EHMA 2025

Taking action to improve health for all

„Automatic data capture techniques and electronic transaction documents enhancing the implementation of the European Medical Device Regulation in a university teaching hospital. A case study from Poland."

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INTRODUCTION – MDR

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

„Health institutions shall store and keep preferably by electronic means the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to class III implantable devices."

OBJECTIVES

1. **To evaluate the impact of automatic data capture techniques on compliance with the European Medical Device Regulation (MDR) in a university teaching hospital.**
This included assessing how technologies such as GS1 barcode scanning or system integrations improve traceability, documentation, and reporting.

2. **To analyze the role of electronic transaction documents in supporting the lifecycle management of medical devices.**
The focus was on how e-invoices, e-delivery notes, and digital records contribute to transparency, auditability, and regulatory alignment.

3. **To identify organizational and technological barriers to implementing digital solutions for MDR compliance in the context of a Polish academic hospital.**
This included examining infrastructure limitations, staff readiness, and interoperability challenges.

4. **To develop practical recommendations for other university hospitals in Poland aiming to enhance MDR implementation through digital transformation.**
These recommendations are be based on lessons learned from the case study and aligned with EU regulatory expectations.

METHODOLOGY

Data Collection Methods

- **Document Analysis**
Internal hospital documentation, MDR compliance reports, procurement records, and electronic transaction documents (e.g., e-invoices, delivery logs) were reviewed.

- **Semi-structured Interviews**
Interviews were conducted with key stakeholders

- **Direct Observation**
Workflows involving medical device tracking, data entry, and compliance reporting were observed to understand how automation was integrated into daily operations.

- **System Audit / Technical Review**
The hospital's IT infrastructure was analyzed, focusing on:
    - Integration of HIS (Hospital Information System), ERP, and inventory systems
    - Use of GS1 barcodes
    - Data flow and interoperability

METHODOLOGY

Data Analysis

- **Thematic Analysis**
Qualitative data from interviews and observations were coded and analyzed to identify recurring themes related to MDR compliance, digital transformation, and organizational challenges.

- **Process Mapping**
Current and improved workflows were visually mapped to highlight the impact of automation and digital documentation.

- **Gap Analysis**
Existing practices were compared with MDR requirements to identify compliance gaps and areas for improvement.

RESULTS

The analysis revealed the following limitations in the management of the flow of medicines and medical devices from the perspective of process digitalization using barcode scanning and digital documents:

- Delays in accessing up-to-date information on inventory levels and their real-time location,
- Maintenance of documentation in both electronic and paper formats,
- Delays in accessing real-time inventory data in clinical departments, which may result in overstocking, expired products, or stockouts,
- A high number of manually performed tasks,
- A large volume of duplicate documents, such as supply requests from hospital wards.

RESULTS

Additionally, the analysis of the examined processes, along with in-depth interviews with selected hospital staff, revealed specific limitations and challenges that hindered the automation of certain activities:

- An insufficient level of utilization of automatic data capture techniques,
- A lack of appropriate devices enabling the remote execution of specific tasks,
- Missing functionalities in the IT system that would allow for more effective and efficient use of barcode scanning in areas where automatic data capture techniques are currently applied,
- The absence of widespread use of standardized electronic invoices (and other transaction documents) by suppliers.

- **RECOMMENDATIONS**

THANK YOU

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