Interoperability in medical devices: the role and limits of HL7

The digital era in healthcare has made interoperability of medical devices a crucial requirement to ensure safety, effectiveness, and continuity of care. According to the FDA, interoperability is "the ability of two or more systems or devices to exchange information and use the information meaningfully." In other words, it is not enough for devices to simply exchange data: the information must be understood, correctly interpreted, and usable by the receiving systems.

This need is becoming increasingly urgent with the growing proliferation of connected devices, from patient monitors to imaging systems, from wearable devices to telemedicine platforms. The lack of shared standards can cause inefficiencies, clinical errors, and delays in decision-making. Interoperability is not just a technical issue; it becomes a cornerstone of patient safety and quality of care.

HL7: A Standard for Application-Level Interoperability

In response to this need, Health Level Seven (HL7) has emerged as one of the main reference standards for exchanging clinical information between different systems. HL7 defines guidelines and protocols for data communication at the application level, ensuring that information is transmitted in a structured and understandable way.

The HL7 standard has evolved over time into several versions, each with specific characteristics and scopes:

- HL7 v2.x: One of the most widely used standards for transferring clinical data between hospital systems. It is characterized by a message-based structure that is flexible but not strictly normalized, which facilitates adoption but can generate variability between implementations.
- HL7 v3: Introduces a more rigorous, semantic data model based on a Reference Information Model (RIM), aimed at reducing interpretative ambiguities. Despite its theoretical advantages, its complexity has limited practical adoption.
- HL7 FHIR (Fast Healthcare Interoperability Resources): The most recent evolution, designed to be modular, flexible, and easily integrated with modern web technologies. FHIR uses standardized resources and RESTful APIs, facilitating the development of interoperable applications.

These versions reflect HL7's commitment to enabling reliable data exchange across heterogeneous systems. However, despite its widespread use, HL7 has some significant limitations that affect its practical effectiveness.

Limitations of HL7

Despite its widespread adoption, HL7 presents some critical issues that impact its practical effectiveness:

1. Partial implementation by medical device manufacturers: Often, only the components of the standard deemed necessary for the device's operation are adopted, while other functionalities are not implemented due to technical, economic, or compatibility reasons. As a result, two HL7-compliant devices may not be fully interoperable: they might share only certain types of data or specific functionalities.
2. Application-level focus: HL7 operates at the application level, focusing on the structure and format of exchanged data but not defining common protocols for lower communication layers (network, transport, message handling). This gap can create challenges when systems need to integrate at an infrastructural level or when continuous communication between heterogeneous devices is required.
3. Flexibility as a double-edged sword: The message structure, particularly in v2.x, allows great interpretative freedom. While this facilitates adoption, it can also lead to variability between implementations, requiring customized adaptations by integrators and increasing complexity and costs.
4. Incomplete handling of auxiliary but critical aspects: HL7 does not fully address issues such as data synchronization, message version tracking, or error handling during transmission. Even though FHIR introduces significant improvements, these historical limitations continue to affect compatibility between legacy systems and modern devices.

In summary, HL7 is a powerful tool for exchanging clinical data, but by itself, it does not guarantee complete interoperability. Achieving a truly interoperable ecosystem requires combining HL7 with additional protocols and guidelines that coordinate infrastructural layers, data management, and system integration.

Moreover, clinical data security, identity management, and access control are critical areas not covered by HL7, yet they are essential to ensure that interoperability does not translate into cybersecurity vulnerabilities.

Conclusions

HL7 is undoubtedly a fundamental pillar for medical device interoperability, providing tools for standardized data exchange at the application level. However, partial adoption by manufacturers and the lack of guidelines for infrastructure and security layers limit its effectiveness. True interoperability requires an integrated approach that includes application standards, security protocols, and data governance.

The evolution toward the European Health Data Space (EHDS) offers an interesting prospect: creating a European ecosystem where HL7 FHIR can operate within a coordinated framework of interoperability and

security. In this scenario, the main challenge remains harmonizing diverse implementations and bridging technical gaps between application and infrastructure layers, transforming interoperability from a theoretical goal into a tangible clinical reality.

References:

1. What Is Code Refactoring? Meaning, Examples & Best Practices
2. Standard di interoperabilità nel settore sanitario: lavori in corso | GE HealthCare (Italy)
3. HL7 FHIR vs HL7 v2 and v3: Comparing Healthcare Interoperability Standards
4. Medical Device Interoperability | FDA
5. HL7 Integration: Types, Use Cases and Implementation Guide
6. https://www.hl7.org/implement/standards/product_brief.cfm?product_id=185
7. https://www.sciencedirect.com/topics/biochemistry-genetics-and-molecular-biology/health-level-7
8. Teoresi Group, *EHDS e interoperabilità dei dati sanitari*, 2025 (PDF)

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