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Infusion Systems & Interoperability in Healthcare Information Systems

A perspective on use cases and standards

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1. Introduction

Drug administration using an infusion pump is something many patients and most nurses will experience at some point in their lives and careers. Used in both inpatient and ambulatory settings, infusion pumps have evolved into infusion systems with advanced capabilities like drug library management and the Dose Error Reduction Systems (DERS) found in today's so called "smart pumps."

At the same time, progress in Electronic Medical Records (EMR) has made a truly paperless Healthcare Information System (HIS) possible. In this context, manually transferring information from one subsystem to another is becoming increasingly difficult to accept.[1]

Medical devices are an integral part of the new HIS landscape. As such, they can play a role in making the tasks caregivers perform every day easier and in enhancing patient care. The automated transfer of infusion data from the infusion system to the patient's electronic chart saves nurses time[2] and reduces the risk of human error[3] inherent to manual record keeping.

Automation also makes end-to-end traceability of infusions workflows possible, from the prescription by a physician to the verification that the drug has been administered. This allows nurses to focus more on care and less on recording information about care[2].

For this to happen, the various components that make up the HIS —including infusion systems—must be interoperable. This means that the different software applications and subsystems must be able to exchange, interpret, and use data safely, securely, and effectively. And an interoperable HIS can support the effective delivery of healthcare services.

Read on to learn what interoperability means for infusion systems through use cases and an analysis of the applicable standards.

1) If you would like to learn more, you might be interested in learning about the HIMSS Electronic Medical Record Adoption Model (EMRAM) for the adoption and utilization of electronic medical records (EMR). https://www.himss.org/what-we-do-solutions/maturity-models-emram

2) Automated clinical documentation: does it allow nurses more time for patient care? https://pubmed.ncbi.nlm.nih.gov/21685832/

3) Comparison of automated and manual vital sign collection at hospital wards https://pubmed.ncbi.nlm.nih.gov/23823371/

2. Toward standardization

2.1 Standardization of communication protocols Vital to infusion system interoperability

Ever since medical devices began incorporating memory and data storage, manufacturers have included data export features. Serial communication, which has been around since the 1960s, has been commonly and historically used for this purpose. Data exports, configuration, and tasks like calibrating devices and retrieving logs have conventionally been done via manufacturer-specific communication protocols[4].

Over time, adaptations have been made to enable data transfer between medical devices from different manufacturers. However, this kind of use case is often limited to areas with a high concentration of medical devices, such as operating rooms and Intensive Care Units (ICUs). Consequently, communication between devices outside these areas is almost non-existent.

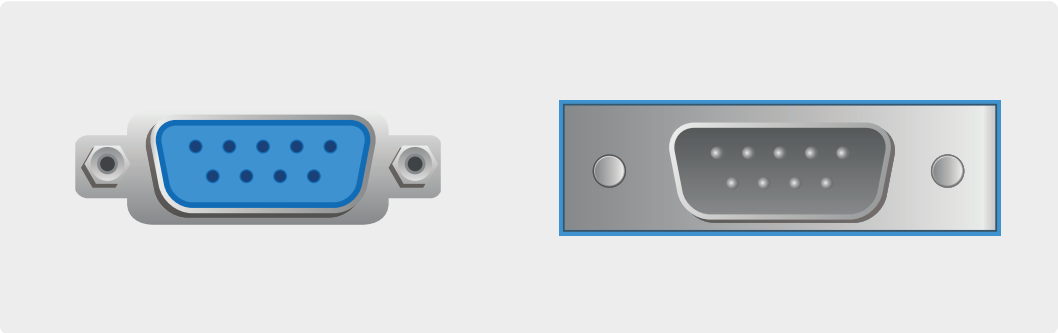


***Figure 1** - RS232 – example of serial physical interface*

Today, serial communication is still widely used, but its practical applications are severely limited. Plus, it is expensive, especially considering the increasing number of subsystems and potential providers involved. Imagine the cost and complexity of developing unique integrations for each medical device manufacturer for today's Electronic Medical Record (EMR) systems. And for medical device providers, supporting all EMRs would mean having to document and constantly update the differences in manufacturer-specific communication protocols.

Infusion systems manufacturers are now following the precedent set by medical imaging and information systems providers through an international organization called IHE (Integrating the Healthcare Enterprise), dedicated to developing and promoting healthcare IT interoperability standards.

4) https://www.researchgate.net/publication/296543546_Medical_device_to_computer_networking_Past_present_and_future

2.2 IHE driving the international standardization movement

"IHE is an initiative by healthcare professionals and the industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively."[5]

IHE (Integrating the Healthcare Enterprise) is organized by domain, one of which is the IHE Devices (DEV) domain. For each domain, working groups develop specific use cases, referred to as "profiles." These profiles provide guidelines for using one or more technical standards, such as DICOM (Digital Imaging and Communications in Medicine) for medical imaging.

For infusion systems, the IPEC (Infusion Pump Event Communication) profile outlines how to use HL7v2 messages to relay infusion data/events to an Electronic Medical Record (EMR), which acts as a consumer of this information.

HL7 is designed for server to server communication, there was not a consideration to include direct communication from device-to-device. More recently, to address the interoperability needs of acute care departments, the IHE Devices domain initiated the SDPi (Service-oriented Device Point-of-care Interoperability) initiative. The use cases in the SDPi initiative now take advantage of the SDC (Service-oriented Device Connectivity) technical standard's capabilities.

Practical examples of profiles and applicable standards for infusion systems (HL7v2, HL7 FHIR, and SDC) will be provided in Chapters 3 & 4.

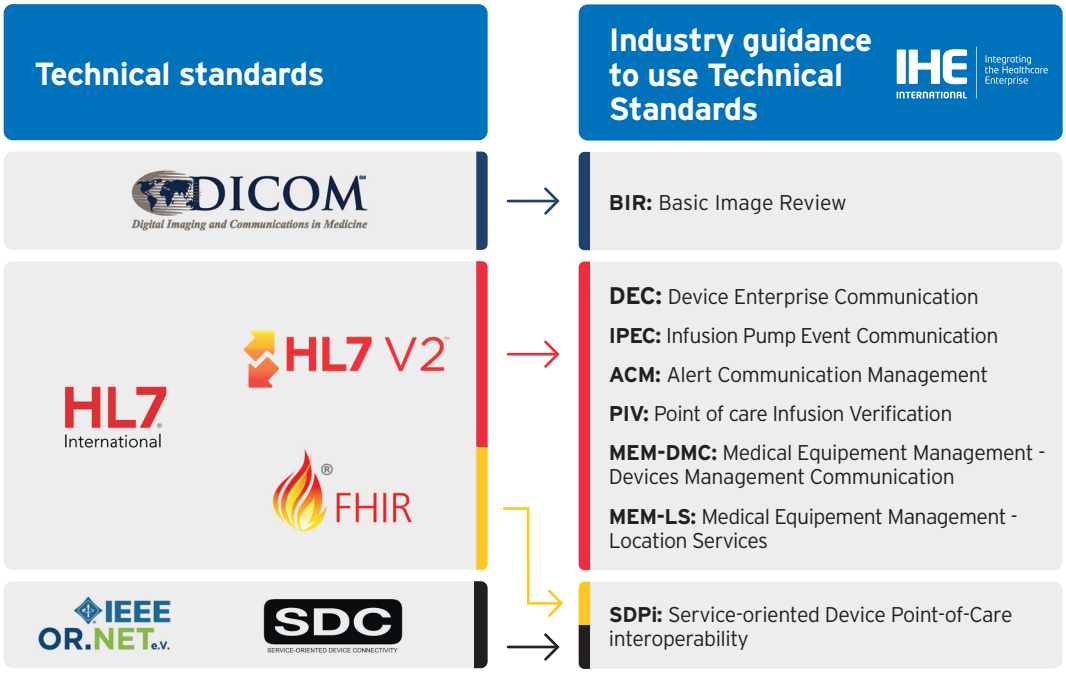


***Figure 2** - Technical standards and the corresponding IHE profiles.*

5) FAQ - IHE International: https://www.ihe.net/about_ihe/faq/#What_is_IHE?

3. Main use cases

IHE has published several infusion device interoperability use cases. Until FHIR and SDPI are more widely adopted by infusion system integrators like EMRs, and Alarms Management platforms, HL-7 v2 remains the dominant protocol in use.

3.1 Automated charting of medical records: auto-documentation

During an infusion, auto-documentation refers to data sent from the infusion pump to the EMR through the infusion system's gateway.

In terms of IHE, IPEC/DEC (Infusion Pump Event Communication/Device Enterprise Communication) profiles, which communicate via HL7v2 messages, are applicable to auto-documentation. HL7v2 messages are defined between the infusion system and EMR gateways, regardless of how data is consolidated and processed by either.

From a nursing perspective, the goal of auto-documentation is to streamline the documentation process associated with infusion pumps. Integration eliminates the need for manual entry of medication administration data, thereby reducing the risk of human error, simplifying nursing tasks, and improving overall efficiency. Crucial information like the volume infused, the name of the drug, and the status of the bolus or infusion can be automatically shared among caregivers.

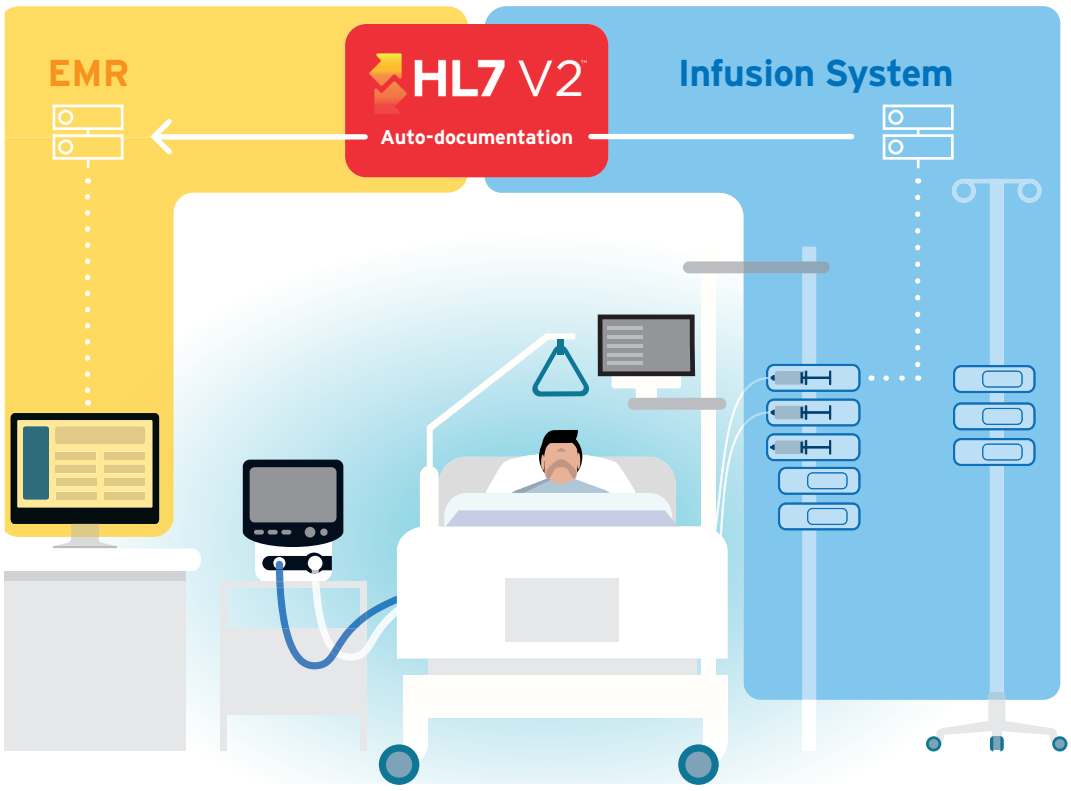


Figure 3 *- Auto-documentation workflow between infusion devices and the EMR*

Workflow-related challenges

Infusion data is more useful if it can be linked to the specific patient in the Electronic Medical Record (EMR) system. The physical location of the device (patient room or bed) is one of the main ways the data is associated with a particular patient. Devices on fixed racks connected to wired networks are easy to locate, because the rack's position in the infusion system is known, and then reported in the autodocumentation message.

For mobile racks or devices not on a rack (that communicate via Wi-Fi), using the device's location as a means of associating it with a patient is potentially problematic. An alternative method for linking a patient to a device is needed.

One practical solution is to make associating the patient and device part of the the "5 Rights" steps for safe drug administration. A Barcode Medication Administration (BCMA) workflow, which typically leverages EMR features like electronic Medication Administration Reports (eMAR), enables this kind of solution. In some cases, the infusion system itself may include its own patient data management features. These aspects and their implications will be further discussed in section *3.4 Bringing patient data into the infusion system.*

3.2 Communication of alarms

The communication of alarms from infusion pumps has a major impact on nurses' efficiency and on patient care[6]. This is why centralizing alarms is so important. Nurses need to be able to see critical alarms (near-end-of-infusion, occlusion, air-in-line) from all infusion pumps on the EMR or alarm management system, so they don't have to repeatedly check each individual pump to know if there's an issue with any of the infusion devices.

The IHE profile for this kind of alarm communication is ACM (Alert[7] Communication Management), which also utilizes HL7v2 messages. Technically, the process for alarm communication is quite similar to that for auto-documentation; however, its focus is specifically on alarm information rather than general infusion data.

Note that alarm communication is rarely implemented in isolation from autodocumentation. This is because alarm information needs to be contextualized with other data from the ongoing infusion to be fully effective and informative. The integration of alarm communication with auto-documentation ensures that caregivers have a more thorough understanding of the patient's status, so they can intervene in a timely and informed manner.

To go further: See *4.1.1 Consolidate alarms: alarm communication (DIS) to alarm delegation (DAS).*

6) https://www.ascom.com/news/blogs/global-blogs/seven-steps-to-better-alarmmanagement-in-healthcare/
7) Alert: alarms and advisories

3.3 From prescription to infusion order: auto-programming

Auto-programming lets nurses send all important prescription details from the EMR to the infusion pump, avoiding the time- and error-intensive task of retyping the information. Pumps with these capabilities also have built-in drug information used to double-check the dosage and provide nurses with access to additional infusion status information.

The IHE profiles for auto-programming are PIV(Point-of-Care Infusion Verification)/IPEC/DEC, which communicate via HL7v2 messages.

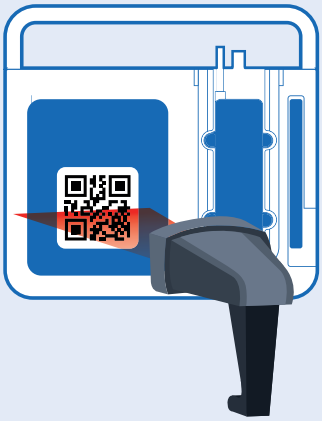
Smart pump to EMR integration, also known as bidirectional ineroperability, requires at least two data flows:

- Infusion order from EMR to infusion system → auto-programming
- Infusion administration status messages from infusion system to EMR → auto-documentation

As described in IHE PIV profile, the auto-programming workflow requires a BCMA (Barcode-assisted Medication Administration) step for an infusion order to be sent to an infusion device.

BCMA is the electronic verification of the "5 Rights":

✓ The Right **Person**	✓ The Right **Drug**	✓ The Right **Dose**	✓ The Right **Route**	✓ The Right **Time**



The **MAR** (Medication Administration Record) in the EMR allows nurses to:

- **Log on with their credentials to access the patient care plan**
- **Select the prescription**
- **Scan the patient's wristband to confirm their identity**
- **Scan the drug container to confirm the drug**
- **Scan the pump to obtain the device ID to which the infusion order should be sent**

Once the pump has been identified on the EMR side, the nurse can trigger the auto-programming message from the EMR user interface.

Figure 4 *- BCMA workflow*

Auto-programming is not a form of remote control and generally does not meet standard medical device risk management requirements like nurse verification of the programmed infusion order for infusion pumps. Therefore, additional verifications are still needed before starting the infusion:

- Technical check of pump readiness
- DERS check to verify that the infusion order is consistent with the drug library configuration (rate and/or dose limits in particular)
- Visual check of infusion parameters by the nurse
- Nurse manually starts infusion

Figure 5 *- Auto-programming workflow between infusion device and EMR*

→ **Drug library synchronization**

The drug library in the EMR used by physicians to prescribe the infusion and the drug library in the infusion device used by nurses to program the infusion must be synchronized.

The DERS check requires the drug parameters sent buy the EMR to be known by the DERS. Therefore, an auto-programming workflow cannot be implemented without first synchronizing the drug libraries.

→ **Analytics**

Auto-programming is a multi-tiered function that adds high clinical value but that is complex to deploy. Analytics help make improvements to practice and efficiency that drive better adoption and compliance with the system and workflows. Complete, easy-to-understand traceability information is also key to mitigating risk and, ultimately, to the success of implementation.

3.4 Bringing patient data into the infusion system

The primary function of an infusion pump is to deliver a specific medication to a particular patient. In essence, infusion pumps operate in what can be described as a "patient-centered" domain, where all activities are directly related to patients under care.

The ability to retrieve patient data from the HIS is important, so that weight, age, sex, and other patient-specific parameters can be factored into the infusion program, and to provide context for auto-documentation and alarm information.

However, because infusion pumps are so versatile and mobile, context for infusion data is generally provided through the EMR, based on location or the BCMA workflow (see *3.1 Automated charting of medical records: auto-documentation and 3.3 From prescription to infusion order: auto-programming).*

Some infusion system manufacturers have developed other solutions.

- Displaying a list of patients on the infusion device itself so nurses can select the patient to associate with the device. This, of course, requires a wide enough display on the device.
- Barcode systems can also be used to associate patients with an infusion station or rack.

In many cases, multiplying barcode systems or specific association/disassociation workflows that exceed the required EMR to smart pump interoperability workflows could be considered to be unwelcome additional work and possible opportunities for error.

Regardless of the patient identification solution workflow, the infusion system should include an interface to the HIS using HL7v2-based Admit, Discharge, and Transfer (ADT) messages.

To go further: see *4.1.2 Point-of-care patient context*

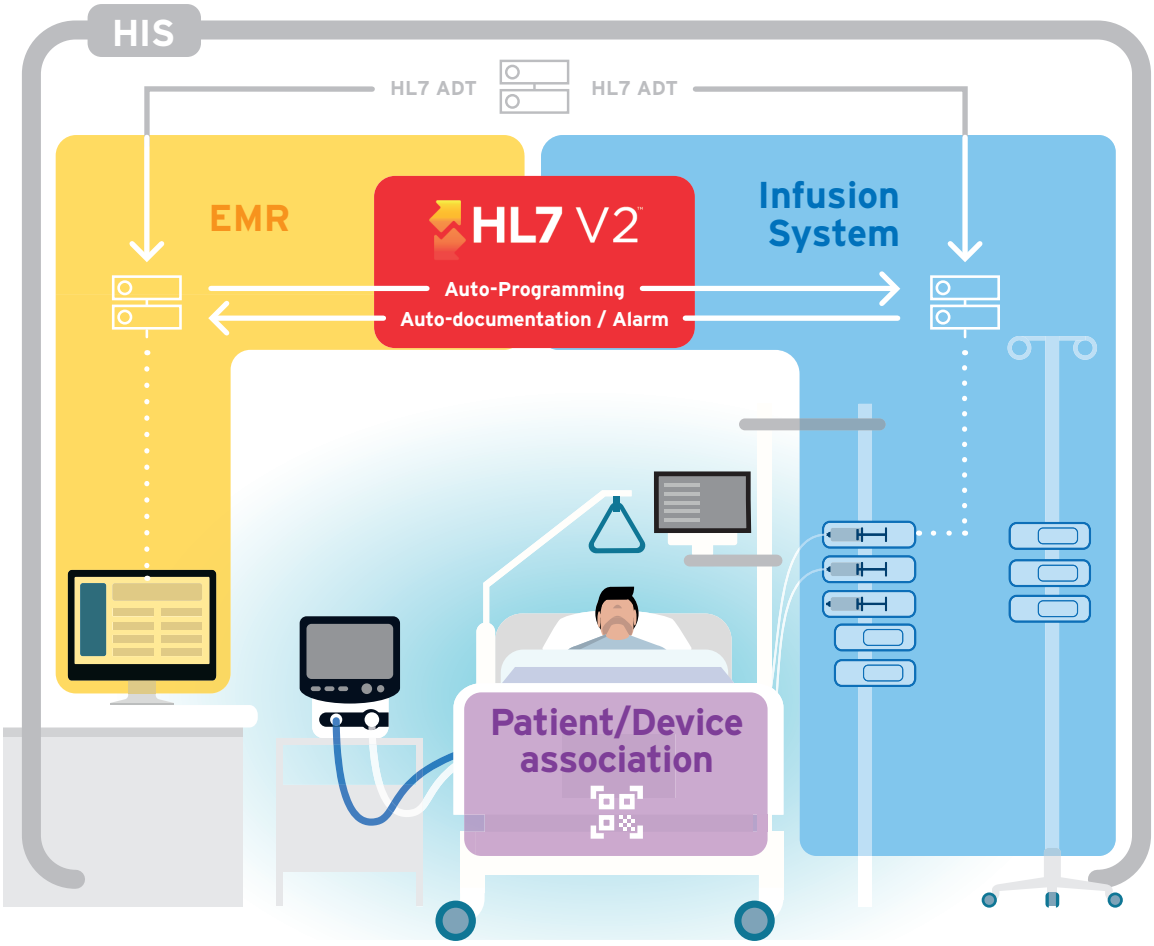


Figure 6 *- Patient dataflow from HIS and bedside association workflow*

3.5 Overview of IHE profiles applicable to infusion systems

The use cases described above are the most frequently encountered and should be understood to cover basic interoperability features.

The following profiles are currently applicable to infusion systems.

- Auto charting of medical record: **Auto-documentation** → IPEC / DEC
- Consolidate alarms: **Alarm communication to Alarm delegation (DAS)** → ACM to SDPi
- From prescription to Infusion order: **Auto-programming** → PIV / IPEC / DEC
- Include patient data in infusion system: **Patient data synchronization** → HL7 ADT messages
- Patient association to infusion system at point of care: **Identity Management** → PCIM
- Supervise location of devices through RTLS: **Device geolocation** → MEM-LS
- Devices maintenance supervicion in a CIMMS: **Device Management** → MEM-DMC
- Centralized point of care cockpit: **Device Remote Control** → SDPi
- Hospital Topology Sync
  External sensor data display
  Safety Interlock
  Automated therapy (close loop)...

Profile officially published and accessible in IHE documentation. Published profiles are subject to change.

Profile not officially published. Generally classified as "trial for implementation" in IHE documentation.

IHE healthcare interoperability working groups are constantly adding new use cases and making improvements to existing ones as technology and needs evolve.

4. Beyond the basics

4.1 Selected advanced use cases & outlook

4.1.1 Consolidate alarms: alarm communication (DIS) to alarm delegation (DAS)

A word about alarm management systems:

Alarm management has the capacity to reduce nurses' stress and alarm fatigue, boosting a clinical care department's overall productivity. Today, we have the technology to determine which alarms are important and to ensure that alarms reach the right person in a timely manner. Implementing an alarm management system requires long-term project and change management. A "good" system should consolidate all alarms —from all medical devices—at bedside. A full discussion of alarm management system safety and performance can be found in the IEC 60601-1-8 and IEC TR 80001-2-5 standards.

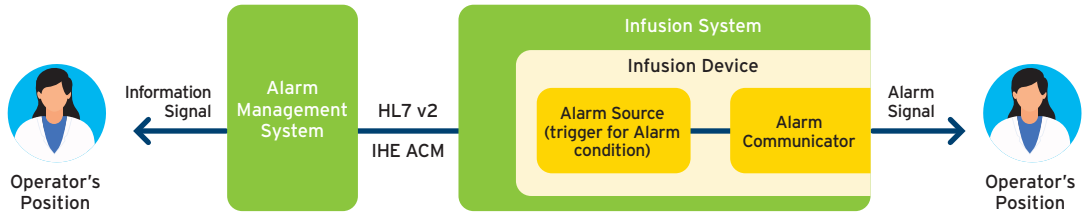
Alarms transmitted using ACM messages are not considered 100% guaranteed, and remote displays cannot be considered a primary alarm system. In fact, most infusion system user manuals (and, sometimes, the displays right on the screen) come with a warning to this effect:

"This is not a Distributed Alarm System for the confirmed delivery of alarms. The alarm centralization system does not exempt the user from checking the pump alarms at bedside."

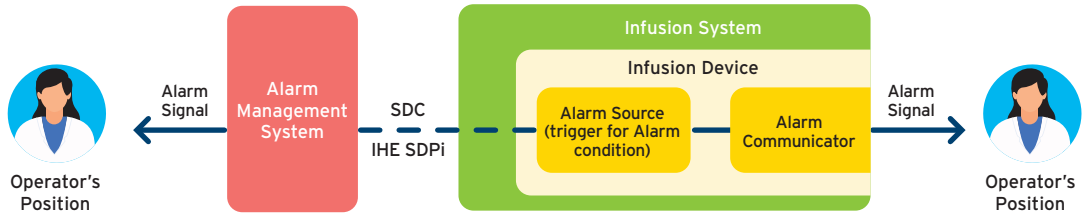
For regulators, this is called a Distributed Information System (DIS). The challenge is to move to a Distributed Alarm System (DAS) capable of providing caregivers with the guarantee no alarms will be missed, even if caregivers are not at the patient's bedside. The IHE Device working groups are addressing this challenge through the SDPi (Serviceoriented Device Point-of-care Interoperability) initiative.

For nurses, the goal is to be made aware of the difference between an "information signal" (DIS) and an "alarm signal" (DAS). Ultimately; "alarm delegation" would make it possible to clear the alarm signal at bedside. The IHE points to SDC standards as a means to achieving this.

1. "Alarm as information" – Remote operator must still verify alarm at bedside



2. "Alarm signal" received remotely – Remote operator can trust alarm management system signal



3. "Alarm delegation" – stops audible alarm from infusion device

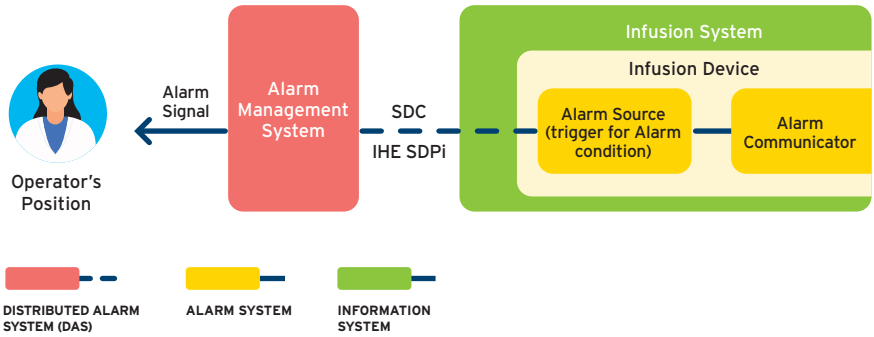


***Figure 7** - Steps toward silent ICU*

In addition to alarm distribution or escalation workflows that are primary uses of Alarm Management Systems, "Alarm Delegation" and "Silent/Quiet ICUs" are todays innovation challenges driven by industrial actors like Dräger, Ascom or Philips.

Alarm prioritization

In an ICU, given the large number of infusion devices in use at the same time in a complex environment, alarm prioritization is a huge challenge. alarm management systems should include a complete alarm escalation workflow. If the DERS included "smart" alarm priorities (like prioritizing "end-of-infusion" of a life-sustaining drug over one for an antibiotic), this would be a major advantage.

4.1.2 Point-of-care patient context

Patient context must be at the center of HIS interoperability. And, in acute care environments, multiplying the number of devices that need to be associated with patients (and the resulting workflows) should be approached with caution.

IHE working groups developed a profile called Point-of-care Identity Management (PCIM, which communicates via HL7v2) to align different manufacturers' solutions and point-of-care practices.

This profile specifies the data and workflows for devices and IT systems at an acute-care point-of-care to exchange and synchronize information about the identity of specific devices collecting clinical information about a specific patient, to:

- Assist in the reliable association of data collected with the right patient record based on first-hand observation and data entry by a person at the point of care; this is specifically intended to avoid incorrect attribution of data from before or after the period of actual measurement on the patient.
- Assist in maintaining a correct "census" of devices that frequently move between patients (infusion pumps and mechanical ventilators, for instance).

The profile covers the association and disassociation of a device with a particular patient, as well as the distribution of this information.

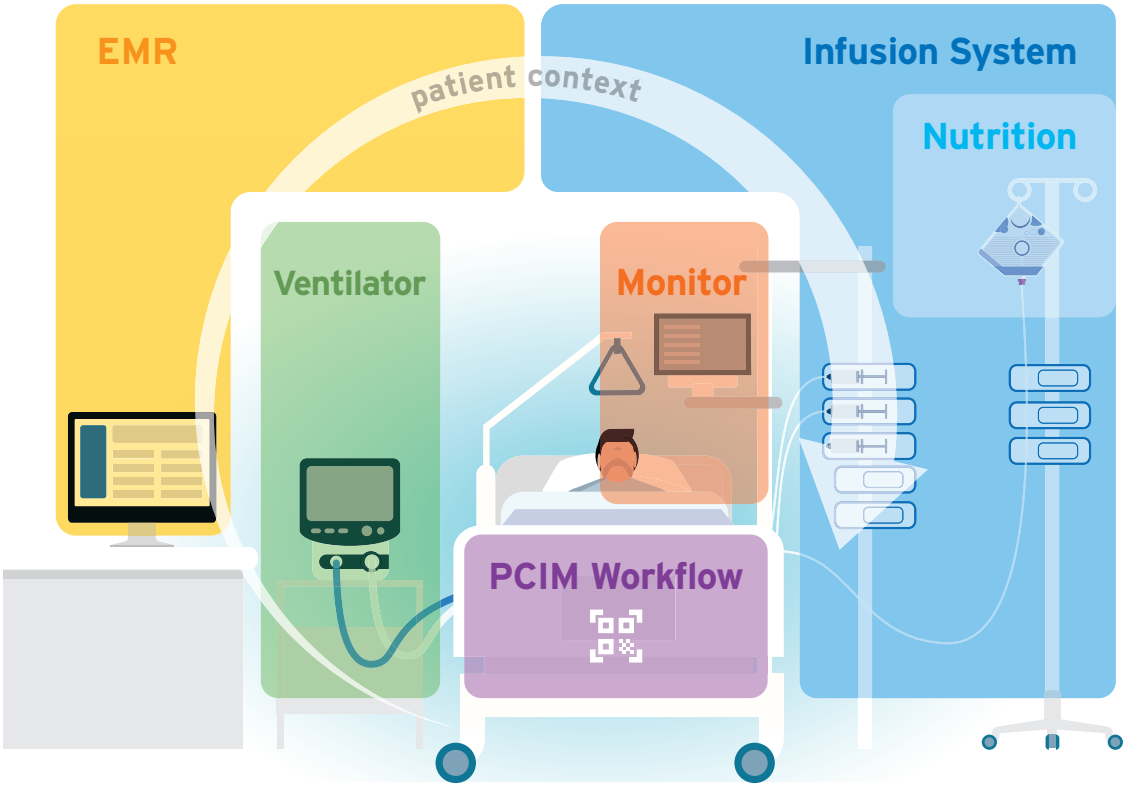


***Figure 8** - Patient information synchronized at bedside*

The key point is that all devices at bedside would use the same association and disassociation workflow.

4.2 Applicability of standards

While specific use cases are helpful in providing an understanding of interoperability, from an infusion system perspective, one standard is unlikely to ultimately address all use cases:

- Machine-to-machine communication in an ICU with advanced clinical cases using SDC to address alarm delegation (DAS)
- Mobile auto-documentation in an ambulatory department using HL7v2

Given how versatile and mobile infusion systems are, interoperability standards must be, as well.

The particular context around HL7 also bears mentioning. Looking at the future of technical standards, HL7 FHIR, under development, would replace HL7v2.

However, since healthcare organizations massively invested in the deployment of HL7v2 interfaces early on, it will take a significant amount of time for HL7 FHIR to be widely adopted.

On the other hand, healthcare IT implementation outside hospitals (regional EMR or EHR and Homecare) is more recent and highlight the need for more mobile technologies.

This is the anchor for first implementations of the new HL7 FHIR.

Therefore, infusion systems are probably facing a more volatile environment than other medical devices. Medical devices in ICUs and operating rooms are often dedicated to acute care and not easily transferable to mobile environments. And devices designed for homecare are generally not suitable for a use inside the hospital. Infusion devices are used in all of these settings. So, depending on where and how they are used, infusion devices would have to align with all or a part of the proposed standards and profiles.

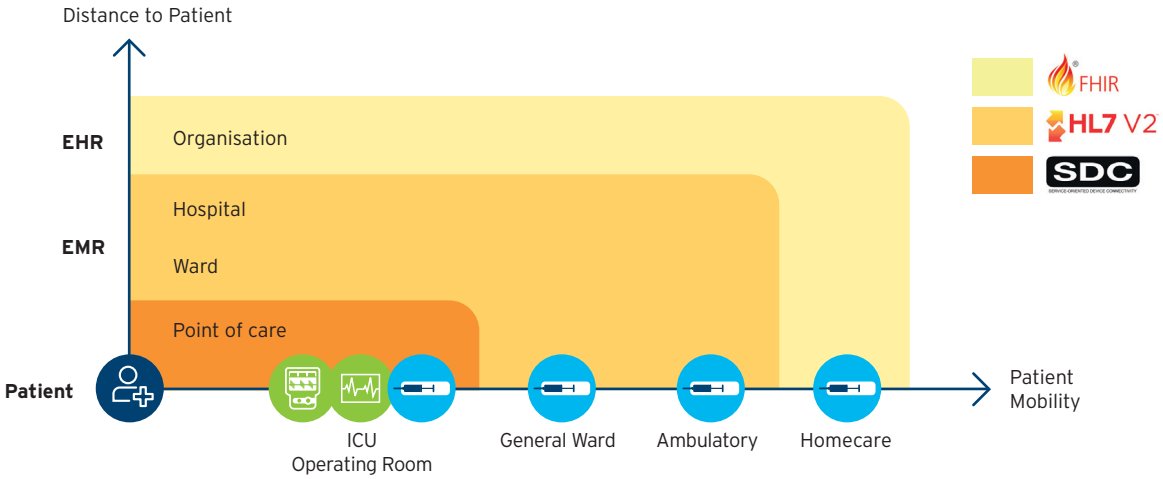


Figure 9 *- Applicability of standards*

5. Standard interoperability: outlook

Today, standard interoperability extends to almost every use of infusion systems.

Most demanding and advanced domain are today settled around acute care areas, where feeding patient records with information (Auto-documentation, Alarm Communication) is today the basic.

Associating devices with patients remains a challenge. To avoid overwhelming caregivers with association options, Point-of-Care Identity Management (PCIM) is emerging as a major topic for IHE working groups.

At the same time, IHE working groups are also determining what the next generation of clinical systems will look like to allow remote alarms and control of medical devices (SDPi/SDC).

Outside of acute care, the interoperability of infusion systems will move toward bidirectional communication (auto-programming and auto-documentation), locationbased alarm communication, and fleet management (HL7v2).

In the meantime, medtech startups are laying the foundations for the Internet of Medical Things (IoMT) leveraging HL7 FHIR capabilities.

For **operating rooms**, knowing the position and status of unused pumps (RTLS[8]) would help optimize fleets and preparation time. And the correct association of patient and device would allow anesthesia closed loop and alarm delegation (DAS) during surgeries, freeing up additional caregiver time to focus on the patient.

For **ICUs**, the ability to follow up on the administration of medication through auto-documentation is a basic feature to support caregiver efficiency. And, given the large number of noisy devices that disturb both caregivers and patients, alarm delegation (DAS) would be next on the list in terms of interoperability.

Ambulatory Oncology, chemotherapy administration, concerns specific and high-level issues in term of follow-up and traceability as well in healthcare and financial domain for a healthcare organization. Bi-directional interoperability (Auto-programming and Auto-documentation) of infusion devices is highly indicated in that context. In addition, high level of mobility of devices and patient during the administration would benefit from a location system (RTLS).

8) MEM-LS profile see 3.5 Overview of IHE profiles applicable to infusion systems

6. Definitions and resources

ADT: Admit, Discharge and Transfer

Alert: physiologic alarms, technical alarms, and advisories (IHE definition)

Alarm communication describes how infusion devices communicate with electronic medical records for near-real-time response to clinically or technically actionable events and situations.

Standard: IHE **ACM** (Alert Communication Management)

Auto-documentation describes how infusion devices communicate with electronic medical records for reporting, charting, and trending data to assist clinicians in tracking patient status for situational awareness and care planning. It defines a means for communicating significant events related to medication administration by infusion pumps.

Standard: IHE **DEC/IPEC** (Infusion Device Enterprise Communication/Pump Event Communication)

Auto-programming supports the electronic transfer of infusion parameters from a Bedside Computer-assisted Medication Administration (BCMA) system to an infusion pump. This capability will reduce errors by eliminating keystroke errors and by increasing the use of automatic dosage checking facilitated by the onboard drug libraries in "smart pump" systems. In addition to the reduction of medication administration errors, this integration may also increase caregiver productivity and provide more contextual information regarding infusion data. (Auto-programming is not possible without auto-documentation.)

Standard: IHE **PIV** (Point-of-Care Infusion Verification)

BCMA: Bedside Computer-assisted Medication Administration

DIS/DAS: Distributed Information System/Distributed Alarm System

IEC 60601-1-8 General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC TR 80001-2-5: Application of risk management for IT-networks incorporating medical devices - Part 2-5: Application guidance - Guidance on distributed alarm systems

EHR: Electronic Health Record

EMR: Electronic Medical Record

EMRAM: Electronic Medical Record Adoption Model
https://www.himss.org/what-we-do-solutions/digital-health-transformation/maturitymodels/electronic-medical-record-adoption-model-emram

HIMSS: Healthcare Information and Management Systems Society

HIS: Healthcare Information System

HL7 FHIR (Fast Healthcare Interoperability Resources):
https://www.hl7.org/implement/standards/product_brief.cfm?product_id=491 / http://hl7.org/fhir/

HL7v2:
https://www.hl7.org/implement/standards/product_brief.cfm?product_id=185

IHE: Integrating the Healthcare Enterprise

IHE Devices (DEV) domain, https://www.ihe.net/ihe_domains/devices/

(e)MAR: (electronic) Medication Administration Report

PCIM: Point-of-care Identity Management
https://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_Suppl_PCIM.pdf

SDC (IEEE 11073): Service-oriented Device Connectivity (Health informatics - Device interoperability - Part 10101: Point-of-care medical device communication)
https://ornet.org/en/

SDPi: Service-oriented Device Point-of-care Interoperability
https://profiles.ihe.net/DEV/SDPi/index.html

Smart pump:

A "smart" pump is the commonplace term given to a programmable computerized drug infusion device that contains a drug library, also known as a dose error-reduction system.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7423573/#:~:text=A%20'smart'%20pump%20is%20the,as%20drug%20concentration%20and%20dose.

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