

The high-reliability ICU

Unifying situational awareness, communication and timely actions to improve patient outcome.

Introduction

Despite continuous advances in medicine, including the advent of personalized medicine and patient-centric care, the increasingly complex operational challenges faced by today's healthcare systems are exposing unaddressed issues, as the present COVID-19 pandemic has demonstrated. Given its substantial impact on healthcare systems globally, COVID-19 has highlighted –some– of the current deficiencies of dramatically important areas of care such as the intensive care unit (ICU). In hospitals and ICUs all around the world, the crisis has revealed a shortage of qualified personnel, a lack of consistent and efficient workflows, and current healthcare systems' frequent inability to adapt to rapidly evolving situations.

In order to mitigate some of these ever-present issues, however, a wealth of technological advances to facilitate the digitalization of healthcare are readily available, aiming to not only modernize hospitals but also revolutionize work operations and organizational processes, thus laying the foundations for a centralized digital healthcare system.

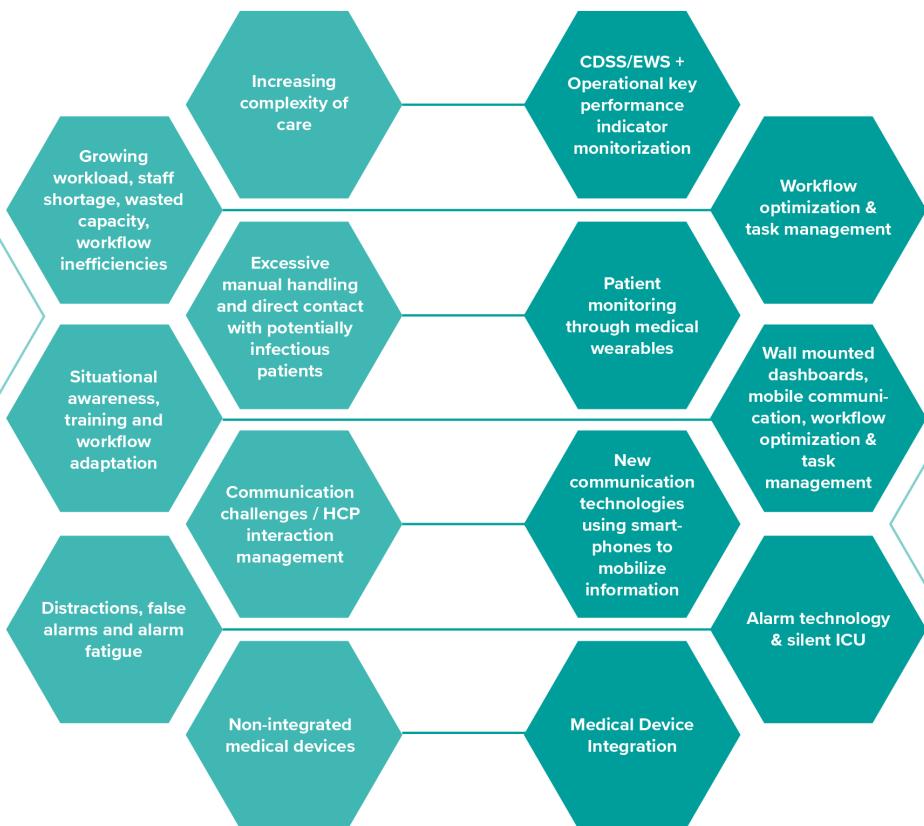
In this report, we aim to review the current challenges faced in ICUs worldwide, and explain how digital technology can help resolve those issues, focusing on its potential and –proven– benefits, and defining the high-reliability ICU as the main objective of this digitalization process.



OBSTACLES TO ACHIEVING A HIGH-RELIABILITY ICU

A number of issues have been found to negatively affect ICU processes:

- **Increasing complexity of care.** Medical knowledge has been expanding exponentially in the last few decades, but diseases, medicine and clinical practice have evolved at the same time.¹ Together, these changes have significantly increased the complexity of determining the right treatment, for the right patient, at the right time.
- **Ever-growing workloads.** Various studies on factors affecting nursing care performance in the ICU found that the increasing workloads affected both the quality and safety of care.²⁻⁴
- **Staff shortages.** Despite projections indicating rising demand for healthcare workers, in 2016 the World Health Organization⁵ estimated that, by 2030, there would be a worldwide shortage of around 18 million healthcare workers; the COVID-19 crisis has exacerbated this need for trained personnel.⁶
- **Wasted capacity.** Healthcare professionals (HCP) often have to dedicate too much time to record keeping⁷ thus keeping them from directly tending to their patients. For instance, one study⁸ reported that ICU nurses dedicate almost 20% of their time to administrative duties, a burden that is untenable even outside of crisis situations.
- **Workflow inefficiencies.** One of the most commonly reported issues concerns inefficiencies relating to patient transport, not only through the acute care setting but also when it comes to triage or testing.⁹
- **Excessive manual handling and direct contact with potentially infectious patients.** Despite this issue posing a serious risk only in the context of infectious diseases, ICUs are not designed/planned to deal with a massive influx of highly infectious patients.¹⁰
- **Situational awareness, training, and workflow adaptation.** COVID-19 has highlighted healthcare systems' need to respond and adapt to extremely demanding and rapidly changing situations.¹⁰
- **Communication challenges/HCP interaction management.** Some reports suggest that more than 90% of all medical errors are due to communication difficulties (e.g., breakdown) and inefficient team collaboration.¹¹ Communication is even more challenging when it needs to occur across disciplines (e.g., ER to ICU).¹²
- **Distractions, false alarms, and alarm fatigue.** More than 70% of all alarms in the ICU have no real clinical significance and therefore prompt no medical action. However, this may potentially lead to ICU personnel ignoring meaningful alarms, especially since there is no standardization of alarm sounds among manufacturers and/or risk implications.^{13,14} For instance, a recent study revealed that alarm fatigue significantly reduced resuscitation success for in-hospital cardiac arrest (IHCA).¹⁵
- **Medical devices not interconnected.** A typical ICU patient may be attached to six or more bedside devices of various kinds from different vendors, each operated by proprietary software. Integrating, aggregating, and analyzing this data can therefore be a tedious and time-consuming process in a setting where split-second decisions can constitute the difference between life and death.¹⁶



DIGITALIZATION WILL BE THE KEY DRIVER OF THE HIGH-RELIABILITY ICU

Let's imagine the following situation: an ICU patient connected to a ventilator, attached to a patient monitor and several infusion pumps. The patient monitor shows an alarm for high blood pressure. This alarm is communicated to the nurse in charge via a clinical smartphone, while she is preparing medications at the nursing station. Immediately, she checks additional vital patient signs on her remote device: normal heart rate, normal sinus ECG rhythm, and normal CO₂ and SpO₂. Next, she checks other possible explanations for the increased blood pressure on the patient's data charts. Checking the parameters of the infusion pumps directly on her smartphone, she observes that the noradrenaline dose is 0.05 µg/kg/min, and that this factor could be a direct cause of the high blood pressure. She therefore goes into the patient room and reduces the dose, later observing the effects of her action on the patient's blood pressure.

This situation is a basic reflection of the possibilities that an integrated digital data management and communication system can offer to solve the previously discussed issues present in ICUs. Such systems should ideally include the following capabilities:

Workflow optimization & task management

Making work processes readily adaptable to changing situations crucially requires a real-time support system in which new workflows/rules can be defined and directly communicate the protocols and guidelines to be followed in a specific manner. Furthermore, and in addition to appropriate patient transport processes, communication and data management are essential to the process of optimizing ICU workflows.¹⁴ . The chosen communication mechanism needs to match the urgency and importance of the information. For time-critical information that requires immediate action, signaling on a mobile device may be the most appropriate means of communication, while a wall-mounted dashboard may be more suitable for less time-critical information.

Patient monitoring through medical wearables (blood pressure, ECG, biosensors...)

Wearables allow for non-invasive frequent measurements, or even continuous monitoring, and can result in substantial time-savings for ICU nurses, in addition to potentially improving patient outcomes.¹⁷ Medical wearables also allow patients to move throughout the facility. As they transition across departments, wearables prevent blind spots in observation. Furthermore, the use of medical wearables connected to a digital data network with the possibility of remote/mobile access allow patient follow-up without close contact, which is an advantage when dealing with infectious diseases.¹⁸ For instance, to adapt to the COVID-19 situation, wearables were employed to monitor patient's vitals in the isolation wards of a hospital in the Netherlands. The use of medical wearables granted caregivers an objective view of who required attention, which was especially critical when the patient inflow became overwhelming. Moreover, collecting near real-time data on every patient in the ICU may enable better control of disease progression, early detection of deterioration and/or treatment effects, and rapid intervention based on both current and accumulated data trends.

Medical Device Integration (MDI)

This capability allows the system to leverage information from different types of medical devices (from ventilators to infusion pumps or patient monitors) for the purposes of documentation, clinical decision support, and alarming. With the near real-time acquisition of clinical data, vital signs, alarms, and technical information from the connected medical devices, workflows can be orchestrated to expedite responses to critical situations. MDI contributes a unique source of objective and reliable medical data. Importantly, to achieve the above purposes, the system needs to be capable of data storage, scalable, and vendor-neutral. It also requires medical product certifications at the appropriate levels.

New communication technologies using smartphones to mobilize information

Communication technologies permit access to information, data, and events from various medical devices, which, combined with the use of both visual and acoustic signals to codify and prioritize information, ensure that all data received by medical personnel is relevant and actionable, thus reducing the cognitive load. Additionally, this remote access system allows for specific alarm redirection to the responsible person, alarm management, and prioritization. This method makes it possible not only to specifically direct alarms but also to transmit precise workflows/process instructions and updates to particular stakeholders. Additionally, it helps to prevent collisions when several clinical staff members need to perform tasks on the same patient, increasing efficiency. As with the device integration component, this part of the system should also be vendor-neutral and scalable to achieve its goals. As important as all these functionalities are, the most relevant is the need to drive collaboration through direct multi-media communication, without physical presence being required, by encouraging patient-centric messaging, leveraging patient assignments to route information and alarms, and allowing for role-based interdisciplinary communication (e.g., ICU bed manager, surgeon on-call). This needs to be based on the use of safe and secure communication channels that protect sensitive patient data.

Wall-mounted dashboards enhancing visibility

The aim of this element is to increase situational awareness (overview/prioritization) by providing a comprehensive view of devices in single-bed and isolated wards, such as in an ICU, and of all or specific patients through an intuitive user interface with access to historic data.

Obtaining visual and acoustic status information from the connected medical devices allows users to contextualize data to help with alert evaluation.

Furthermore, by converging the information from multiple devices and their alarms into a single prioritized overview, and being able to drill down to further details from this overview, clinicians can manage information and alerts more effectively. Moreover, HCPs can also obtain information about the situation in the ward without needing to enter it, viewing all patients at once, or specific ones, though an intuitive user interface. This may reduce the need for personal protection equipment –which requires considerable time to set up–, or unnecessary exposure to infectious patients. A function that can be further improved by the integration of a video feed to remotely observe the situation in the room: is the patient cramping, attempting to extubate – or is a nurse presently in the room, and in fact responsible for the alarm? All these functions should be implemented with maximum data integrity to comply with audit requirements.

Alarm technology/silent ICU

A centralized alarm notification system improves, among other factors, alert management workflows. By removing non-actionable alarms (those that are not clinically relevant and do not require intervention), HCPs can focus on the important ones and improve on their response times and decision-making abilities. It also reduces alert fatigue in caregivers, thus improving the quality of care. For instance, a case study in a hospital in Southern California showed it is possible to filter out about 58% of alarm notifications to caregivers.¹⁸ But even more important than this alarm technology is the silent ICU. Beyond the alarming functionality described before that improves the support for caregivers, this integral concept aims to reduce noise near patients, thus improving their comfort and assisting in the healing process, for example by reducing the occurrence of delirium and associated problems such as increased ICU length of stay (LOS).^{16,17} To achieve this goal, the silent ICU requires a full delegation of alarms from the source medical device to the distributed alarm system, which is still under development. Today's "silent ICUs" are therefore more of a mixed environment including "silent" and legacy –noisy– medical devices.

Clinical decision support system (CDSS) based on early warning scoring (EWS) and other relevant patient data

Research on diseases of differing etiologies such as sepsis,^{19,20,21} polytrauma,²² INCA,²³ or ST-Elevation Myocardial Infarction (STEMI) has shown that early prediction of disease worsening was associated with improved patient outcomes, be it LOS,¹⁹ operative cost,^{24,25} or mortality.^{20,21} This is the basis for a CDSS, which helps HCPs in their decision-making through the use of rules of action and algorithms which, based on the available data, help avoid misdiagnosis or predict patient outcomes such as worsening disease or effective treatment responses. HCPs provided with the corresponding alarms in advance can better intervene to avoid patient deterioration.¹⁵ With the involvement of artificial intelligence (AI), for instance, a rapid response system was able to accurately predict patient deterioration better than conventional methods.²⁶ In another hospital, a remote centralized monitoring unit applying standardized cardiac telemetry indications and electronic records could provide early notification of cardiac rhythm and rate changes in critically ill patients within one hour before the majority of emergency team activations, and was associated with a reduced need for patient monitoring outside the ICU without increasing the occurrence of cardiac arrest.¹⁵

Operational key performance indicator monitoring

To facilitate a continuous improvement effort, operational KPI monitoring permits the recording of data and information not only on vitals, but also on variables such as ICU-LOS, mortality rates, time management, etc. This data can be leveraged in the process of resource optimization, both human and material.

BENEFITS ASSOCIATED WITH HEALTHCARE DIGITALIZATION

Despite the lack of clinical data on integrated clinical communication and collaboration platforms that offer medical device integration, alarming and CDSS, there is some related evidence that goes to demonstrate how such a system can generate material benefits:

- Increase the quality and accuracy of medical records.²⁷
- Decrease the incidence of medical errors.²⁷
- Reduce prescription errors.²⁸
- Gather and share useful information both at the bedside and remotely.²⁹
- Avoid deficiencies during handover.³⁰
- Shorten ICU-LOS.³¹

In addition, a meta-analysis showed that the combination of a computerized data entry system together with a CDSS was associated with an 85% reduction in prescribing errors and a 12% reduction in ICU mortality.²⁸ This effect should only be stronger with medical device interfacing in place where the charted data is taken directly from the medical device avoiding the transcription risks that remain in place when the data is manually entered into an information system.

Integrated systems supporting the implementation of telemedicine in the ICU (Tele-ICU) could help address the critical shortage of skilled personnel and insufficient staffing, especially during nights and weekends. Using a platform that facilitates Tele-ICU patient monitoring, alarming, workflow orchestration and collaboration, multiple ICUs can support each other with expertise 24-7 independent of geographical location.³² A meta-analysis on the effects of telemedicine in the ICU showed that Tele-ICU approaches may not only reduce ICU and hospital mortality, but also shorten ICU-LOS.³³

Although the evidence above arises from either partial or preliminary data on systems that commonly include only parts of the described clinical communication and collaboration platform, future studies on the full application of a holistic platform approach are expected to expand on the individual potential of each strategy.

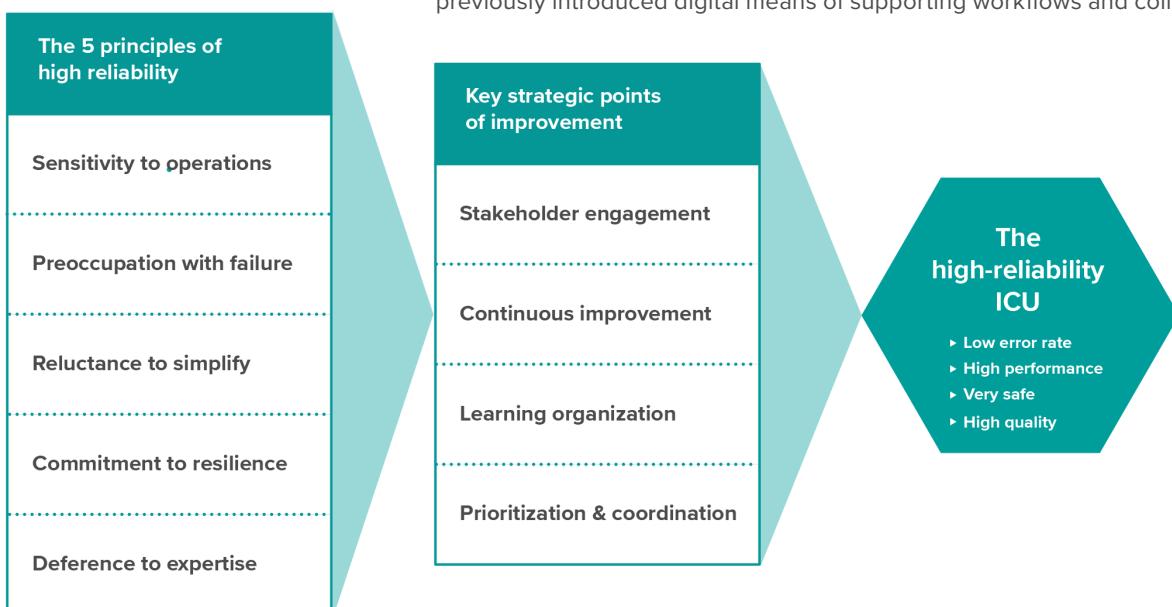
The high-reliability ICU

In an environment where normal accidents are expected to occur but cannot be foreseen or prevented, high-reliability organizations³⁵ (HRO) have designed their operations to successfully avoid catastrophes that would emerge from an inefficient management of normal accident situations. For this purpose, HROs leverage management principles that aim to ensure operation at high levels of efficiency while reliably achieving the best possible outcomes.

The ICU is an environment in which normal errors can be expected due to risk factors and complexity. Given this characteristic, an ICU constitutes an organization that exposes the typical attributes of a high-reliability organization. The projection of the HRO principles towards the ICU would then drive a high-reliability ICU³⁴ with improved patient outcomes and a good standard-of-care.

A high-reliability ICU will be organized in a way that consistently and sustainably avoids mistakes and inefficiencies. This leads to improved performance, a reduction in error rates, and, ultimately, the achievement of a very safe, high-quality environment. Safety in this context protects both patients and caregivers from the risks they are regularly exposed to.

A high-reliability ICU requires compliance with the five principles of high-reliability organizations. Most importantly, all stakeholders need to demonstrate a high level of commitment towards each of them. Operationalizing the five principles can be achieved by leveraging four key strategic points of improvement³⁶, of which continuous improvement, prioritization and coordination can be facilitated by the previously introduced digital means of supporting workflows and collaboration.

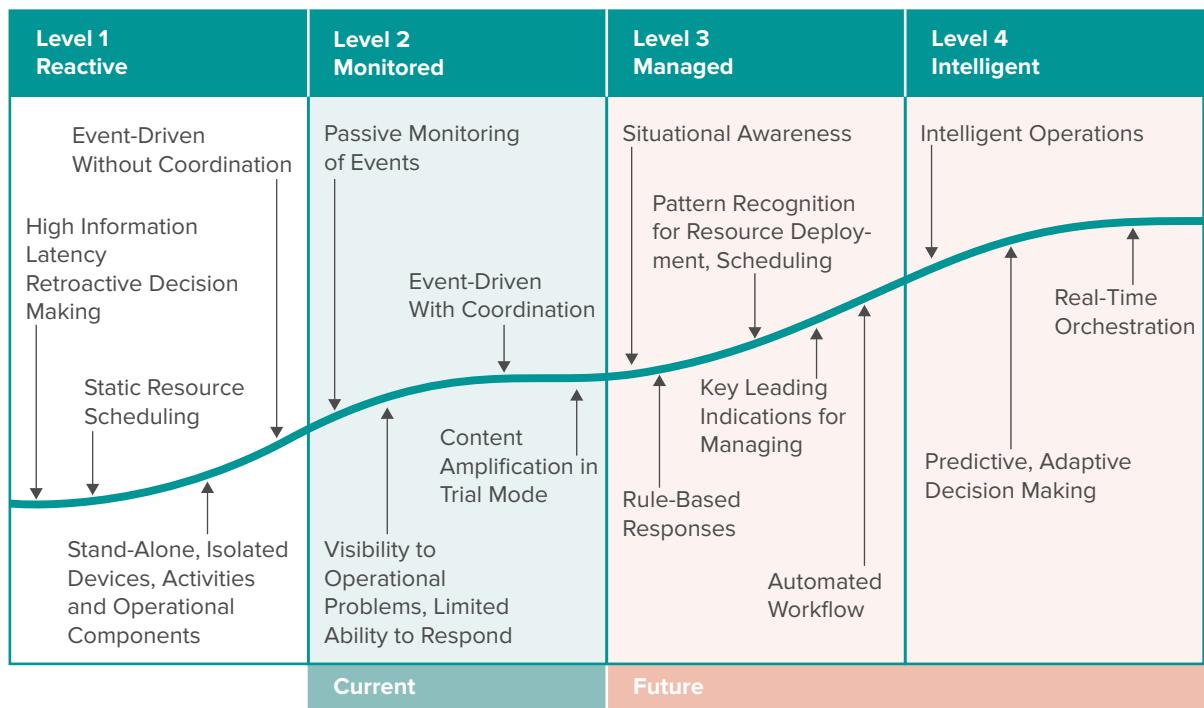


To achieve this goal, an integrated patient data and communications management system can help at various strategic levels, from assisting with continuous improvement, to prioritization and coordination, through learning organization.

Digitalization will be of assistance not only as an analysis tool of progress in the process of monitoring the errors, near misses, and changes occurring during ICU operation, but can also help to drive the improvement process itself by supporting workflow organization and task administration. Additionally, a CDSS can assist on decision-making processes, and the alarm filtering and prioritization tools can help better stratify risk and orient team responses. Concurrently, the remote communication capabilities of the system can help improve the coordination of response teams and the actualization of action protocols and constant learning, thus helping shift ICUs towards high-reliability.

Future improvements

Despite the remarkable advances in healthcare digitalization in the last few years, its application to healthcare systems³⁷ is still evolving. Currently, the reality of healthcare still corresponds more to a reactive than a predictive model, despite proactive elements such as the CDSS gradually becoming more commonly used.



Aside from the development of predictive algorithms and the use of AI systems that brings an ICU to the “intelligent” phase in which errors in diagnosis or treatment will be so reduced as to define maximum reliability, there are other foreseeable improvements, namely:

Usability optimization

A number of reports on critical care information systems’ user satisfaction levels reported that usability was one of the key aspects driving high clinical staff satisfaction with digital data management tools,³⁸⁻⁴⁰ while the number of functions did not seem to be so important. Additionally, among the most important usability factors were intuitiveness and visualization.⁴⁰ As the supporting digital solutions that have been discussed here aim to reside on a mobile device or a wall-mounted dashboard, the applications have to be tailored to the exact context of their use given the limited real-estate of the screen on a mobile device and the limited ability to interact when it comes to a wall-mounted dashboard.

Hands-free communication and voice recognition

Although hands-free communication smart devices, defined as wearable devices with WiFi and voice control,⁴¹ are already available in clinical settings, their extended use will also help improve communication speeds,^{42,43} free up nursing time,⁴⁴ and reduce the risk of infection/cross-contamination by excessive manual handling. Further, the application of voice recognition software to allow recording of patient data, instructions to staff, or even to directly control medical devices will be a welcome development for clinical staff, who have already expressed interest in such developments^{45,46} as long as a high level of speech recognition accuracy can be ensured to reduce the possibility of introducing errors into the system.⁴⁷

Patient visibility

The current trend towards individual ICU rooms, which offer significant benefits in terms of disease transmission control⁴⁸ and patient privacy,⁴⁹ requires new methods of close patient monitoring and observation, especially as it then has to occur from remote locations. While the monitoring of vitals can be achieved with technology that is available today, other parameters and developments cannot be captured through a traditional sensor attached to the patient.

There has been some research in this area; for instance, a study⁵⁰ using pervasive sensing and deep learning on ICU patients could distinguish between delirious and non-delirious patients based on non-invasively and remotely recorded parameters such as changes in illumination or facial expressions, showing their future potential for ICU patient care.

Training to improve user perceptions

Several studies have reported that clinical staff, especially in high workload areas such as ICUs, expose a general lack of trust towards digital solutions, fear of increasing workloads and the loss of clinical skills. There also appears to be a lack of awareness of available digital technologies.⁴⁰ To overcome these perceptual barriers around state-of-the-art technological implementations and to prevent increasing workloads due to lack of knowledge/operating skills, appropriate training protocols/procedures, including end-user and trainer-to-trainer training and knowledge assessment tools must be in place so as to maximize the benefits of the ICU digitalization.

It is also crucial for users to fully understand the exact way the systems reacts to inputs, especially when its use goes beyond collaboration and covers alarming and workflow orchestration. A flawed mental model of what the system will do in specific situations can lead to important alarms not receiving the attention they require.

Conclusions

Despite recent advances in healthcare, there are still a number of unresolved issues that the latest global pandemic has underscored – to which digital technology may offer the answers. Through the digitally-driven continuous improvement of ICU processes and workflows, a reduction in error rates, and an improvement in staff performance, a high-reliability ICU can become a reality. An integral data and communications system including alarm technology, integrated medical device data, remote patient monitoring, and a CDSS, as well as efficient and rapid communication methods among medical staff will be the driver of the high-reliability ICU.

Abbreviation list

AI, artificial intelligence [^]	ICU, intensive care unit
CDSS, clinical decision support system	ICU-LOS, intensive care unit length of stay
ECG, electrocardiogram	IHCA, in-hospital cardiac arrest
ER, emergency room	LOS, length of stay
EWS, early warning scoring	MDI, medical device integration
HCP, healthcare professionals	Tele-ICU, telemedicine in the ICU
HRI, high-reliability ICU	STEMI, ST-elevation myocardial infarction

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