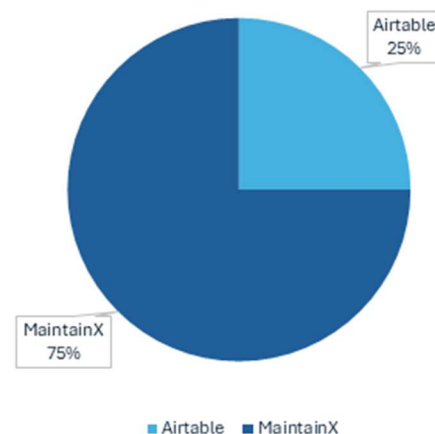


Fig. 2. Biomedical Staff Perception of Platform Integration.

Both platforms demonstrated clear advantages over traditional documentation methods. MaintainX stood out for its real-time updates, visual evidence, and centralized tracking, which enhanced traceability and collaboration. Feedback from the pilot suggests that adopting such digital systems can optimize workflows, improve data quality, and boost efficiency, laying the foundation for a scalable maintenance model in hospitals.

The pilot implementation of the digital traceability system showed high applicability in hospital settings that still use manual methods. Platforms like MaintainX and Airtable, integrated with QR codes, proved functional and easy to adopt within clinical and technical workflows. Supported by widely available mobile devices and hospital WiFi, the system

enhances medical device vigilance by improving incident reporting, traceability, and response times. Its scalability aligns with national digital health strategies, promoting proactive maintenance. With proper training and institutional backing, it presents a solid foundation for broader adoption.

IV. CONCLUSION

This study confirmed that digital traceability systems like MaintainX and Airtable are feasible and effective alternatives to improve medical equipment maintenance in Honduran hospitals. Unlike the manual system, which showed data fragmentation and administrative overload, the digital platforms enabled streamlined reporting and centralized management. MaintainX was the most accepted by clinical and technical staff due to its hospital-oriented features, while Airtable stood out for its flexibility. Overall, the pilot demonstrated their potential to modernize biomedical processes, improve patient safety, and enhance efficiency in public healthcare.

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