UNIVERSITAT DE BARCELONA

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PhD Thesis:

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Author: Bruna Corrêa Volpini

Supervised by:

Dr. José María Nicolás Arfelis
Dra. Neus Vidal Martínez

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Author: Bruna Corrêa Volpini

Thesis submitted as part of the Doctoral Programme in Biomedicine of the University of Barcelona

Director: Dr. José María Nicolás Arfelis
Medical Intensive Care Unit of Hospital Clínic in Barcelona

Neus Vidal

Director and Tutor: Dra. Neus Vidal Martínez
Department of Electronics and Biomedical Engineering. Faculty of Physics. University of Barcelona

Barcelona, 2021

UNIVERSITAT DE BARCELONA

"You can't connect the dots looking forward; you can only connect them looking backwards. So you have to trust that the dots will somehow connect in your future. You have to trust in something — your gut, destiny, life, karma, whatever."

Steve Jobs

ACKNOWLEDGMENTS

La realización de esta tesis no sería posible sin el apoyo incondicional de mis dos directores. Me gustaría agradecer al Dr. José Maria Nicolás por acogerme en su unidad y por haber dejado que transformáramos su antiguo despacho en un Laboratorio de Bioingeniería. Por haber apostado por mí y por haber propuesto la desafiante tarea de transformar el entorno de las Unidades de Cuidados Intensivos (UCIs) en un lugar más seguro y al mismo tiempo más humano. También por haberme dado la oportunidad de trabajar de forma presencial al lado del gran equipo clínico del Área de Vigilancia Intensiva (AVI) del Hospital Clínic de Barcelona (HCB).

A la Dra. Neus Vidal por apoyarme en esta iniciativa y por ser una persona muy abierta a nuevas ideas y con gran capacidad de adaptarse a entornos complejos y multidisciplinares. Por guiarme en todos los momentos de incertidumbre y de ayudarme a tener un pensamiento crítico. Por ser un gran ejemplo de mujer científica, fuerte y trabajadora, en un entorno predominantemente masculino. Por incentivarme a salir de mi zona de confort, por enfrentar las dificultades, miedos y no darme por vencida. Por encorajarme a seguir adelante con la tesis y a publicar los resultados en congresos y en revistas de alto impacto.

A la gran familia de la AVI: Pedro, Sara, Inma, Adrián, a todas las enfermeras, médicos, residentes, auxiliares, fisioterapeutas, farmacéuticas, administrativas, personal de limpieza, camilleros y gestores. A cada uno de ellos que han contribuido para el éxito de este trabajo y que con su sonrisa, gratitud, amistad y actitud positiva han estado diariamente a mi lado. A todos ellos que han estado en la primera línea de batalla contra el Covid-19, que han dado lo mejor de sí mismos y que no han medido esfuerzos para ofrecer la mejor atención posible a los pacientes en los momentos difíciles. He aprendido a ser mejor persona, profesional y también he vivido inolvidables momentos durante estos años. A los profesionales sanitarios y de soporte de áreas transversales del hospital: Maria Cabezos, Tere Hospital, Laura Trigo, Ema León, Gloria Martínez, Dolors Estrada, Carolina Fernández, Marga Rombau, Miquel Sanz, José Antonio Rodríguez, Xavier Francás, Ana Casadó, Xito Jiménez, Dr. Alex Soriano, Dr. Joan Ramón Badia, Dr. Javier Fernández, Carmen Frias, Jorge Fernández, Gemina Santana, Isabel Fortes, Laura Rodríguez, Eli Uria, Xavi García y Amadeu Bergés.

A todos los informáticos del Departamento de Sistemas, una mención especial a Dani Gutiérrez, Dani López, Óscar Subirana y Felipe Geva por su inestimable colaboración, compañerismo y apoyo en todos los problemas técnicos que hemos tenido durante la realización de esta tesis. A ellos les debo mi sincero 'muchas gracias' por el soporte en el seguimiento de las gestiones tecnológicas de esta tesis.

He aprendido muchísimo sobre cómo gestionar proyectos de innovación tecnológica en el sector hospitalario con ellos. A Jordi Montoya y a Carles Varea de Tecnopixel, por su apoyo diario en los desarrollos de software y por su gran coraje y sentido de compromiso con el hospital. Un ejemplo de liderazgo efectivo a seguir.

A todos los trabajadores del Departamento de Infraestructuras y Mantenimiento por su gran disponibilidad e interés en ayudar a mejorar las instalaciones de la AVI y del Laboratorio de Bioingeniería con las tecnologías más innovadoras del mercado. Un especial agradecimiento al Sr. Joan Vila-Massana, Sr. Ferrán Rodríguez, Mario García, Gerard Trías, Manuel Sanz, Felipe López, Javier Aliaga, José Antonio Marín, Antonio Luque, Justo Holguera y Sergio Niño.

A mis queridos alumnos de TFG y prácticas externas: Marc Casillas, Biel Crespí, Pablo López, Seiji Bernabela, Elia Gil, Julia Soler y Maria Guerrero. Una experiencia enriquecedora haber desarrollado muchos trabajos académicos en entornos de laboratorio y de UCI. Al Dr. Aleix García, quien ha sido codirector del trabajo del alumno Marc Casillas, muchas gracias por compartir la experiencia y los aprendizajes.

A la Dra. Montse Cruz, coordinadora de proyectos de innovación del Vicerrectorado de Emprendimiento, Transferencia e Innovación de la Universidad de Barcelona (UB), por el apoyo en las propuestas aplicadas a las convocatorias del EIT Health. A los coordinadores del EIT Health España por haberme seleccionado para la beca de estudios del curso de 2019 y por las varias consultas respecto a los proyectos de innovación. A las profesoras de la UB Dolores Rodríguez, Eva Guix, Laura Igual y Petia Ivanova por la colaboración en las propuestas de las convocatorias del EIT Health.

A la Dra. Isabel Román de la Universidad de Sevilla y al Dr. Josep María López Villegas de la Facultad de Física de la UB por aportar los comentarios, correcciones y motivación cada año de seguimiento de la presente tesis. A Silvia, Rocío, Mauricio, Kenneth, Eva y Sergi del Laboratorio de Simulación y del Servicio de Grabación de Clases de la Facultad de Medicina por la amistad y por ayudarme en las grabaciones de los videos del lavado de manos y de los protocolos clínicos.

A los proveedores de productos médicos y no-médicos por su inmensa ayuda diaria en resolver problemas de instalación y conexión, Paulo Silva y Rafa Ibáñez de Axis Communications, Cristhian Calafat de CCS Ingeniería, José Salcedo de Simón, Gustavo Tomás de Grifols, Carlos Jiménez y Francisco Martín de Beckton Dickinson España, Mircea Despa de Beckton Dickinson Estados Unidos, Elisenda Perich, Javier Morales y Guillermo Morantes de Hill Rom España, Julio Cesar y Toni Plazas de Draeger España, Lloyd Stern de Draeger Estados Unidos, Arne Weignand, Jasper Diesel y Meike Frischke de Draeger Alemania.

A mi madre, Fátima, y a mi hermano, Lucas, por el amor y cariño y por haber estado a mi lado en todos los momentos. Por todos los sacrificios que han tenido que hacer para que hoy pudiera estar aquí, por apoyar mis decisiones y por ser mis fundamentos. A mis tíos, Lunalva, Luciano, Dalva, Marcos, Tania, Pardal, José, Marli, Julia, a mis primos, a mis abuelos, Eustaquia, Francisco y Regina, por incentivarme a ir en busca de mis sueños y por siempre transmitirme un profundo afecto y serenidad, aunque sea de forma online. A Ángel por ayudarme a venir a Barcelona y por apoyarme en todo lo que he necesitado durante los tres primeros años. A mi pareja, Marc, por ser el sol de mi vida, por llenar mis días de color y alegría, y también por estar a mi lado en todos los momentos. Gracias, cariño por ser el mejor compañero del mundo ;) A la familia del Marc, por hacerme sentir en casa y por estar siempre presente.

A mis amigas Fabi y Montse por el apoyo diario y los momentos de desconexión. Por los cafés y por la sincera amistad. A Thi, Leo, Rafa, Gabi, Kati, Lu, Pat, Irene, Annamma, Cristian e Iván por compartir excelentes momentos. Por el apoyo y ejemplo de Flavio Augusto da Silva.

A los profesores del grado de Ingeniería Biomédica de la UB por haber implementado este ciclo de estudios durante el año de 2010. He podido estar hoy aquí presentando esta tesis gracias el esfuerzo conjunto de todos. Al haber pertenecido a la primera promoción de este grado me siento muy orgullosa de haber tenido una formación académica y personal inmejorable, de alto nivel y de haber tenido muchas experiencias y convivencias con médicos e ingenieros.

Gracias al gran dinamismo y conocimiento en diversos ámbitos que nuestros maestros nos han proporcionado hoy somos más conscientes de nuestro papel como investigadores y emprendedores en el sector biomédico. Nos corresponde a nosotros cambiar los paradigmas existentes sobre las tecnologías médicas para probar que tanto el ser humano como la ciencia están en constante evolución. Y que motivados por una fuerza interior que nos impulsa a llegar a nuestros límites podamos caminar al lado de los médicos, ingenieros y una multitud de profesionales en búsqueda de mejorar la atención para y por los seres humanos.

ABSTRACT

In the late 1990's, when sophisticated personal computers and electronic devices with miniaturized sensors were being mass produced, the concept of *ambient intelligence* (AmI) emerged. An environment that has AmI is a space containing objects which includes technologies that are not visible to users, and which generates intelligent responses when appropriate. When people interact with an AmI environment, they intuitively use technologies according to their own needs and gain more awareness of their actions, thereby improving their quality of life, comfort, and empowerment.

Currently, healthcare professionals work inside a complex adaptive system in which the clinical environment and the health status of patients vary dynamically, and resources are limited. This can generate an increasing number of adverse events as well as medical errors and consequently patients are more exposed to potential harm during a hospital stay. Many researchers are creating new AmI tools to overcome these challenges. This is especially important in intensive care units (ICUs), where there are seriously ill patients who need advanced infrastructure and equipment to receive continuous clinical monitoring and treatment in as safe a way as possible. Three out of every ten patients in an ICU suffer some type of clinical safety issue, which puts their lives at risk.

In this context, the main aim of the work I present in this thesis is to develop an AmI environment for improving the efficiency of processes related to patient safety in ICUs. I have written this thesis with the collaboration of the clinical and engineering team of the Smart ICU at the Hospital Clínic in Barcelona (HCB). That AmI environment is equipped mainly with technologies related to the Internet of Things (IoT) that provide an adaptive and dynamic distribution of clinical information based on the role and location of each professional as well as the clinical health status of patients.

I divided the development of this thesis into three phases. Firstly, I designed, built, and tested a prototype to simulate the AmI environment in a laboratory setting, considering the main patient safety issues which arise in ICUs. I considered 5 patient safety issues: a code blue, a code red, a code pink, control of nosocomial infections and drug-related errors. Secondly, that prototype was adapted and implemented in a Smart ICU at HCB. Thirdly, I collected and analysed data generated by the AmI. It is important to highlight that part of the data collection and analysis related to the AmI environment took place during the SARS-CoV-2 epidemic (Covid-19).

To summarize, my thesis evaluates the efficiency of the use of new technologies to improve patient safety processes in critical care. It improves clinical

and educational standards in terms of patient safety processes at the unit concerned. Moreover, it enables quantification of events related to patient safety as well as heightening awareness of them.

RESUMEN

A finales de la década de 1990, cuando las computadoras personales sofisticadas y los dispositivos electrónicos con sensores miniaturizados se producían en masa, el concepto de inteligencia en el entorno (*AmI – Ambient Intelligence* en inglés) surgió. Un entorno que contiene AmI es un espacio con objetos que incluyen tecnologías, invisibles para los usuarios, y que les generan respuestas inteligentes cuando sea necesario. Cuando las personas interactúan con un entorno AmI, éstas utilizan intuitivamente estas tecnologías de acuerdo con sus propias necesidades y ganan más conciencia de sus acciones mejorando su calidad de vida, comodidad y empoderamiento.

Actualmente, los profesionales sanitarios están trabajando dentro de un sistema complejo adaptativo en el que el entorno clínico y el estado de salud del paciente varían dinámicamente, y además los recursos son limitados. Esto genera un número creciente de eventos adversos y errores médicos, y como consecuencia los pacientes están más expuestos a daños durante su estancia hospitalaria. Muchos investigadores están creando nuevas herramientas de AmI para superar estos desafíos. Esto es especialmente importante en las Unidades de Cuidados Intensivos (UCIs), donde hay pacientes gravemente enfermos que necesitan infraestructuras y equipos avanzados para recibir monitorización clínica y tratamiento continuo de la forma más segura posible. Tres de cada diez pacientes en una UCI sufren algún tipo de problema de seguridad clínica, hecho que pone en riesgo su vida.

En este contexto, el objetivo principal del trabajo que presento en esta tesis es desarrollar un entorno AmI para mejorar la eficiencia en los procesos relacionados con la seguridad del paciente en las UCIs. He elaborado esta tesis con la colaboración del equipo clínico y de ingeniería de la UCI inteligente del Hospital Clínic de Barcelona (HCB). Este entorno de AmI está dotado mayoritariamente de tecnologías provenientes de la internet de las cosas (*IoT – Internet of Things en inglés*) que permiten una distribución adaptativa y dinámica de la información clínica en función del papel y de la ubicación de cada profesional, así como del estado de salud de los pacientes.

He dividido el desarrollo de esta tesis en tres fases. En primer lugar, he diseñado, construido y probado un prototipo para simular el entorno AmI en un escenario de laboratorio considerando los principales problemas de seguridad clínica que ocurren en las UCIs. He considerado cinco problemas de seguridad clínica: el código azul, el código rojo, el código rosa, el control de infecciones nosocomiales y los errores relacionados con los medicamentos. En segundo lugar, este prototipo ha sido adaptado e implementado en una UCI inteligente del HCB. En tercer lugar, he recogido y analizado los datos generados por el entorno inteligente.

Cabe destacar que parte de la recogida y análisis de datos clínicos y ambientales generados por el entorno de AmI coincidieron con el periodo de la epidemia por coronavirus SARS-CoV-2 (COVID-19).

En conclusión, mi tesis evalúa la eficiencia del uso de nuevas tecnologías para mejorar los procesos de seguridad clínica en cuidados críticos, mejora los estándares clínicos y educativos sobre los procesos de seguridad del paciente en esta unidad y, finalmente, permite cuantificar los eventos relacionados con la seguridad clínica, así como ganar más conciencia sobre ellos.

RESUM

A finals de la dècada de 1990, quan les computadores personals sofisticades i els dispositius electrònics amb sensors miniaturitzats es produïen en massa, el concepte d'intel·ligència en l'entorn (*AmI – Ambient Intelligence* en anglès) va sorgir. Un entorn que conté AmI és un espai amb objectes que inclouen tecnologies, invisibles pels usuaris, i que els genera respostes intel·ligents quan sigui necessari. Quan les persones interactuen amb un entorn AmI, aquestes utilitzen intuïtivament aquestes tecnologies d'acord amb les seves pròpies necessitats i guanyen més consciència de les seves accions millorant la seva qualitat de vida, comoditat i apoderament.

Actualment, els professionals sanitaris estan treballant dins d'un sistema complex adaptatiu en el que l'entorn clínic i l'estat de salut del pacient varien dinàmicament, i a més els recursos són limitats. Això genera un número creixent d'esdeveniments adversos i errors mèdics, i com a conseqüència els pacients estan més exposats a danys durant la seva estada hospitalària. Molts investigadors estan creant noves eines d'AmI per superar aquests reptes. Això és especialment important en les Unitats de Cures Intensives (UCI), on hi ha pacients greument malalts que necessiten infraestructures i equips avançats per rebre monitorització clínica i tractament continu de la manera més segura possible. Tres de cada deu pacients a les UCIs pateixen algun tipus de problema de seguretat clínica, fet que posa en risc la seva vida.

En aquest context, l'objectiu principal de la feina que presento en aquesta tesi és desenvolupar un entorn AmI per millorar l'eficiència en els processos relacionats amb la seguretat del pacient en les UCIs. He elaborat aquesta tesi amb la col·laboració de l'equip clínic i d'enginyeria de la UCI intel·ligent de l'Hospital Clínic de Barcelona. Aquest entorn d'AmI està dotat majoritàriament de tecnologies provinents de la internet de les coses (*IoT – Internet of Things en anglès*), que permeten una distribució adaptativa i dinàmica de la informació clínica en funció del paper i de la ubicació de cada professional, així com de l'estat de salut dels pacients.

He dividit el desenvolupament d'aquesta tesi en tres fases. En primer lloc, he dissenyat, construït i provat un prototip per simular l'entorn AmI en un escenari de laboratori considerant els principals problemes de seguretat clínica que succeeixen a les UCIs. He considerat cinc problemes de seguretat clínica: el codi blau, el codi vermell, el codi rosa, el control d'infeccions nosocomials i els errors relacionats amb els medicaments. En segon lloc, aquest prototip va ser adaptat i implementat en una UCI intel·ligent de l'HCB. En tercer lloc, he recollit i analitzat les dades generades per l'entorn intel·ligent van ser realitzats durant el període de la tesi . Cal destacar que

part de la recollida i anàlisi de dades clíniques i ambientals generats per l'entorn de AmI van coincidir amb el període de l'epidèmia per coronavirus SARS-CoV-2 (COVID-19).

En conclusió, la meva tesi avalua l'eficiència de l'ús de noves tecnologies per millorar els processos de seguretat clínica en cures crítiques, millora els estàndards clínics i educatius sobre els processos de seguretat del pacient en aquesta unitat i, finalment, permet quantificar els esdeveniments relacionats amb la seguretat clínica, així com guanyar més consciència sobre aquests.

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CHAPTER 1. INTRODUCTION

According to the Organization for Economic Cooperation and Development (OECD) [1], one out of ten patients has safety issues during hospitalized care and more than 50% of these issues can be avoided. Particularly in intensive care units (ICUs), patients are most exposed to harm because they need continuous monitoring of their vital signs and medication treatment, in addition to high nurse-to-patient ratios and the use of highly technological medical devices for a prolonged period [2]. When in an ICU, the proportion of safety issues that occur increases to three out of every ten patients [3].

Professional healthcare workers (HCWs) must move in a complex adaptive system in which the clinical environment and patient health status vary dynamically, and resources are limited. These factors, added to the pressure, fear, incidence of burnout syndrome, and the use of new clinical protocols, also place patients at risk [4], [5]. Currently, only half of patient safety issues are reported, and application of better practices in the healthcare field can help to provide more data concerning harmful events [6], [7]. Previous studies demonstrate that 15% of hospital expenditure is allotted to treating safety failures and the occurrence of errors leading to adverse effects is one of the ten most common causes of death and disability across the world [8].

It is a priority for government healthcare departments around the globe and also for the private sector to find solutions to mitigate the high level of hospital mortality and morbidities associated with unsafe clinical practices [9], [10]. The solutions must help interprofessional teams take clinical decisions at the right time and identify patients at risk of deterioration or of suffering adverse events. To accomplish this, many researchers are creating new digital tools embedded in an ambient intelligence (AmI) environment to monitor this new clinical scenario and to create the proper environment for healthcare transformation [11],[12],[13]. New solutions integrate the use of data analytics tools to provide useful clinical information, as well as developing clinical guidelines and advanced educational training to guarantee their success.

In this PhD thesis, I propose the creation of an AmI environment to improve the efficiency of processes related to patient safety in ICUs, with the collaboration of the clinical and engineering team of the Smart ICU at HCB. It is important to highlight that part of the data collection and analysis carried out for this thesis took place during the SARS-CoV-2 (Covid-19) epidemic [14].

In this first chapter, I present the state of the art of the main concepts related to the use of emergent technologies used to support the assistance provided to critically ill patients and the main objectives of this thesis. The goals of Chapter 1 are:

- To provide an understanding of what an AmI environment is and how it is used in an ICU setting.
- To introduce the infrastructure, installations and equipment used in the Smart ICU.
- To present the connection between the virtual and physical elements in the Smart ICU.
- To describe the profile of a critically ill patient and the strategies used to improve patient safety.
- To detail the main objectives of the thesis as well as the methodology I use.

1.1. The Paradigm of the Ambient Intelligence Environment

The new paradigm of AmI emerged in the context of technological development in the late 1990's in the United States of America [15]. In 1991, when sophisticated personal computers and electronic devices with miniaturized sensors were being mass produced, Marc Weiser published the study "The Computer for the 21st Century", which had a great impact on our understanding of the evolution of technology up to that time [16]. In his study, Weiser defines the concept of *ubiquitous computing*, which preceded the concept of AmI and became one of its main characteristics. Ubiquitous computing is defined as a technology that is embedded in everyday objects and is invisible to users [17]. Such technology is programmed to self-activate in order to anticipate user needs and to move from the background to the foreground of the physical infrastructure only when necessary. The concept of ubiquitous computing also refers to the importance of knowing the location and identification of users and objects in order to have context awareness and to take decisions [18][19].

The idea of ubiquitous computing has become better understood and more widespread since the development of the wireless sensor network (WSN), which is used to monitor different ambient conditions such as temperature, humidity, pressure, lightning conditions, the presence of chemicals, or the mechanical characteristics of objects, among others [20][21]. WSN technology uses a network

architecture that is cable of sensing physical parameters, collecting data from different sensors, establishing communication between them, processing data and providing feedback for users. Different commercial applications are on the market and provide automation of homes, buildings, or industrial spaces; smart devices which have this capability are called Internet of Things (IoT) devices [22].

In addition, the techniques used in artificial intelligence (AI) began to be used to analyse the large amount of data produced by IoT devices, in order to provide task scheduling, security, optimal deployment, and the location of objects and people [23]–[25]. AI techniques—such as neural networks, fuzzy logic, evolutionary algorithms, swarm intelligence, artificial immune systems and reinforcement learning—were capable of providing the capacity of decision and autonomy to IoT devices when facing event detection, without the need for human intervention. Useful information for users, which is the result of these processes, is displayed on interfaces — mobile screens — which allow communication to be established between humans, as well as between humans and the machines, in a very simple way [25]. These interfaces are personalized to meet user needs and are equipped with media and entertainment resources in order to attract the attention of users. Currently, communication is via keyboards, cameras and different support elements [26].

As a result, AmI is a mixed discipline composed of different branches of computer science, as represented in Figure 1. Philips Research coined the term AmI in 1998 [27], [28]. In 1999, Philips participated in an international consortium of industrial partners, named the Oxygen Alliance, to develop new ambient technologies for the coming century. In that same year, the European Commission's Information Society and Technology Advisory Group (ISTAG) adopted the term AmI. From that point on, the concept, and applications of AmI have been expanding in all countries.

1.1.1. Definition of Ambient Intelligence Environment

According to Philips Research [27] the term *AmI* environment is defined as:

"A digital environment that supports people in their daily lives in a nonintrusive way".

An AmI environment is thus a space composed of a set of technological elements that are not visible to users, which creates a proactive environment and generates intelligent responses. When people interact with an AmI environment, they intuitively use the technologies according to their own needs and gain increased awareness of their actions. This improves people's quality of life and

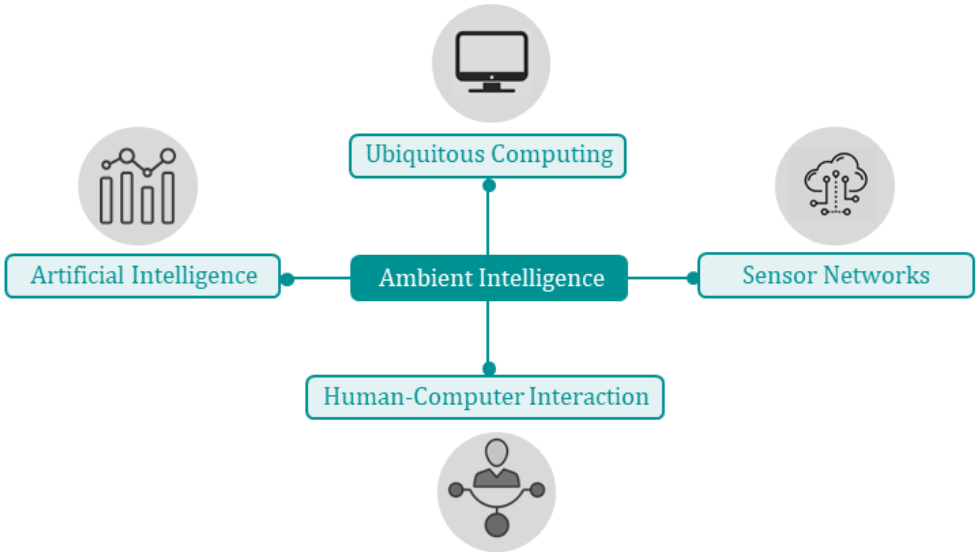


Figure 1. The term AmI is the result of the fusion of four branches of computer science: ubiquitous computing, sensor networks, artificial intelligence, and human-computer interaction.

comfort, and empowers the users [28], [29]. The idea is to place a digital environment inside a physical environment as naturally as possible. The AmI environment also proposes the use of social intelligence, in addition to AmI in order to offer more advanced ways of communicating using the voice, gestures, movements, facial recognition and habits, among other possibilities. The main features of the AmI environment [19], [20] are presented in Table 1.

1.1.2. Applications of Ambient Intelligence

The AmI environments are being developed in different spheres of society (Figure 2). Some examples of applications of AmI systems are presented below. Through smart screen interfaces it is possible to check services based in AmI technologies and receive feedback about all the "things" we need.

1.1.2.1. Smart Home

Smart homes are built with the aim of improving the living experience and providing awareness of the household [30]–[32]. Information and communication technology (ICT) devices and systems are distributed throughout different areas of the home, providing more comfort, security, and efficiency for users. These systems can be remotely controlled and can manage many devices including temperature via HVAC (heating, ventilation, and air conditioning), lighting, energy and water consumption, alarm systems, speakers, voice assistants and intelligent home appliances. Users can access different home functionalities and visual charts using

Characteristic	Description
Sensitive	The environment can detect the presence of people and objects. Objects include physical infrastructures, installations, devices and furniture. It can recover measurements taken by the sensors.
Responsive	The environment can act in response to daily activities and users' needs.
Adaptive	The environment can adapt in order to match user preferences, habits and behaviour. It can adapt itself based on the role of people and the situational context: the concept of *situation awareness*.
Ubiquitous	The AmI elements are everywhere and are embedded in everyday elements of the environment.
Intelligent	The environment can recognize people and objects, it can also analyse and predict them as well as being able to take decisions based on AI algorithms.
Social	The environment can adapt its responses according to social conventions as well to as the physiological state, emotions and behaviour of the users. The environment must also consider cultural diversity and the moral values of users, and the relationship between them.

Table 1. List of the main characteristics of an AmI environment and their respective descriptions.

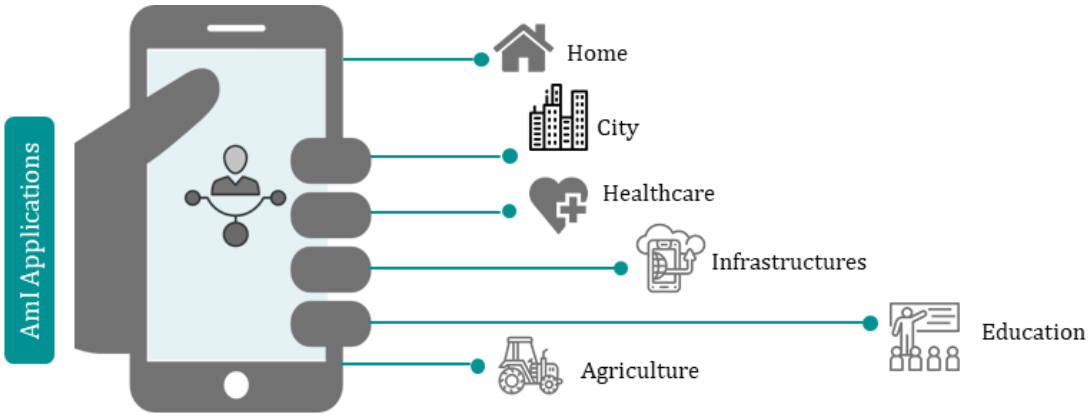


Figure 2. AmI applications in the home, the city, healthcare, infrastructures, education, and agriculture.

interactive displays integrated seamlessly into the environment. In addition, the displays can also show personal reminders and suggestions for energy saving based on the detection of patterns of the daily activities of those who live in a smart home. The use of such displays will help users change bad habits, make better decisions and gain self-confidence.

For specific users — such as the elderly [33], people with mental illness [34] or chronic diseases (diabetes [35], pulmonary diseases [36]), as well as disabled people [37] — ambient assisted living (AAL) systems [38] are being constructed to monitor their activity, supervise rehabilitation processes, or warn of risk situations, as well as detecting and notifying police, doctors and firelighters of adverse incidents in homes.

1.1.2.2. Smart City

Smart cities are being built in urban environments with the objective of providing users with real-time contextual information [26], [27]. In order to achieve this, it is necessary to deploy a massive number of infrastructure elements, including a variety of ICTs and wireless sensor networks (WSNs) [39]. The sensors should enable the geolocation of objects and their intelligent control remotely. Transportation and environmental monitoring are two of the many scenarios in which research centres and industry are investing the most effort.

In the field of transportation, mobility can be improved through the use of sensors which form part of an intelligent transport system (ITS) [29]. Such systems can predict traffic, manage available parking spaces, automatically detect incidents and guide autonomous and interconnected vehicles. For citizens, an ITS will be able to indicate the best route to choose, according to the flow of people and vehicles in real time. Meanwhile, unmanned aerial vehicles (UAVs) [40]—commonly known as drones—can also be managed by an ITS and can be useful in emergency situations, such as traffic accidents and incidents of cardiorespiratory arrest.

In the field of environmental monitoring, different sensors are used to monitor the quality, temperature and humidity of the air; water and energy consumption; urban noise [34]; and gas emissions [31]. In addition, sensors can be installed in trash containers in order to indicate when they are full and to detect potential landfill toxicity. Drones are also being extensively used to carry out environmental monitoring in cities. The current challenge in the construction of smart cities is the analysis of the massive volume of data generated by sensor networks [32]. The data recovered by the sensors is heterogeneous and needs to be processed quickly by an

intelligent system for it to be effective in the detection of adverse environmental events or catastrophes.

1.1.2.3. Smart Healthcare

Smart healthcare applications are being developed with the aim of improving patient safety and quality of life, as well as clinical environments [33], [34]. A major part of these developments can be divided into two important types of applications: those which affect patients directly, and those which affect clinical environments used by both patients and professionals.

Small sensors can be placed directly on the body surface of patients, or they can be attached to clothing or implanted under the skin [35]–[37]. The development of a set of miniaturized biomedical sensors gave rise to the so-called Body Area Networks (BANs). BANs can continuously monitor vital signs such as heartbeat, body temperature, blood oxygen saturation, respiratory frequency, blood pressure, and physical activity, among others. Once the body sensors have remotely streamed the data to a server located in a hospital or to a medical device, the data will be processed using intelligent algorithms in order to detect abnormal events which can indicate an abrupt change in the health status of patients (such as the onset of an epileptic episode, or a psychiatric or cardiorespiratory crisis). For example, DemaWare2 [41] is an ambient assisted living system designed to support the care of people with dementia, which integrates sensors, multimedia and semantic analysis. It was deployed in two different settings. First, a laboratory trial was designed to clinically assess patients through AmI technologies. Second, a home scenario was developed for long-term monitoring of the daily activities of patients, such as sleeping, cooking and watching TV. Another example of an AmI system is EM-Psychiatry [42], whose creators propose a psychiatric home care service via which patient data are continuously analysed using biosensors to detect psychiatric emergencies; it is modelled using the discriminative maximum-entropy Markov model.

Personalized interfaces can be developed to combine environmental control of a room (such as control of lights, blinds, door and window polarization, temperature via HVAC, volume levels, TV, cameras and presence control) with patient monitoring (vital signs, scheduled health tasks, medical prescriptions and reminders, as well as the latest diagnostic tests) [38], [41]. Moreover, the environment can be provided with WSNs and a real-time location system (RTLS) based on radiofrequency identification (RFID) technology to detect the presence and activity of visitors, including healthcare professionals and relatives [38]. In each case, interfaces can display information adapted to the personal profile of the different person present (doctor, nurse, assistant, family member, physiotherapist,

technician, etc.) and the situational context (visiting time, patient hygiene, introduction of an invasive device, medical information and so on).

1.1.2.4. Smart Infrastructures

Smart infrastructures are being constructed in order to facilitate the monitoring and maintenance of critical infrastructure through the development of intelligent hardware and software [43]–[45]. For example, many companies are using low cost WSNs to control the construction and maintenance of bridges and highways.

Meanwhile, the development of intrinsic self-sensing concrete (ISSC) will enable smart infrastructures (buildings, nuclear power stations and bridges, for example) to be built more safety and with better durability. ISSC is a type of material that can monitor its own characteristics—such as stress, strain, cracking, and other types of damage—by measuring its own electrical resistance without using sensors. In addition, new AmI technologies are being developed to help generate completely renewable energy [44].

Many applications are also being developed in the context of information management. Complex structures—such as hospitals, research centres, factories and commercial buildings—have complex nonstop (24/7) working facilities (such as mechanical, electrical and plumbing systems) and need applications which can help managers to detect incidents and take decisions quickly in order to avoid catastrophic consequences.

The most advanced software uses intuitive interfaces which allow managers to control different facilities remotely at the same time and also provide augmented reality (AR) [45]. AR enables visualization of different infrastructures in a virtual layer over the real installation design in three dimensions and thereby aids in rapid identification and location of possible failure points.

1.1.2.5. Smart Education

In the field of smart education, AmI technologies are being used to improve the teaching-learning of the new generation of “millennial” students [46]–[48]: how teachers teach and the educational environment in which this takes place. These improvements will occur through implementation and daily use of intelligent devices—such as touch-sensitive screens, virtual assistants, video cameras, microphones, head speakers, social robots, computers and tablets—in a physical classroom, in order to strengthen collaborative learning, teamwork and knowledge

transfer. The new classrooms will have digital panels which can connect to students online who can then participate of class activities in addition to having virtual space for holding conversations, making notes and working in a team. The role of teachers and students will change with the increased implementation of online courses and with new trends in educational trainings. Teachers will become coaches who help students in their field of expertise to learn by themselves through the execution of different tasks.

Traditional university lectures will disappear and will be substituted by interactive learning platforms. In this way, students will become more autonomous and responsible for organizing their own study. The range of subjects on offer will tend to become more multidisciplinary and adapted to the cognitive capabilities of each student. Furthermore, more frequent gamification [49], [50] will increase student awareness of the learning process, improve their capabilities (oral and verbal communication, time management, task prioritization, etc.) and their participation in classes.

1.1.2.6. Smart Agriculture

Smart agriculture is expanding in order to achieving overproduction of food so as to be able to feed the global population in a cost-effective way [50], [51]. AmI technologies are also being developed in the field of agriculture to minimize the impact of climate change and water crises on crops, cattle, dairy farming, and fisheries, among other type of agricultural exploitation [52]. A large variety of devices use a set of sensors, controllers, drones, RFID systems and GPS (Global Positioning System) technology in order to capture and process data from the environment, such as temperature, rainfall, and soil moisture content, conductivity or acidity, as well as ambient light conditions, quality of air and water, and plant luminosity. Different environments (such as greenhouses, gardens, and cattle ranches) are using such devices; their use enables data analytics to manage many activities such as: optimal watering schedules to improve the health, quality and traceability of crops; the prediction of microclimatic conditions or the risk of insect intrusion, and when it is necessary execute pest control measures. Moreover, automated fertilizer applicators are rapidly being developed in order to apply the optimal quantity and spread pattern of fertilizer and estimate the levels of nitrogen, phosphorus and potassium in the yield. In the field of viticulture, WSNs are used to control heat summation and potential frost damage: two important parameters in wine production.

Farmers can monitor all the ambient parameters and track animals through web-based applications on a smartphone and can receive personalized recommendations and alerts about the status of soils, plants, and animals. Animal

and pasture monitoring can help control of individual animal and herd behaviour, such as sleeping, grazing, ruminating, and patterns of mobility.

1.2. The Emergence of New Digital Tools to Support the Smart Intensive Care Unit

The intensive care unit (ICU) is a specialized area of tertiary hospitals that provides support for severely ill patients with dysfunctional organs and with a high risk of death or permanent disability [53]. In this environment, there is a high level of technology and a highly qualified multidisciplinary team at work, as illustrated in Figure 3. The goal of doctors and nurses who work in ICUs is to avoid patient deterioration while they receive the treatment indicated for their diseases. Increasingly, team members are prepared to take decisions rapidly in emergency and disasters situations and they also have the skills necessary to carry out a continuous process of improvement of the quality of patient care through active research and educational training.

The term "smart hospitals" was defined by the European Union Agency for Network and Information Security [54] thus:

"A smart hospital is a hospital that relies on optimized and automated processes built on an ICT (Information and Communication Technology) environment of interconnected assets, particularly based on IoT, to improve existing patient care procedures and introduce new capabilities."

An ICU is one of the departments in a hospital where most medical and non-medical devices are connected to the hospital network 24 hours per day, and a **smart ICU** could be defined in a way similar to the definition of a smart hospital. The trend is for the devices in a hospital to become autonomous, ubiquitous and interconnected, thereby providing interoperability between them [55].

The data generated by the devices can be integrated within an electronic health record (EHR) using middleware applications, and they can be supported via smart displays and real-time intelligent monitors [56]. Such a system can analyse the data, interpret them and notify staff of the latest test results, in addition to automatically identifying patients at risk of deterioration, generating alerts for medical staff, and providing support for clinical decisions [55], [57], [58]. Furthermore, the electronic systems installed in the smart ICU should decrease the time spent daily by healthcare staff recording data in the EHR and facilitate the tracking of medical care activities.

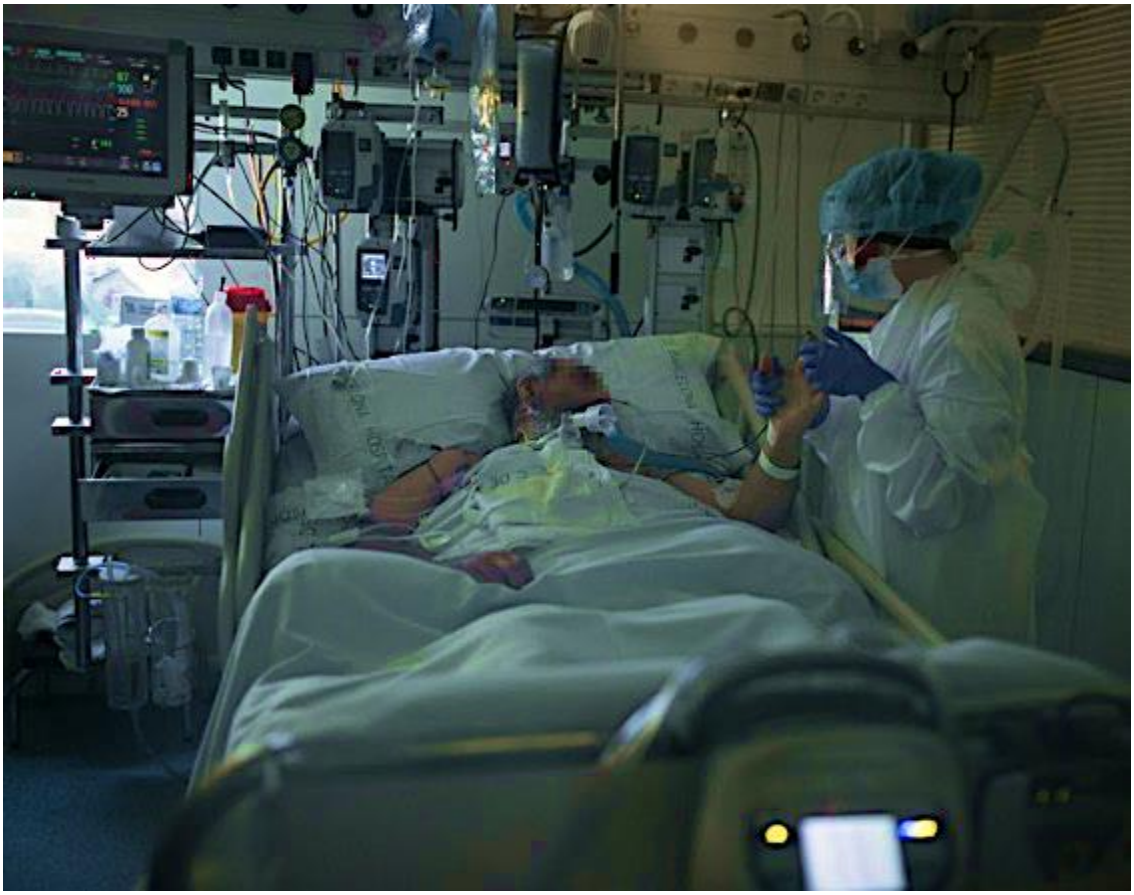


Figure 3. A critical patient surrounded by the human and material resources of one of the ICUs at HCB [70].

1.2.1. Infrastructures and Facilities in Intensive Care Unit

The goal of the construction of new or renovated ICUs is to obtain a safe healing environment in accordance with current design guidelines [2], [59] [59], [60], [61], [62]. In the last few years, it has been demonstrated that the physical environment patients are in affects their physiology, their psychology, and the related social behaviour. This design process is known as *evidence-based architecture* [63]–[65]. It involves the creation of a healing environment which includes materials and finishes that reduce noise levels, while minimizing workplace injuries and stress through the incorporation of natural light. These aspects also help to reduce medical errors, together with other actions that use the best evidence from current research and the practice of critical decision-making [66], [67].

The ICU design has evolved with changing patient demographics and disease patterns. In addition, increasing life expectancy brings about a permanent need to reduce the hospital stay of a patient, to optimize resources and organize the flow of information in order to attend to all the demand.

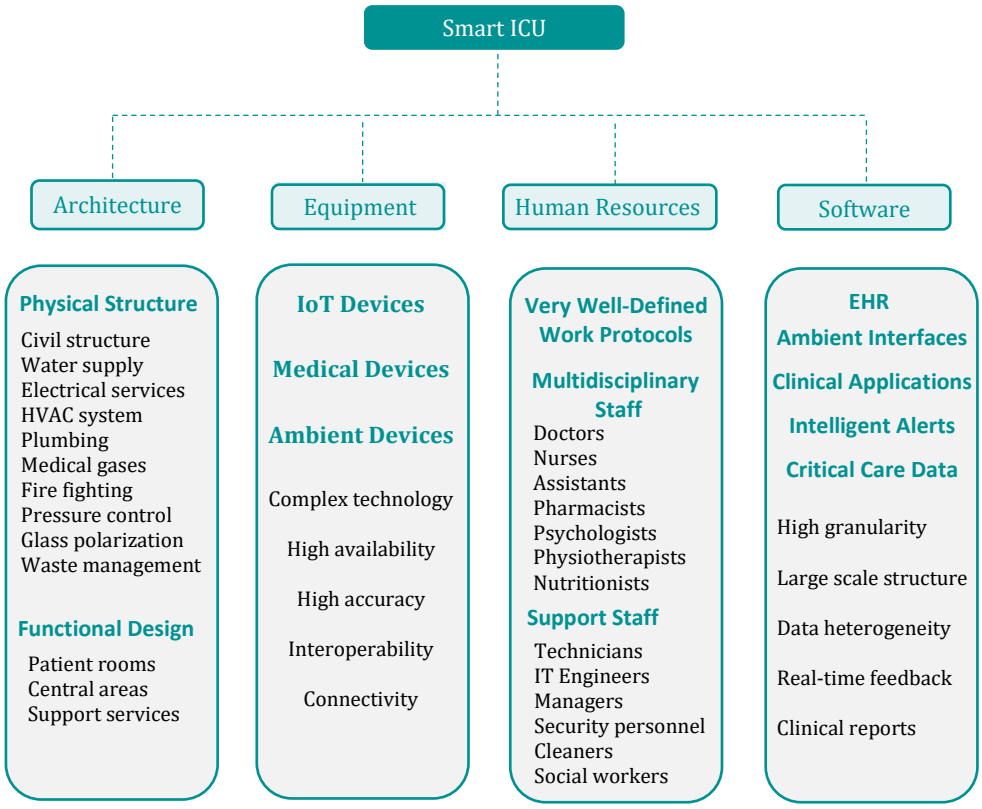


Figure 4. Description of ICU requirements to guarantee a safer healthcare for the patient.

The creation of clinical and technical guidelines that quantify the desirable and minimal resources needed to guarantee a more efficient, more effective and safer environment for the patient [59], [68] (Figure 4) is a priority in the most advanced ICUs. These requirements are related to those needed of the architecture, equipment and human resources. New ICUs present robust wired and wireless infrastructure, as well as a large number of network adaptors that are capable of connecting smart devices and RTLS hardware [69]. In the most advanced ICUs, it can be observed that all staff as well as patients and devices use an RFID tag that provides their identification and location. Moreover, the ICU should be near an imaging department, laboratories, a post-anaesthesia care unit, an emergency department, and operating rooms. Moreover, the transport of patients, staff, visitors, waste and equipment should be coordinated to maximize the efficiency of the workflow[70], [71].

Finally, ICUs can be dedicated to a single area (such as cardiac, hepatic, surgical, coronary, or respiratory ICUs) or polyvalent. In a polyvalent ICU, patient profiles are highly heterogeneous, and the patient has a set of acute clinical complications; while in the dedicated ICU, the profile of the patients is more strictly defined, and the patient has a specific type of disease, such as respiratory failure, pneumonia, trauma, or acute myocardial infarction.

1.2.2. Morphological Evolution of Infrastructures, Installations and Equipment in ICUs

During the Crimean War, in 1854, the nurse Florence Nightingale and her nursing team created a specific space to give treatment to the sickest soldiers; this was precursor of the creation of the first ICU in 1953, in Denmark. Within a decade of the first ICU opening, more units were implemented in hospitals around the world and intensive care became distinguished and recognized as a medical specialty due to its specific characteristics [72], [73].

In California, systems of ventilation were designed to serve critical patients with acute respiratory insufficiency. In Copenhagen, Dr. Bjorn applied manual methods of positive pressure ventilation by recruiting medical students who used bag ventilation for the victims of the worldwide poliomyelitis epidemics. In 1958, Dr. Weil and Dr. Shubin opened a four-bed "shock ward" in Los Angeles to improve the recognition and treatment of serious complications in critically ill patients [74], [75]. That same year, Dr. Safar opened a multidisciplinary ICU at Baltimore and introduced for the first time the term "intensive care unit". Over the following decade, ICUs were created in hospitals across Europe, the USA, and Australasia. In Spain, the first ICU was established in 1969 in Madrid, thanks to the initiative of Dr. Jimenez [76], [77].

From the end of the 1960's until now, the definition, functionality and design of the ICU have evolved to embrace the development of new technologies that give support to failing organ systems—such as the lungs, the cardiovascular system, or the kidneys—and provide for them to be monitored. These innovations include vital signs and neurological monitors, mechanical ventilators, haemodialysis machines, intravascular catheters and electronic pumps, as well as technology to prevent the spread of infections and to increase awareness of patient needs. In this evolution, new healthcare worker (HCW) profiles — such as respiratory therapists, physiotherapists, pharmacists or nutritionists — have been incorporated to give clinical support in the daily tasks of the ICU, making it more multidisciplinary [78], [79]. The space occupied by patients has also changed considerably due to the scientific advances in medicine and engineering. Firstly, the monitoring of infrastructures and central services (electricity, medical gases, lighting and HVAC systems: heating, ventilation and air conditioning) has been improved by using middleware and intelligent systems that allow for constant control of environmental variables [80], [81].

In the first decades of the development of the ICU, oxygen and vacuum pipes as well as new electrical plugins were introduced and then improved through their installation in the walls of the ICU building, with outlets at the head of each bed space. In addition to these elements, desks, telephone, chart space, and an alarm

Figure 5. Example of a hospitalization room at HCB from 1906 (top) and an ICU patient room built in 2013 (bottom) [82].

button were also added. Furthermore, infusion pumps with the capacity to infuse different quantities of fluids, medication, or nutrients into a patient's circulatory system have been installed. Figure 5 shows an example of an old hospitalization unit built in 1906 at HCB, and an example of a current patient room in the ICU at HCB, built in 2013, with the most advanced devices on the market.

The first ICUs followed an open design with some kind of slight separation between the beds in order to guarantee maximum accessibility from the nursing station [83]. Generally, the barriers used were textile curtains that allowed the transmission of nosocomial infections and everyday practice verified that they limited the movement of the personnel and equipment while reducing access to the patient in the case of an emergency. This disposition was suitable when the patient

was heavily sedated for a few hours and privacy was not an important factor in the design of the space. However, when the patient had to stay for a long time due to health complications, this model did not offer the best conditions for recuperation.

Since the late seventies, a closed design of the units has been developed with individual rooms that are observed visually from the nursing station desk through glass panels with venetian blinds on the inside and a video camera system. These patient rooms allow better attention to be paid to critical patients with appropriate privacy conditions, including acoustic insulation and bacteriological and pathogen protection. An example of an open hospitalization unit and a closed ICU at HCB can be seen in Figure 6. In addition, this design offers more control of the environmental conditions in the room of each individual patient—like temperature, pressure and humidity—and personalizes care for each patient [84]. In other words, this type of distribution of resources decreases the probability that the instruments and medication of one patient are improperly used on another patient and decreases the possibility that the staff attend patients in inadequate sanitary conditions. The choice between these two types of design depends on the architectural plan of the hospital—which can follow a "cross" model, a pavilion model or a mono-block model—and the space available for the construction or renovation of ICUs [60] . Nevertheless, there are common areas shared by these two types of design.

Three clearly differentiated elements in ICUs—patient rooms, central areas and universal support services [59]—can be differentiated and together constitute an ecosystem, as can be observed in Figure 7. The central areas consist of the nursing stations, corridors, supply rooms, equipment rooms, pharmacy, laboratory, staff lounge, visitor waiting room, conference rooms, social-work office, family office, medical office, nursing office, administrative office and research office. The universal support services include infection prevention, finishings and flooring, staff communications, signage and route indicators, security, fire prevention, and safety. The patient room is the main zone of an ICU and is divided into three dynamic areas: patient area, nursing area and family area. The patient area contains invasive and non-invasive devices used to monitor patient heath status. The health status of critically ill patients can change abruptly, and these devices should emit audible alarms and alerts to warn HCWs [85]. In the nursing zone there is a dispenser of an alcoholic solution, water taps and a work area for the preparation of medication, laboratory tests, treatments and bandages. There is a cabinet containing medical supplies used in everyday healthcare. In the lower part of the nursing cabinet there is a special tube used to connect to the residual fluids of the haemodialysis machine. Physiotherapists also use this table to organize their support devices.

Figure 6. Example of an open and a closed unit: top, a hospitalization ward at HCB; bottom, the closed surgical ICU at HCB [86].

The family zone is a space reserved to receive family members and visitors. It contains chairs and it is recommended to have a room near the unit where family members can rest in case they need to stay overnight [87], [88]. The objective is to involve the family in the healthcare process, given that they can provide emotional support, improve the quality of life of patients and consequently can decrease the length of stay in ICUs.

1.2.3. Electronic Health Record and its Interoperability in Intensive Care

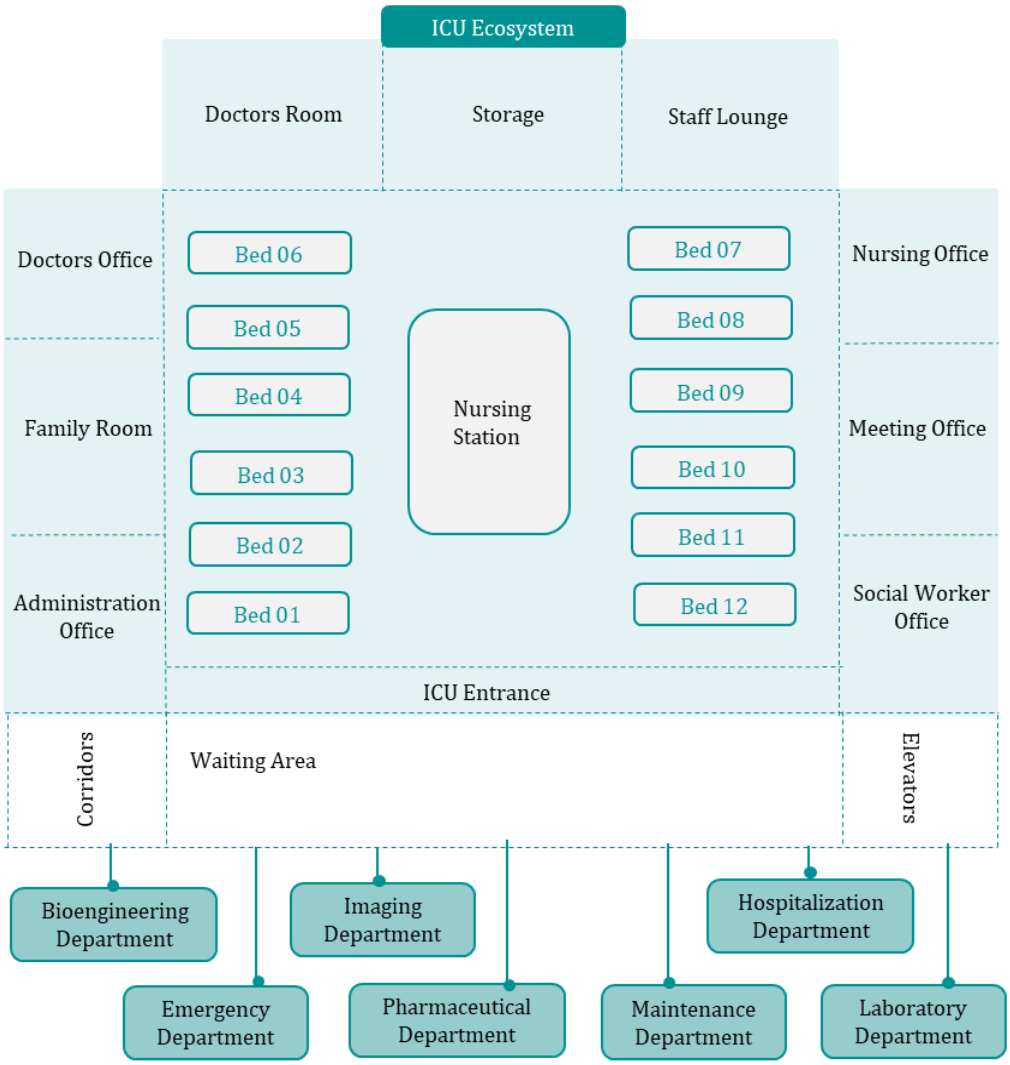


Figure 7. Example of an ICU ecosystem based on the department distribution at HCB.

An electronic health record (EHR), also called a hospital information system (HIS), is a computer system that recovers, processes and charts data from different sources — such as from patients, healthcare staff, or medical and non-medical devices — and presents them in a clinical practice [89]–[91]. The EHR is a complex and expensive element in ICUs that needs continuous collaboration from professionals in the hospital IT department, the quality department, infrastructures department, and maintenance department, as well as healthcare staff and technological providers. Coordinated work is necessary from all these people to guarantee the success of the implementation of the system and new features over time [92]–[94]. The most advanced EHRs incorporate many branches of artificial intelligence to transform data into useful clinical information and to improve the quality of care. For example, advanced systems can search for data patterns and can generate notifications of clinical suggestions, alerts and predictions to healthcare staff.

Another example is the use of processed data to generate calculated parameters in real time, such as the calculation of a severity of illness score (e.g. the Acute Physiology and Chronic Health Evaluation (APACHE) [95]–[97], the Sequential Organ Failure Assessment score (SOFA) [98]–[101]) or an early warning system (EWS) [102]–[111]. Moreover, EHRs incorporate intermediate telemedicine platforms that automatically capture data from medical devices and transmit them remotely to EHR interfaces [112]. The concept of intercommunication between different devices is called interoperability: a term which has many definitions in the field of healthcare.

The Institute of Electrical and Electronics Engineers (IEEE) defines interoperability as [113]:

"The ability of two or more systems or components to exchange information and use the information that has been exchanged".

This definition implies that the data generated by one device should be detected and understood by other devices and servers connected to the network. Interoperability means that data are not limited only to being transferred, but they can also be understood by other devices and by people. The major problem for interoperability in healthcare systems is that each provider of medical devices has its own communication protocol and works in a specific programming language. To solve this problem, Drager® has developed a new interoperability standard protocol for hospitals [114] which it launched in 2018. The protocol is called Service-oriented Device Connectivity (SDC) and is part of the IEEE 11073 Standard [115]–[117]. SDC can establish two-way communication between medical devices with end-to-end encryption; in this way, one device can transmit and receive information at the same time in a safe way and without a loss of data quality. Finally, the SDC protocol can also establish data transmission from medical devices to the EHR without the use of intermediate telemedicine platforms.

Interoperability is divided into many layers, due to the complexity of its implementation. The two most important layers are technical and semantic interoperability. In technical interoperability, there is a communication protocol between systems that enables data exchange. The most common standard of communications used in healthcare is Health Level Seven (HL7). In addition to the HL7 standard, many devices support complementary technologies (such as Service-Oriented Architecture (SOA), REST (Representational State Transfer) or Multi-Agent Systems (MAS)), proprietary web service interfaces and Extensible Markup Language (XML) in order to optimize integration with EHRs. In the same way, in the field of medical imaging, Digital Imaging and Communications in Medicine (DICOM) is the standard most commonly used to exchange medical images and the related information. Recently, the standard HL7 has incorporated a new standard of

communication named Fast Healthcare Interoperability Resources (FHIR), given the technical limitations of programming of past versions of HL7 [118], [119]. This new standard enables a two-way exchange of medical data between the EMR and third-part applications, which distribute it to different mobile devices (computers, smartphones and tablets).

In semantic interoperability, data can be integrated into other systems and can be interpretable without the need for human intervention and without ambiguity through the use of standard terminologies [120]. The Systematized Nomenclature of Medicine-Clinical Terminology (SNOMED-CT) is the standard for representing clinical information that is most commonly used in clinical environments and it provides more interoperability in clinical environments given that it enables the unification of medical terminology in EHRs, thereby improving healthcare delivery [121]–[123]. SNOMED is mainly used to store, retrieve, and aggregate clinical data in EMRs. Another standard of semantic interoperability that is very commonly used is the International Classification of Diseases, version 10 (ICD-10), which is used to classify and codify diseases for statistical purposes and reimbursement, as well as to compare them between different countries. The classified data allows us to access the profiles of patients hospitalized in different institutions as well as to know rates of mortality and the most commons comorbidities in each region.

1.3. Critically ill patients and the mechanisms that guarantee their safety

After examining the evolution of the physical environment of ICUs, I will now present the characteristics that define the critical patient in order to understand the problems that the medical and nursing personnel have to face every day. Two types of patients are likely to benefit from admission to an ICU [124], [125]. Patients who require monitoring and treatment because their vital functions are threatened and also those who have already suffered vital function failure for different reasons (an acute disease, due to the effects of surgical or other intensive treatment leading to life-threatening conditions, for example) can be admitted to an ICU. Moreover, there are some especial cases in which patients are admitted to ICUs, such as expected brain death and subsequent organ donation, or the need for palliative care at the end of life. The most common characteristics that critically ill patients share are the need for continuous advanced vital signs monitoring, the high complexity and instability of their diseases, as well as the capacity for potential vital function recovery.

The European Society of Intensive Care Medicine (ESICM) defines three levels of care (LOCs) to distinguish the level of severity of ICU patients:

- Level of care I (lowest) indicates patients with signs of organ dysfunction and with high risk of developing single or multiple acute vital organ failures. These patients are unstable and needs continuous monitoring as well as minor pharmacological or device-related support.

- Level of care II indicates patients with only one acute vital organ failure, and they need pharmacological and/or device-related support.

- Level of care III (highest) indicates patients with multiple acute vital organ failures, and they depend on pharmacological as well as device-related organ support [126].

This classification of the severity of illness enables the health conditions of patients to be followed and managed properly, providing the necessary bedside resources in each case. The most common diseases managed by HCWs in ICUs are cardiac, respiratory, and neurological conditions. The prevalence of diseases and therapies over a period of ten years in one cardiac ICU is shown in [127].

With the emergence of Covid-19, respiratory diseases increased exponentially and currently are the most common type of disease [10], [14], [128], [129]. Around 5% of people who have acquired this disease need an ICU bed and suffer acute respiratory distress syndrome (ARDS) [130], [131]. In this new scenario, the patients need to be admitted to isolation rooms and the clinical protocols for prevention of the spread of infection must be rigorously applied for all HCWs and patients. In all cases, the physicians use a specific clinical examination sequence (the airway, breathing, circulation, disability and exposure (ABCDE) approach) at the bedside in order to assess patient health status. This clinical protocol considers the evaluation of the vital signs and treatment prescribed regularly to establish if patients present signs of deterioration or if their clinical status will improve.

1.3.1. Definition of Patient Safety

The term *patient safety* (PS) has been defined by numerous health organizations since 2002. This term was broadly conceptualized in many studies of different healthcare disciplines — such as medicine, nursing, pharmacology, clinical laboratory practice, occupational therapy and physical therapy — but it is not clear how this term can be measured and related to other situations [132], [133]. Empirical referents to measure PS are being developed by many researchers.

The World Health Organization (WHO) currently defines PS as [3]:

"Patient Safety is the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment. Every point in the process of caregiving contains a certain degree of inherent unsafety."

The main goals of PS are i) to prevent medical errors and avoidable adverse events, ii) to protect patients from harm or injury, iii) to improve collaborative efforts of HCWs, and finally, iv) to improve healthcare systems and the use of technologies. In all previous studies, PS is defined as a process in which HCWs should identify and apply preventable strategies to protect patients from harm. In all the steps of this process, HCWs should be trained with the competences, skills, knowledge and attitudes necessary to minimize the risks and progression of avoidable events [134]–[136].

The main outcome indicators of PS in hospitals are the mean length of stay (LOS) of patients, the mean mortality rate, percentage of ICU patients with ICU stays longer than 7 days, the mean number of days on mechanical ventilation, mean readmission after less than 72 hours and family satisfaction. The clinical team has to promote an environment of trust in order to discuss openly the possible causes of unsafe practices and the risks of adverse events in a transparent way without fear that they will be penalized or that they may lose their jobs [137].

The capacity for communication, leadership and collaboration of all the members of the clinical team is crucial for the reduction of preventable adverse events given that human factors (such as a high workload and lack of communication) and system factors (such as the lack of integration of EHR, organizational management, infrastructures and resources) are the main types of factors that contribute to preventable adverse events in hospitals [138]. In ICUs, the development of new clinical standards based on the clinical evidence promises to improve PS and the quality of care in daily practice [139]–[141], as well as improving the detection of critical events. For example, Portela et al. [142] used data mining techniques to predict critical blood pressure events in the immediate few hours considering a set of clinical variables collected in real time. The results of the application of their algorithms were very promising with a sensibility of around 95%. Other studies [96], [143], [144] have demonstrated that the application of supervised machine learning techniques—such as an Artificial Neural Network (ANN) and Logistic Regression (LR)—performed better at predicting mortality in critical patients than the static methods currently used, such as all versions of APACHE, the Simplified Acute Severity Score (SAPS) [145], [146], and the Mortality Prediction Model (MPM) [147], [148] and could be transferred to clinical practice.

The prediction of mortality is important in ICUs because it is a very important indicator of quality of care and safety in this environment; the use of new methodologies can provide more accuracy in its calculation [149], [150]. Moreover, many researchers are working on the development of predictive models of management of the diseases that are most common in ICUs, taking into account clinical and non-clinical data [151]. Bhatia et al. [152] propose a framework for monitoring vital and non-vital events in an ICU using environmental and clinical sensors. The data were analysed using the Temporal Associative Granulation technique, and medical alerts were generated if a pre-established data threshold was exceeded. Davoudi et al. use wearable sensors on patients and in the ICU environment to collect data and characterize the health evolution of critically ill patient and the influence of the environment [153],[154]. They found that there are significant differences in data collected between patients with and without delirium. Lins et al. [155] propose an approach to reduce risk for artificially ventilated patients and enhance patient safety using environmental sensors. They use low-cost power sensors, RGB-D sensors and matrix infrared temperature sensors as well as cameras to detect possible critical situations in the ventilation process and generate context-sensitive alerts for nursing staff.

1.3.2. Relevant Practices for Improving Patient Safety in Critical Care

Appropriate preventive plans should be designed in hospitals in order to promote patient safety in the hospital environment [156]. Preparation and use of these plans is mandatory, and monitoring them closely will guarantee the application of best practices in bedside care.

The first step in the design of these plans is the identification of those adverse events that are most frequents and threaten patient safety in hospitals, together with the relevant practices to avoid them. The main causes of these events and the factors that contribute to them which have been reported in developing countries are presented in [157]. Operative adverse events include events which can cause harm to a patient due to the failure or inadequate use of internal procedures, human resources or technology including ICT systems, and from unexpected external events.

To enact the practices necessary to improve patient safety it is necessary to maintain constant communication between HCWs, inter-professional collaboration and a culture of safety in the healthcare environment. It is important that the healthcare team is kept up to date with the most current policies and procedures, and that they receive educational training as well as periodically reviewing the functioning of equipment.

The design of AmI environments in healthcare settings should follow the principles of evidence-based architecture and should be performed by multidisciplinary teams, in which HCWs, IT engineers, other engineering staff, designers, technicians, policy makers and managers can identify and apply strategies to decrease the risk of adverse events in patient care processes. The inputs and outputs in the design of an AmI environment for improving patient safety are described in Figure 8. The AmI environment must provide useful information in the process of clinical decision-making and improve the performance of the clinical team, such as communication between HCWs, workflow and their cognitive skills [158]. To accomplish these requirements, AmI environments have to be precise and finely tuned.

Precise medicine [159]–[161] is an approach that considers the large-scale data related to individuals — such as genetic data, lifestyle data, social data, clinical data and biomarker information — more than the traditional signs and symptoms, in order to identify the best disease prevention and treatment for patients as well as maximizing their effectiveness. Moreover, the application of data security and privacy policies guarantees correct access only for authorized personnel. With the integration of data provided by the use of wearable devices in daily life and clinical data provided by the hospital, it will become possible to know a considerable amount about all the patterns of people's physical and mental behaviour and then to propose individually tailored disease treatment based on advanced analysis of these new biomedical data. The application of this data analysis and the interoperability between the medical and non-medical devices will be essential in building a safer clinical environment. The creation of online educational platforms for HCWs, enriched with multimedia content and serious games, will enable access to information on the most recent advances in clinical procedures and medical knowledge, as well as continuous review of the working of EHRs, devices, clinical algorithms, and employee skills. Periodic educational training, debriefing, and simulation sessions, using this type of platforms in the clinical environment, will also bring more awareness of the best practices used to improve patient safety in daily work.

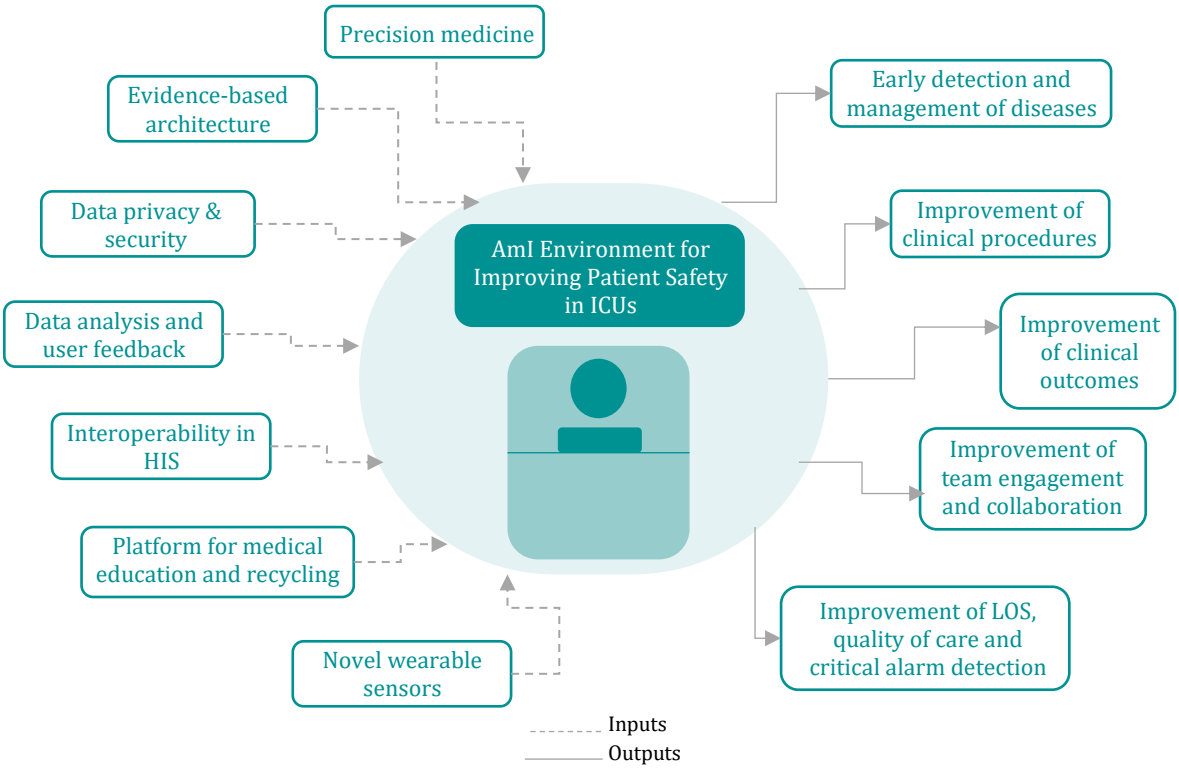


Figure 8. Design of AmI environments for improving patient safety.

In the United States, the Agency for Healthcare Research and Quality (AHRQ) has offered grants to build Patient Safety Learning Laboratory (PSLL) projects since 2002 [162], [163]. In these projects, researchers can propose engineering approaches to improve the detection, management and prevention of clinical practices that may place patients at risk. In critical care, for example, some projects have been funded to improve cognitive and communication processes inside ICUs; to develop a tool to engage patients, families, and professional care team members by reducing patient safety threats; or to study our understanding of the interplay between the factors contributing to diagnostic error or delay in critical care settings.

1.4. Data Management in Critical Care: Daily Practice and Research

After introducing the AmI environment and PS into ICUs, now I will present data management in critical care, in order to clarify how the data generated by a patient and the environment will be treated. In an ICU, a large amount of data is generated each hour by patients. These data are highly heterogeneous and are recovered by different devices and by the EHR [164]–[166]. All these data require a powerful infrastructure to be stored, processed and feed systems for the intuitive visualization of clinical data in real time. Currently, the registry and storage of

clinical data in the ICU is performed hourly and it is therefore difficult to develop intelligent algorithms. All the data generated are processed and useful information is generated to support clinical decisions. Currently, researchers and the healthcare industry are developing key performance indicators of quality of care and models of predictive analysis in order to improve patient outcomes [167].

Many researchers use a cluster of servers with a distributed architecture to process data in an efficient way [168]–[170]. It is often the case that information is sent from medical devices to the EHR automatically. Medical devices, which are connected in patients, generate alarms to keep the patient safe as well as to notify healthcare staff of risk situations and the end of treatments—such as renal replacement therapy or parenteral nutrition. Genomic data, social networks and mobile data will be considered in the treatment of the patients in the future.

1.4.1. Data Analytics and Visualization in Critical Care

The development of advanced analytics applied to healthcare has made patient care more personalized [171], [172] and a new vocabulary has emerged. The massive collection of data has given rise to "big data", which can be defined thus [173]–[175]:

"Big Data is the Information asset characterized by such a High Volume, Velocity and Variety to require specific Technology and Analytical Methods for its transformation into Value."

Big data, statistics and computer engineering are generating new values for intensive care through the application of advanced data analytics. Its volume is characterized by the large quantity of data measured in units ranging from terabytes (10^{12} bytes) to zettabytes (10^{21} bytes). It is also characterized by the fast growth and processing of data to generate real-time responses in different environments. Its variety is characterized by different data formats—such as free text, images, videos, audio, etc.—and it can be structured in different ways—such as Word, pdf, Media Logs, XML (Extensible Markup Language) and JSON (JavaScript Object Notation). Its technologies include IoT devices used to recover data, which require a high storage capacity. Its analytical methods are applied to process data and transform it into useful information. Its value is characterized by implementation of novel useful information to generate economic and social benefits for companies and for society. Figure 9 shows the big data lifecycle used to transform critical care data into useful information for doctors.

One of the main problems in the application of techniques of data analysis in ICU data is the need to pre-process data, which is very costly given that there is a

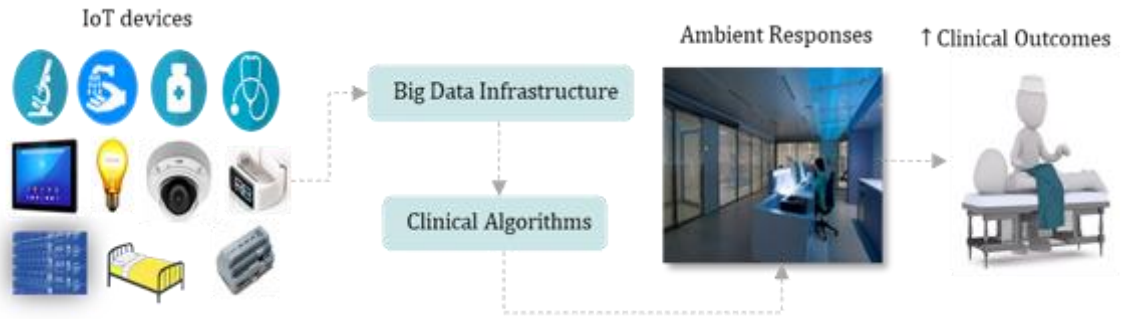


Figure 9. Data lifecycle in intensive care. IoT devices generate data and its data it is saved in a big data infrastructure which has clinical algorithms. These algorithms generate ambient responses which could improve clinical outcomes.

large amount of erroneous data, missing data and imprecise data collected every day [176]. In order to reduce this problem, many methods have been proposed, such as moving average models [177], Bayesian forecasting [178], support vector machines [179], relevance support machines [180], decision trees [181], fuzzy logic [182], and discriminant analysis classifiers [183], [184], among others.

Healthcare staff must visualize a set of clinical data—on paper or electronically—to interpret them and take clinical decision concerning patient health. Currently, medical devices and EHRs are visualized using a large range of displays which are interactive, as presented in Figure 10. These displays present intuitive user interfaces with the aim of reducing the time needed to interpret clinical data and making it easier to identify patient health trends and understand interventions over time [185]–[188].

A set of approaches was designed to visualize multiple organs systems and a diversity of data, which are intercorrelated, such as data related to infectious diseases including the latest microbiology results, antibiotics prescription, temperature trends and reports on potential sources of infection.

At present, studies aim to understand data use in EHR and patterns of navigation performed by workers in order to improve usability and reduce cognitive overload. The unstructured and semi-structured texts in EHRs are being transformed and integrated with other clinical data to build multiple shapes of real-time charts and plots.

1.4.2. Data Quality in Critical Care

Data quality is a challenge in data analytics as it is essential to obtain relevant results. In daily clinical practice and in clinical research, data quality is related with

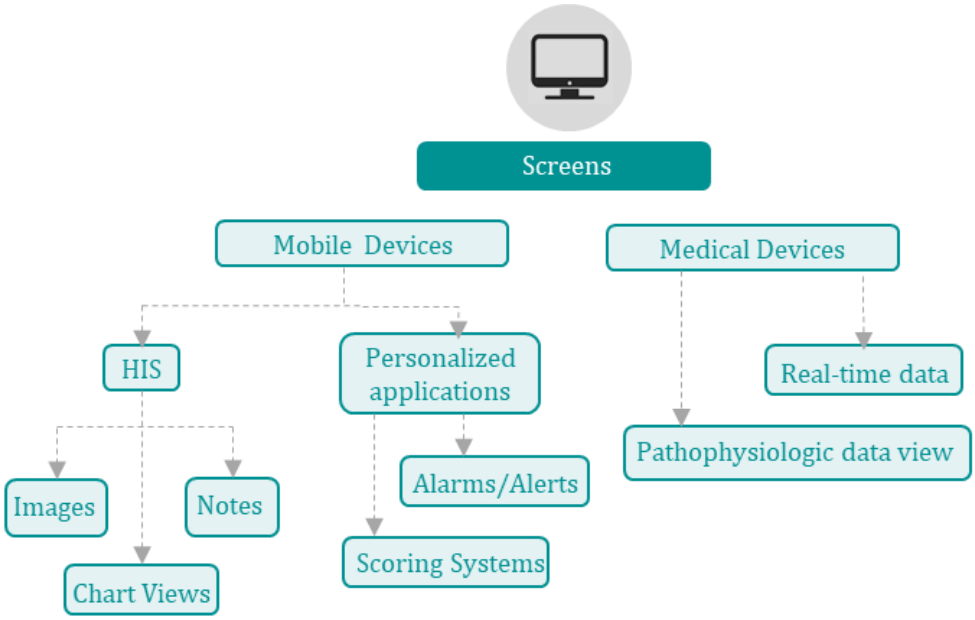


Figure 10. Visualization of medical data using screens. There are two types of screens: mobile devices and in medical devices.

good documentation practices in all steps of the data evolution life cycle: consistent, effective, and efficient data management is necessary throughout data collection. Rigorous data management is a way to ensure correct clinical decisions, conclusions, and recommendations. Moreover, it is also important to identify aberrant data and artefacts in clinical datasets, as well as to understand the reasons why they occur.

Currently, healthcare workers annotate clinical data manual with a high frequency, which can lead to human errors in EHRs. The increasing complexity of EHRs, with a more boxes to fill in (unstructured and structured clinical notes, treatments, and diagnosis) can also contribute human errors, which affect the quality of the data recovered by the EHR and its posterior analysis. The moments at which data quality can be evaluated are shown in Figure 11. Current studies [188], [189] propose the use of automatic tools for extracting clinical variables from a minimum dataset with high data quality, detecting and correcting errors in data collected daily.

1.4.3. Data Privacy and Data Security in Critical Care

In the context of data management, privacy is defined as a set of measures and policies which determine who can view, manage, and recover data. The concerns involving data privacy are related to how data are legally managed, how they can be shared with third parties and what the current regulations are which protect

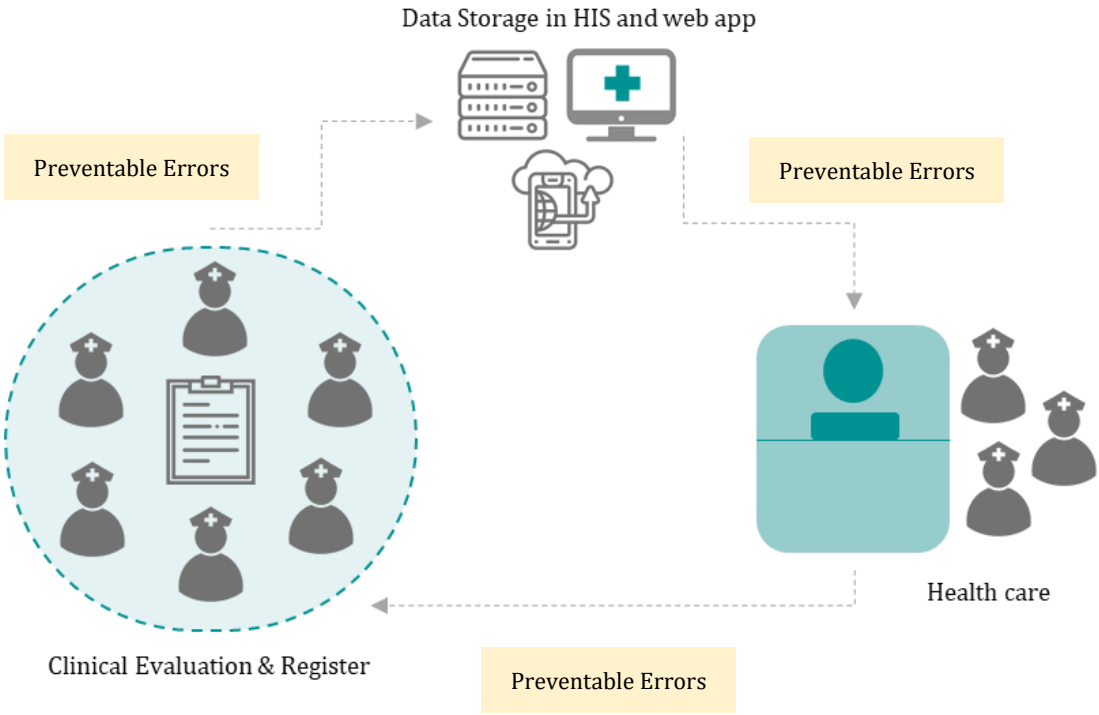


Figure 11. Evaluation of data quality and preventable errors at three different moments of care in an ICU: 1. Moment of delivering healthcare, 2. Moment of clinical evaluation and registry; 3. Moment of data storage in HIS and web apps.

personal data. Different laws concerning data privacy have been established in many countries and the clinical institutions must comply with them.

In Europe, we now have the General Data Protection Regulation (GDPR): the law governing personal data protection and privacy. In the United States, the Health Insurance Portability and Accountability Act (HIPAA) ensures the privacy and security of healthcare data [190]. It is possible to have data security without data privacy, but the inverse situation is not possible. An example of this situation in clinical settings is if you have access to databases used for biomedical research with the personal identification information of patients and with additional information about their health status. In such a case, the database is encrypted previously, and access to it is restricted to a small group of users in a secure network. In addition, a monitoring system to control database access is also implemented.

However, the data in the database used for the research is recent and was obtained without the informed consent of the patients; moreover, the data has not been previously treated to hide the identity of the patients. Some technologies used to preserve the privacy of clinical data are presented in Annex 1 [191]–[193] and many of these methods are used in a combined way. However, if data is not safe are personal identifiers are not removed, for example, malicious people can access it, and depending on the level of data manipulation applied, they can re-identify patients.

In the context of data management, security is defined as a set of measures used to protect sensitive data against unauthorized access. Healthcare institutions should apply security techniques in their data management systems (e.g. EHRs) to prevent security incidents and the access of sensitive information by malicious people.

Hackers can attack systems and create breaches in the EHRs of the world's hospitals, blocking sensitive information and demanding a large ransom (in virtual currencies such as Bitcoin) to return the clinical information. Sensitive information accessed by hackers can include demographic data (national identification numbers, age, sex, and address, among others) and can be used to open bank accounts, to buy drugs to sell on the dark web, to secure loans or to obtain passports. The main techniques used to protect healthcare data are described in Annex 2. In software development it is common to use more than one of these techniques to comply with national data protection laws.

Indeed, it is important that these institutions can provide their workers with educational training on best practices when using confidential information and data security with the same seriousness and obligation as disaster training periodically carried out in hospitals [194], [195]. Hospital staff are vulnerable to attacks through inappropriate behaviour, such as the misuse of passwords, erroneous security settings or responding to phishing (fraudulent) emails.

1.4.4. Data Repositories in Critical Care

Currently, the main intensive care free data repositories oriented towards research are MIMIC-III, eICU Collaborative Research Database, CCHIC and the Danish Intensive Care Database. In all cases the data is de-identified, and privacy is guaranteed to the hospitals ethics committees and national entities specialized in data protection.

- **MIMIC-VI**, acronym for Medical Information Mart for Intensive Care Unit VI, which is the third generation of the MIMIC critical care database developed by researchers at Massachusetts Institute of Technology in the USA [196]–[198]. It is the critical care database most widely recognized and used by researchers. It contains clinical data of forty thousand patients who stayed in critical care units of the Beth Israel Deaconess Medical Center between 2008 and 2019. The data includes vital signs, medication, laboratory results, clinical notes, demographic data, mortality rates, procedures, imaging reports, and waveforms, among other parameters.

- **eICU Collaborative Research Database** is a multicentre database for critical care research [199] developed in collaboration with researchers at Philips Healthcare, Massachusetts Institute of Technology and eICU Research Institute in the USA. It contains data from two hundred thousand patients admitted to intensive care units at different US hospitals between 2014 and 2015. The data also include vital signs, medication, treatment, laboratory results, patient history, admission diagnosis, and administrative data, among others.

- **CCHIC** is the acronym of the Critical Care Health Informatics Collaborative: a multicentre United Kingdom intensive care database developed in collaboration with the UK National Institute of Health and five leading National Health Service (NHS) hospital trusts [200]. It contains data on 18,074 patients admitted to eleven adult ICUs in UK teaching hospitals between 2014 and 2017. An R software open package called *cleanEMR* [201] was created to make these data more accessible, easy to process and useful for the extraction of information. The data include vital signs, laboratory tests, drug administration, demographic data, and diagnostics, among others.

- **The Danish Intensive Care Database** is a database of critical care data developed in collaboration with researchers from the Danish Society for Anaesthesiology and Intensive Care, the Danish Society for Intensive Care and Aarhus University Hospital [110], [202]. It contains clinical data on 335,564 patients admitted to Danish ICUs between 2005 and 2015. Only Danish citizens are included in this database for administrative reasons. The data include demographic parameters, treatments, diagnosis, procedures, quality indicators, and specific ICU admission and discharge parameters, among others.

1.4.5. Data Simulation in Critical Care

In a simulation environment, doctors and nurses can test different scenarios using advanced life support manikins, different devices, and techniques to generate simulated data. Simulation in intensive care is mainly used to recreate clinical situations from daily practice thereby allowing for the improvement of both medical skills — such as clinical procedures and clinical performance under stress — as well as personal skills — such as teamwork, communication, leadership and collaboration [203]–[207]. In fact, caregivers do not only bring their knowledge to actual situations of medical practice but they also bring their cognitive skills, thus allowing them to review their internal behaviours and to be more aware of their actions [208].

The main goal of simulation sessions is to decrease medical errors in ICUs and consequently to generate a positive impact on patient clinical outcomes and patient safety. The main cause of medical errors in ICUs is suboptimal communication between caregivers. This fact has made in evident that it is necessary to carry out regular and effective simulation sessions in hospital installations, engaging caregivers and including the use of equipment that they are expected to use in daily practice, in order to improve their clinical performance. In addition, debriefing sessions with caregivers are recommended in order to analyse the clinical case and the points where a team can improve.

Today, simulation is used in traditional educational institutions in healthcare science degrees in order to teach competences before professional insertion. The next step is to develop simulation applications based on software in which students and active caregivers can simulate risk and crisis situations and can be evaluated continually.

1.4.6. Ethics in Intensive Care Data Management

In a clinical practice, the ICU is the department in which ethical conflicts are highest, more than in general wards and other hospital departments [209]–[213] . The ICU is the place where ethical conflicts frequently occur given that patients are very sick, and the clinical environment is very stressful for both caregivers and families. This environment generates behavioural issues caused by knowledge deficits, poor communication between physicians and nurses, or issues related with the lack of respect of patient autonomy. Such behaviour causes more than a half of medical errors studied in ICUs.

In intensive care research [214], [215], there are more ethical challenges in obtaining patient data in order to carry out studies to improve disease treatments, improve the quality of life and increase the survival of patients, as well as to develop best practices based on clinical evidence. Research projects need to be approved by hospital ethics committees before they start. If clinicians carry out research in an ICU, and need some patient data or biological samples, they first need to ask the patient for permission using informed consent. ICU patients have the right not to participate in any proposed studies or to stop participating in a previously authorized study if they so wish, without their medical care being affected by this. This must be explicit in the informed consent and must be explained verbally to patients.

In addition, informed consent is obtained from a legally authorized person, such as a family member, in cases in which patients do not have sufficient autonomy to take decisions. In most of these cases, families are under considerable pressure

and have to decide if their relative will participate in the study, thus causing them distress and anxiety. It is also common for families to confuse research tasks with daily treatment and care [211]. The Belmont report presents the principle of respect for people, justice and beneficence in order to protect patient rights in ethical research. So, it is necessary to have a balance between the benefits of research for patients and the risks for their health above standard care.

1.5. Objectives

Considering the high incidence of unsafe clinical practices and the consequent preventable adverse events on the health of critical patients as well as the possibilities that AmI offer to minimize them, this thesis aims to develop an AmI environment to improve patient safety in ICUs. To fulfil this goal, I define four specific milestones and their corresponding objectives, as I describe in what follows.

Milestone I: Analysis of environment and needs

- To analyse the intensive care environment and the needs to be met with regard to patient safety.
- To study the newest strategies available to improve patient safety in ICUs.

Milestone II: Development of prototype and its functionalities

- To create an AmI environment model to improve patient safety in ICUs that allows value to be added to the current systems.
- To build a prototype of the AmI environment to test the clinical concepts and its technical feasibility.
- To propose a communication and information architecture for the AmI environment prototype.
- To develop a secure multiplatform software application to support data collection, analysis and notification on a small scale for the prototype.
- To test the main functionalities of the prototype in different conditions.

Milestone III: Implementation in a real environment

- To install an AmI environment in a Smart ICU at HCB based on the experience previously obtained with the prototype.
- To configure all the functionalities of the IoT devices pertaining to the AmI environment in the Smart ICU.

Figure 12. Bioengineering office of the medical ICU at HCB.

- To develop and implement a communication and information architecture for the Smart ICU.
- To develop and implement a secure multiplatform software application to support data collection, analysis and notification on a large scale for the Smart ICU.
- To test the main functionalities of the AmI environment in different conditions at the Smart ICU.

Milestone IV: Data Analysis of the AmI environment in ICU settings

- To collect and analyse the data obtained from the real environment as well as to determine how the model I developed behaves.
- To train and evaluate the data collected using machine learning techniques.

1.6. Methodology

A bioengineering office was created in a medical ICU at HCB in order to develop this thesis (Figure 12). This space was created to discuss clinical ideas with the multidisciplinary team in the unit and to develop proof of concepts of technologies for improving patient safety.

I performed an exhaustive literature search centred on AmI environment models, patient safety and technologies related to ICUs. I also carried out

observations at the medical ICU as well as individual interviews with HCWs to understand ICU needs and the moments at which preventable and unpreventable risks for the critically ill patient occur. I reviewed the relevant concepts needed to work successfully with AmI environments, and clinical and non-clinical strategies to improve patient safety in ICUs.

After this bibliographic research and my first contacts with the ICU environment, I developed the AmI model. With my model in mind, I contacted different providers of IoT devices with the aim of finding the best technical solutions adapted to the needs of my thesis. I built a first prototype of an AmI environment using sensors and actuators with a flexible and secure communication architecture as well as the facility to programme all the electronic modules without having to use many complicated and proprietary codes in the bioengineering office.

Meanwhile, I also contacted the providers of medical devices—such as vital signs monitors, mechanical ventilators and infusion pumps—and the technicians responsible for the development of the hospital information system (HIS) at HCB in order to learn how to integrate clinical data into the architecture of the AmI environment.

With all the technical information provided by the different partners and the posterior programming of the prototype, I commenced the testing of its main programable functions. Once all the functions of the prototype were correctly checked, an AmI environment was implemented in five patient rooms around a nursing station in the Smart ICU at HCB, based on the technologies developed in the prototype. Finally, I concluded this work with analysis of the data generated by the elements in the real environment.

1.7. Outline and Original Contributions

This thesis is composed of three phases. In the first phase I present the development of the AmI environment model designed for critical care spaces. In the second phase, I focus on the implementation of this model in a real environment. Then in the third phase, I present the analysis of the data obtained from the AmI environment. In what follows I briefly describe each chapter of this thesis.

PHASE I: FRAMEWORK AND DEVELOPMENT

Chapter 2. Ambient Intelligence Environment for Critical Care

In this chapter I present the framework and development of an AmI environment designed for critical care settings. This AmI environment is composed

of four interconnected layers (the physical, communication, information and decision layers) in order to obtain information from the critically ill patients and from the environment at each moment and to generate the correct responses for HCWs and visitors.

Furthermore, in this chapter I describe the creation of my AmI environment prototype as well as its construction and main modules (functional, visual, and data-transforming modules). This prototype was created to test the main clinical ideas generated by the multidisciplinary team for improving patient safety in ICU settings.

Chapter 3: Testing the Prototype

In this chapter I describe the working principles of the prototype and I evaluate its performance in executing all the previously predefined responses. The prototype is prepared for generated responses for seven types of situation: in a basal state, in a code blue event, in a code red event, in a code pink event, in a hand hygiene event, in a noise event and in a medication event.

PHASE II: IMPLEMENTATION IN A REAL ENVIRONMENT

Chapter 4: Implementing the Prototype in a Real Environment

My objective in Chapter 4 is to describe the implementation of the AmI environment in a Smart ICU at HCB. I divide this implementation into three main phases: implementation of the building automation system, implementation of the clinical sources, and implementation of the hand hygiene monitoring system.

In the first phase, I install a new electrical panel in the unit as well as the ambient control interface in patient rooms and the nursing station. In the second phase, I implement a web application to manage the clinical resources generated in the unit and implement the interface used to access all the resources. In the third phase, I install all the elements of the hand hygiene monitoring system and implement real-time feedback in the unit as well as monthly feedback for the professionals in the unit.

PHASE III: DATA ANALYSIS

Chapter 5: Critical Care Data Management and Analysis

In this chapter, I present the retrospective data analysis of the data provided by the AmI environment, such as the data generated by the building automation

system, code blue events, code red events, medication events, and finally hand hygiene events.

Chapter 6: General Discussion, Conclusions and Future Work

The aim of this chapter is to present the final discussion and conclusions regarding the framework, development, implementation and data analysis of the AmI environment created to improve patient safety in critical care. Finally, I finish this chapter by commenting on the future perspectives for the work in this thesis.

Annex 1. Table of privacy requirements

Annex 2. Table of security requirements

Annex 3. Table of clinical data

Annex 4. Table of environment data

Annex 5. Ethics committee approval of artificial intelligence study

Approval sheet of the artificial intelligence study from the Ethics Committee of the Hospital Clinic in Barcelona.

Annex 6. Ethics committee approval of hand hygiene study

Approval sheet of the hand hygiene study from the Ethics Committee of the Hospital Clinic in Barcelona.

Annex 7. Informed consent for the hand hygiene study

Form giving informed consent for the hand hygiene study, distributed to workers in the Smart ICU at HCB.

Annex 8. Ethics committee approval of optical system study

Approval sheet of the optical system study from the Ethics Committee of the Hospital Clinic in Barcelona.

Annex 9. Meaning of statistical parameters in Weka® software

Annex 10. Acronyms

Annex 11. Curriculum vitae of the author

PHASE I.
FRAMEWORK AND DEVELOPMENT

CHAPTER 2. AMBIENT INTELLIGENCE ENVIRONMENT FOR CRITICAL CARE

2.1. Introduction

In this chapter I describe my analysis of the requirements for the environment and the creation of an AmI environment in the Smart ICU at HCB centred on the needs of critical patients and professionals. The aim of this AmI environment is to track all the activities carried out in this ICU and enable an adaptive and dynamic distribution of clinical information based on the role of each professional and the clinical health status of patients. In this way, I aim to provide a clinical environment that is safer and of greater quality for all.

My objectives in Chapter 2 are:

- To analyse the environment in order to identify needs and unsafe situations for critical care patients and HCWs.
- To present the framework for the AmI environment designed for ICU settings.
- To describe each layer of the AmI framework and understand how they are interconnected.
- To present the AmI prototype built to test the clinical concepts for improving patient safety in ICUs.
- To characterize the data from patient bedsides and data from the environment.

2.2. Analysis of Environment Needs

In the first phase of this thesis, Framework and Development, I performed a set of visual observations in the main working areas of the Smart ICU at HCB during daily clinical practices. The aim of these observations was to identify all the processes which put patients at risk, categorize them and finally prioritize the most important processes to be developed in this thesis. The patient room (Figure 13) and the nursing station (Figure 14) were the main working areas analysed, in accordance with the most current evidence from clinical engineering research. I

Figure 13. Patient room in the Smart ICU at HCB.

Figure 14. Nursing station of the Smart ICU at HCB.

analysed root causes in both cases and produced a fishbone diagram to summarize all my findings [216].

2.2.1. Identification of Needs in Patient Rooms

In the first working area, the patient room, I periodically observed the flow of HCWs, patients and family members to understand how and why HCWs move, manage medical devices, and take notes and collect clinical data in the HIS. A major part of their activities is related to the direct care of the patient and clinical assistance varies depending on the health context of each patient. Some clinical vital signs are transmitted automatically to the HIS, but many other variables are evaluated and measured by HCWs hourly and manually entered into the HIS.

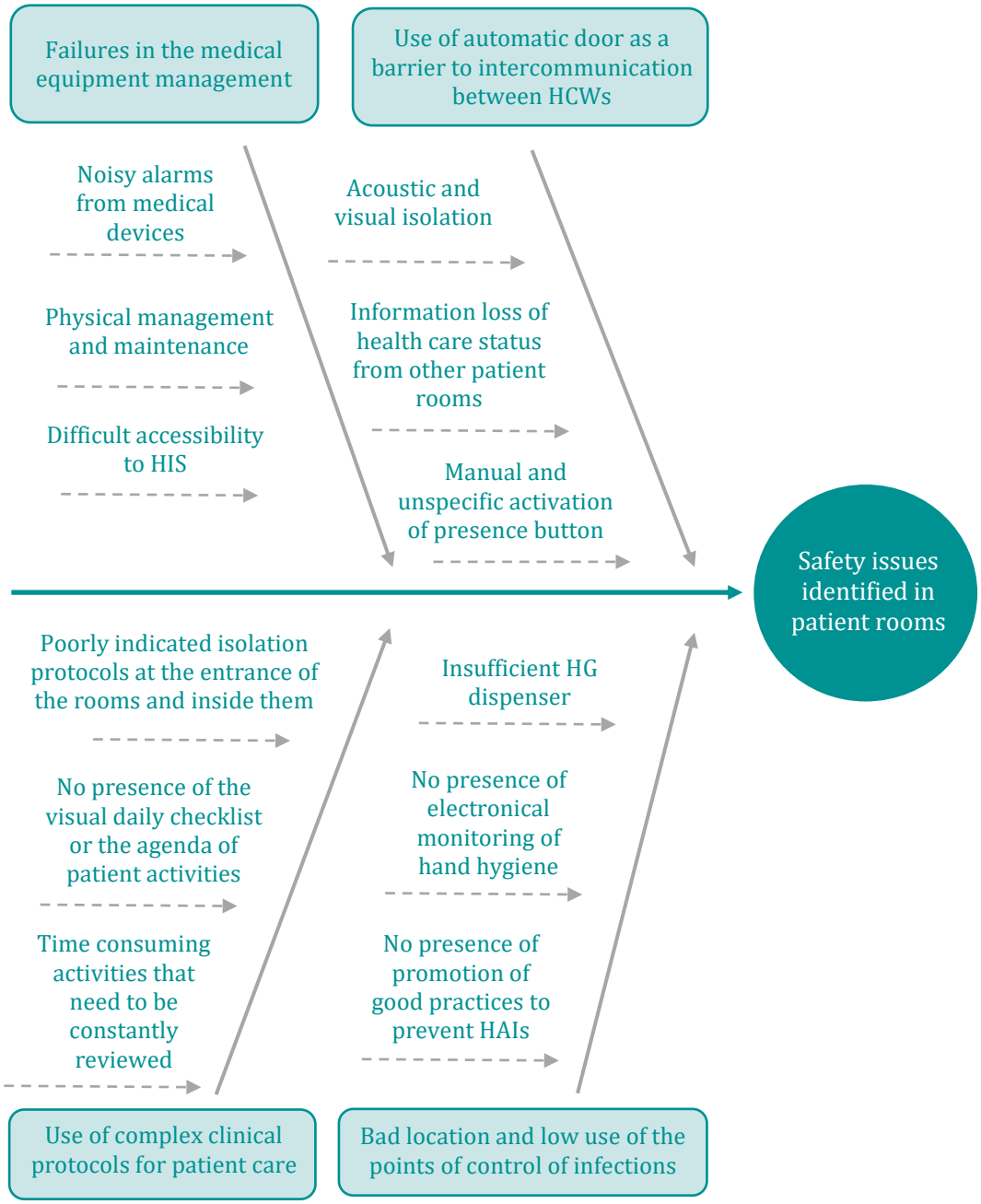


Figure 15. Fishbone diagram of safety issues identified in patient rooms.

Generally, families are informed of the health status of patients inside patient rooms at 1 p.m. every day. If patients are not conscious or have some psychiatric problem, families are informed in a family room. I identified four categories of safety issues that can cause adverse events for the health of patients. Figure 15 is the fishbone diagram representing my main findings.

The medical equipment in an ICU room is managed daily by nurses and doctors and is the cause of many safety issues. The most commonly used medical devices (vital signs monitors, mechanical ventilators, infusion pumps and haemodialysis machines) emit noisy alarms locally and at the nursing station. The noise generated

by these devices is annoying for both patients and HCWs, and it can affect patient sleep and recovery [64], [65], [217]. The screens of the medical devices have an interface that is not user-friendly and most of the devices are not easy to use. Some studies reveal that the adverse events generated by medical devices are due to product design factors and to them being used incorrectly [115], [117]. In addition to these factors, in this unit, the patient monitor has a connection to the HIS. The connection works correctly, and nurses note down the clinical data immediately without needing to move to the nursing station. But the ergonomics of the access arm is not optimal because the space for the keyboard is very small and it is very close of the tubing of the mechanical ventilator.

The use of the transparent automatic doors made of glass with polarization control represents an advance in the prevention of nosocomial infections, but it is a significant barrier to intercommunication between HCWs and between HCWs and patients. The doors provide acoustic isolation and when the polarization is active (opaque state) they also provide visual isolation. For some clinical purposes, such as the process of patient hygiene or family visiting hours, this is very useful. However, when nurses are inside a patient room, they do not have access to the information about the healthcare status from other patient rooms and in the case of an emergency they cannot help their colleagues. To solve this problem, the hospital installed an intercommunication panel from Honeywell (Honeywell S.A., USA) [218] at the entrance to the room with a presence button to indicate the presence of HCWs. If a HCW presses this button, they can establish communication with other patient rooms or with the nursing station when necessary. The disadvantage of this system is that it is unspecific: it cannot differentiate who presses the button or their professional category.

The management of critically ill patients integrates many clinical techniques and the continuous preparation and assembly of many medical devices as well as of their respective fungible materials. This is one of the most time-consuming tasks for HCWs because the providers are constantly updating the machines and related products, so it is difficult to access all the updated instructions rapidly to assemble them. Moreover, the process of disinfection of the equipment and materials is also a time-consuming task and the disinfection products used for each device are very specific. In addition to these processes, there is no visual daily checklist of pending tasks or an agenda of patient activities. Another problem related to critical care is the poorly indicated isolation protocols at the entrance of the rooms and inside them. This leads to people entering rooms without completing clinical protocols (for example, the use of specific masks, gloves or a disposable gown) and thus increasing the risk of cross contamination [219].

The last safety issue I identified was the bad location of the points of control of infections and the low percentage of use of hydroalcoholic gel (HG) and soap inside

patient rooms. There are insufficient HG dispensers in the patient area and there is no presence of electronical monitoring of hand hygiene for HCWs. Finally, there is no presence or promotion of good practices for preventing health care-associated infections (HAIs).

2.2.2. Identification of Needs at the Nursing Station

In the second working area, the nursing station, I also periodically observed the flow of HCWs, technical personal and families in order to understand the flow of daily activities that can affect the health of patients. In this space, nurses and their assistants prepare all the treatments, note down all the important clinical data and discuss the clinical evolution of diseases with other HCWs in order to follow-up on patient healthcare status. This space is also the setting for collaborative work between different HCWs in order to prepare medical devices and disposable materials. During the shift changes, nurses and assistants use the nursing station to review the clinical cases with the staff on the next shift and this generates peaks of noise in this space. It is the space where there is most flow of people and activities. In addition, on many occasions, this space is the first contact families have with the ICU environment. HCWs receive families here and give them instructions before entering patient rooms. In this case, I also identified four categories of safety issues that can cause adverse events for the health of patients and that originate at the nursing station. Figure 16 is a fishbone diagram representing my main findings.

Currently, the remote patient monitoring carried out at the nursing station presents many problems. The false alarms of the vital signs monitors cause distractions to staff, and make it difficult to detect real alarms. Moreover, there is no video surveillance patient rooms and consequently the risk of falls or pain detection is not controlled. The nursing call system does not enable communication between patients and HCWs, it only activates the colour and sound alarms.

Use of the HIS represents a very slow process of registering and reviewing useful clinical data, and it does not visually show important events that occur to the healthcare status of patients. HCWs have to review all the past clinical notes to understand the clinical context and analyse each one of the laboratory tests and image tests to recover all the important information. Furthermore, the HIS does not have alerts for the risk of early deterioration of critical patients in real-time nor does it analyse important events in the future.

Remote monitoring of the environment and location of people was not available. HCWs had to enter each patient room to change the state of lights, pressure levels, and also the polarization of doors and windows. In addition, no elements provided automatic location and detection of technical failures in the

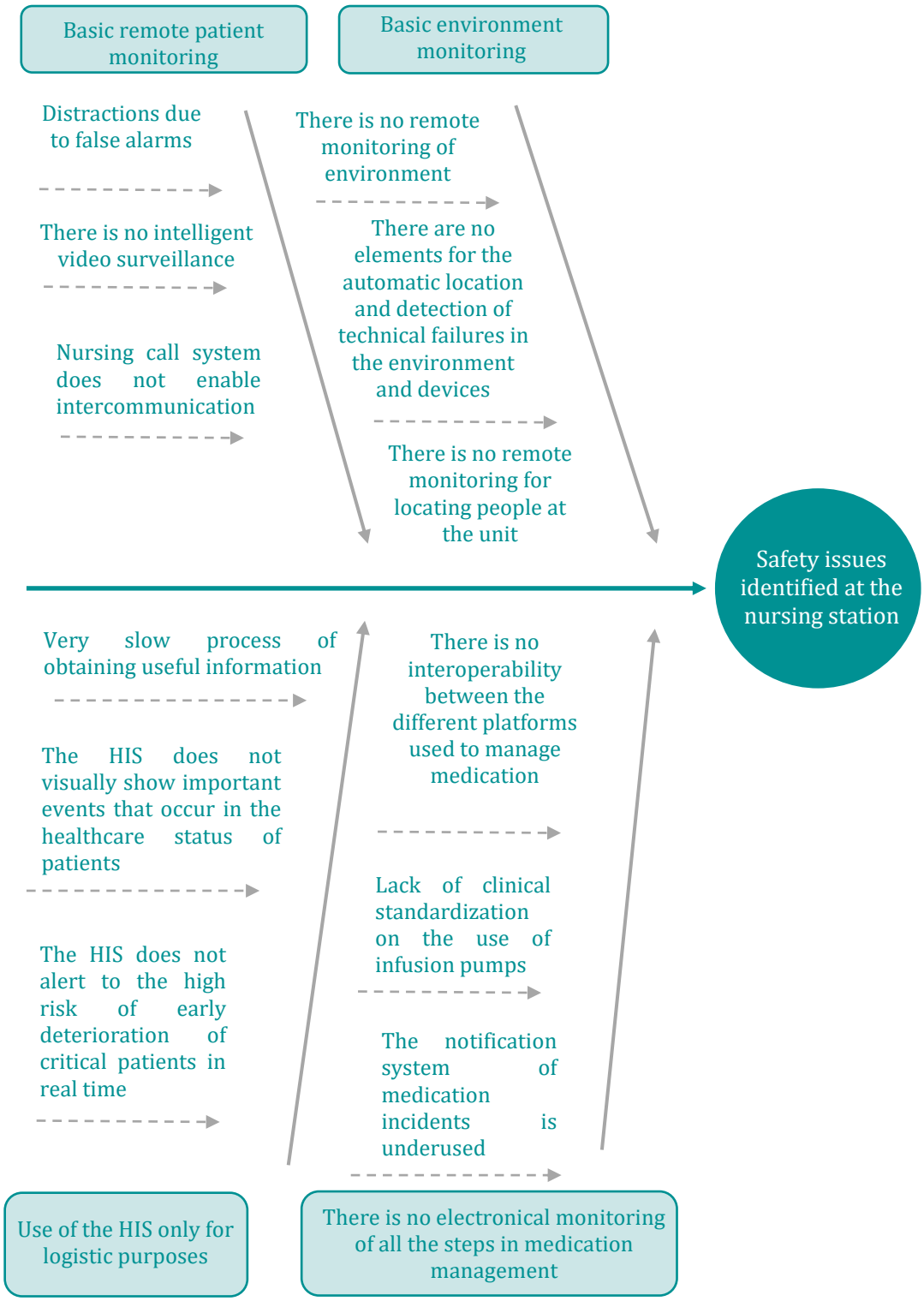


Figure 16. Fishbone diagram of safety issues identified in the nursing station.

elements of the environment and devices. The last safety issue I identified was the lack of monitoring of all the steps in medication management. The nursing station is the place where a lot of the medication is managed, but there is no interoperability between the different platforms to aid in this management. The machine used to dispense medication is not connected to the HIS and nobody checks whether the

data match with the prescriptions and the administration orders. Furthermore, the system of notification of medication incidents is underused, and neither are the data generated by infusion pumps integrated into the HIS.

2.3. The AmI Environment I Apply

A novel AmI Environment for ICU settings was designed considering the needs I observed in patient rooms and the nursing station of the Smart ICU at HCB during daily HCW practices. The IoT devices used in the phase of design and manufacturing of the AmI environment were acquired based on those needs. A global IoT architecture model was proposed to monitor the different elements of the environment. There is no consensus among researchers as to the best IoT architecture model [22], [220]–[224]. Some models have been proposed by researchers since 2005, such as 3- and 5-layer architectures, as well as cloud- and fog-based architectures.

The framework of the AmI environment I applied was divided into four interconnected layers, due to the high degree of complexity of the electronic devices and compute servers used. The first layer, the physical layer, contains the system hardware. It includes ambient sensors and actuators which provide the data from the environment, as well as the medical sensors and actuators which provide the data from the critical patients in real time. Once measurements are taken with these IoT devices, it is necessary to communicate the data generated to a management server. The second layer, the communication layer, is responsible for the communication between the hardware components and a management server, as well as the communication between the different servers. The third layer, the information layer, collects and analyses the data from the patients and the environment. In this layer, all the data are analysed using data analysis and methods of AI to obtain useful information. Missing data and erroneous data are eliminated while the corrected data are validated and are used to build predictive mathematical models. The fourth and final layer, the decision layer, executes actions based on the information generated in the previous layers to anticipate future events or prepare a response to a new need. It can generate responses, alerts at the user interfaces and dashboards, or it can notify users in the case of necessity. It can also change the behaviour of the actuators in the system and adjust the programming of devices. In addition, this last layer presents the data analysis in an accessible way for final users through intuitive graphical user interfaces (GUIs). In what follows, I describe the main uses of the GUIs for this AmI environment.

- *Real-time monitoring of clinical and environment variables*: the process of data collection from different sources is monitored and quantified daily,

monthly and yearly. In case of technical incidences with different devices or servers, the application notifies administrators and users.

- *Application for clinical event detections*: the results of the data analysis are used in the detection of clinical events and early patient deterioration. Patient status, clinical recommendations and clinical checklists are displayed on the interfaces.

- *Feedback for HCWs*: automated responses to the environment are generated in order to attract the attention of HCWs for important events using lights, acoustic alarms and specific messages on screens.

- *Reports of events detected:* the HCWs can access the reports of important clinical events via the GUIs. The smart application can record the evolution of the parameters forty-eight hours before and after a completed *clinical* event in a database for further analysis, in addition to the video streaming captured by the cameras. Authorized medical and nursing staff can visualize all the data collected.

2.4. Design and Construction of the AmI Environment Prototype

The first sketches for the new AmI environment took the patient as the starting point of the process flow and considered the real infrastructure of the Smart ICU at that moment. A physical prototype of the AmI environment was designed and manufactured in order to simulate and understand the AmI responses in ICU settings as well as to study the viability and usability of the technologies used. This prototype was composed of three main modules — the functional, visual and data-transforming modules — which were built successively, and which are described below.

2.4.1. Functional Module

The functional module was composed of technologies which control the environment variables and the generation of programming responses in the ICU setting. This module is in the physical layer of the AmI environment and provides all the physical support to keep one patient room and one nursing station working. In addition, this module also represents part of the communication layer, given that it is able to send and receive information of IoT devices and compute servers. Figure

17 shows a sketch of the functional module and its final manufacturing prototype. The **functional module** included six main elements:

- A set of wired modules to control the lights, polarization (change of mode from opaque to transparent, and vice versa) of the door and window, as well as environmental alerts generated by the prototype, referred to as the "control modules".

- Light and presence sensor (LPS) that is used to measure the luminous flux per unit area and to evaluate the presence of people inside a room.

- A "Scena" device that has a dual function: to control the RGB colour of the panel at the nursing station and to control the circadian cycle function inside a room.

- A set of RGB and circadian LEDs controlled by the "Scena".

- RTLS system associated with hand hygiene electronic dispensers.

- A set of acoustic elements: head-speaker, microphone and sound meter.

A set of sensors and actuators from Simon (Simon S.A., Spain)[225], [226] were used to create the building automation system of a prototype of this AmI environment. The automation modules used in the development of the project included four relays, a controller with four multi-sensors and a DMX (digital MultipleX) bus, a digital input module, two digital signal converters, two DMX-PWM (pulse width modulation) RGB converters, a power supply, an LPS, RGB and circadian LEDs, and the "Scena" device from Simon.

All these modules are controlled by a control node through the network, which is known as the "i.Lon Smart Server" (iSS), developed by Echelon (Echelon S.A, USA) [227], and which establishes communications through FTP (foil screened twisted pair) cables following the bus topology. The iSS has a web interface based on a service-oriented architecture (SOA) protocol that allows it to manage all the connected devices and to transmit system information remotely. Moreover, two digital-analogue converters (DACs) were used in the manufacture of the environment.

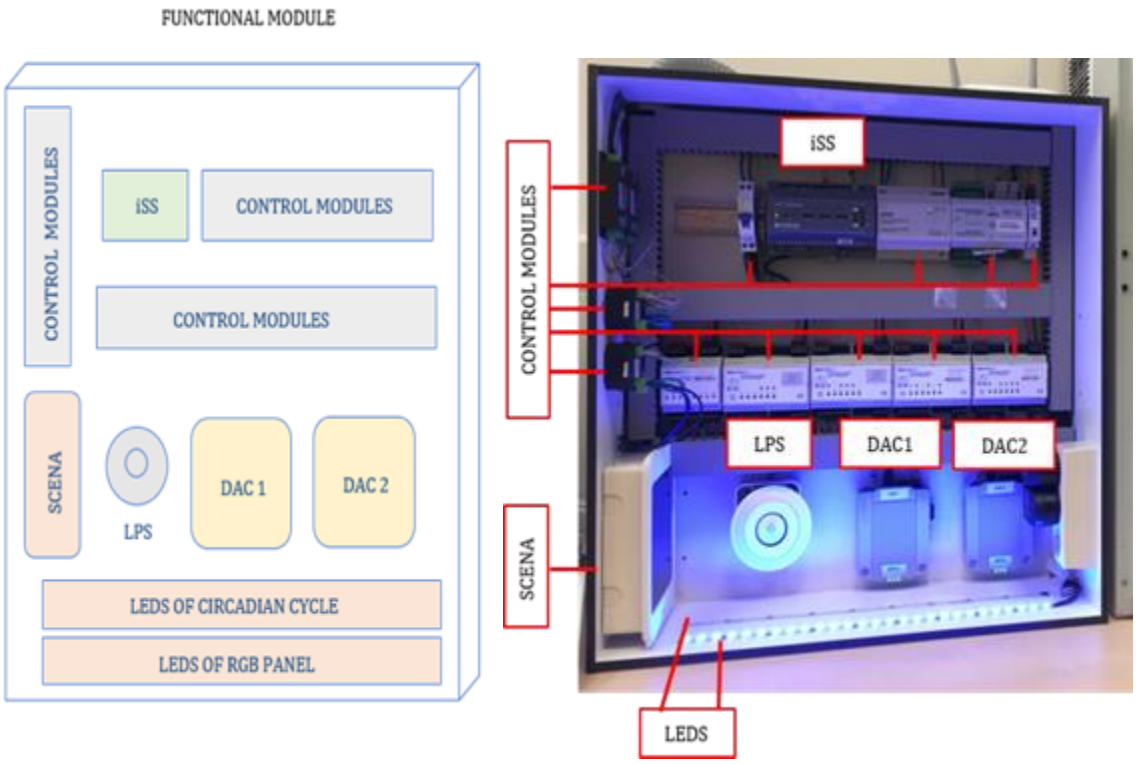


Figure 17. Functional module of the prototype AmI environment for ICU settings. Left: sketch; Right: physical manufactured prototype of the module with all its elements highlighted. iSS: i.Lon Smart Server; LPS: light and presence sensor; DAC 1, DAC 2: digital-analogue converter 1, 2; CAM: video camera; SCENA: "Scena" device; LEDS: light-emitting diodes.

A set of RGB LEDs is used to simulate the RGB panel at the nursing station, which changes colour from day to night and in the case of activation of a code blue, red or pink. This panel is turquoise during the day and lilac at night. A set of circadian LEDs is used to simulate the circadian cycle function of the patient room. I tested the head-speakers and microphones from Axis Communications (Axis Communications, Sweden) [228] as well as the sound meter from Sound Ear (Sound Ear, Denmark) [229] separately to collect acoustic data from the clinical environment.

2.4.2. Visual Module

The visual module is composed of graphical elements to simulate the domotic response of the environment. A domotic response is a set of pre-programmed activations of the functionalities of the environment such as the lights automatically turning on, a change of multimedia content, or the polarization of doors and windows. This module is in the communication layer and information layer because it communicates with the IoT devices and sends them useful information. The visual module connects to the functional module through electrical cables. Figure 18 shows a sketch of the visual module and its final manufactured prototype. The **visual module** includes three main elements:

Figure 18. Visual module of the prototype used to simulate automated responses in the room and nursing station of the ICU. On the left side, there is the sketch and the right side there is the resulting manufacturing physical prototype of this module with all its elements highlighted. CAM: camera; ICU: Intensive Care Unit.

- A graphic representation of the automation response in the patient room and at the nursing station.

- Two tablets to be used by the medical staff. Tablet 1 shows clinical information about the patient or the room and Tablet 2 works as a GUI for the building automation system.

- An IP video camera to record predefined events and simulate RFID events from Axis [228].

A graphical representation of the patient room and nursing station in more detail are presented in Figure 19. In the patient room, there is a bed, a set of lights and two movable suspended columns classified as “dry side” and “wet side”. The lighting functionalities of the patient room which were tested in the prototype are described below:

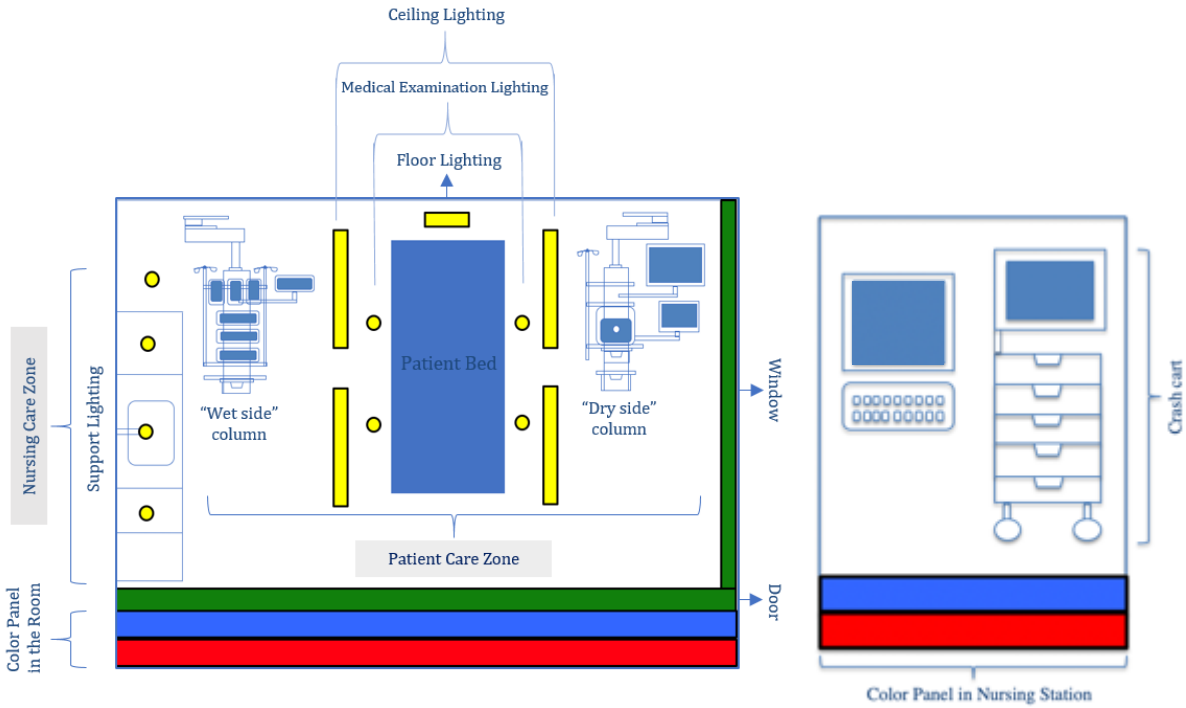


Figure 19. Graphical representation of the ICU patient room and nursing station. Left: elements of the patient room; Right: elements of the nursing station.

- Activation and deactivation of a set of lights in the nursing care zone of the room: "Support Lighting". In Figure 19, this functionality is represented by four yellow circles.

- Activation and deactivation of a set of lights above the patient's bed: "Medical Examination Lighting". In Figure 19, this functionality is also represented as four yellow circles.

- Activation and deactivation of a set of lights in the patient care zone of the room: "Ceiling Lighting". In Figure 19, this functionality is represented as four yellow rectangles.

- Activation and deactivation of the opacity state of the sliding glass door to the room: "Door". In Figure 19, this functionality is representing as a green strip.

- Activation and deactivation of the opacity state of the glass window of the room: "Window". In Figure 19, this functionality is representing as a green strip.

Figure 20. GUI of the building automation system. The function "Treball" corresponds to support lighting; "Exploració" corresponds to medical examination lighting; "Sostre" corresponds to ceiling lighting; "Vetlla" corresponds to floor lighting; "Circadià" corresponds to circadian lightning; "Vidre" corresponds to the state of polarization of the door; "Finestra" corresponds to the state of polarization of the windows; "CAM" corresponds to the state of video streaming from the camera (on/off); "Escena 1" corresponds to "Scenario 1"; "Escena 2" corresponds to "Scenario 2"; "Codi Blue" corresponds to a code blue; and "Codi Vermell" corresponds to a code red.

- Activation and deactivation of the light in the floor, behind of the patient's bed: "Floor Lighting". In Figure 19 this functionality is also represented as a yellow rectangle.

- Activation and deactivation of the colour panel in the room and in the nursing station: there are a strip of the two different colours at the room entrance and nursing station which indicate two clinical alerts: a code blue and a code red. In Figure 19 this functionality is represented as a blue strip and red strip, respectively.

Moreover, in the nursing station there are two visual elements: a computer and a crash cart (Figure 19). The crash cart has a blue LED which comes on when there is a "code blue" activation.

The building automation control of the room is composed of a set of buttons located on Tablet 2 which controls some functions commented on previously and three more functions described below (Figure 20).

- Activation and deactivation of 2 scenarios: Scenario 1 and Scenario 2. Scenario 1 is activated to decrease the brightness of all the displays in the room by 80% and Scenario 2 is activated to notify the Maintenance Department.

- The “Ceiling Lighting” presents two states: it can be an on/off switch for 100% of the light intensity or it can have a circadian cycle function during the day called “Circadian Lighting”. Both functions are indicated on Tablet 2. If “Ceiling Lighting” is “ON”, then “Circadian Lighting” is “OFF”, and vice versa.

- Activation and deactivation of a control button to start video-streaming from the camera.

2.4.3. Data-Transforming Module

The data-transforming module is composed of a set of connections that are needed to keep the AmI environment working correctly. This module has a virtual prototype which monitors all the connections between the IoT devices and servers in real time. Its elements belong to the communication layer, information layer and decision layer because it interchanges useful information between different services. The relationship between the data-transforming module, the functional module and the visual module of the prototype together with the layers of the IoT architecture model designed for my AmI environment is represented in Figure 21.

The virtual prototype of the data-transforming module is divided into two sub-networks, which are illustrated in Figure 22. The first sub-network, called Sub-network for Servers, establishes remote communication between the servers and wired communication between the IoT ambient devices. The main IoT ambient device used in my AmI environment was the Smart Server. This device reports the state (online/offline) of the ambient sensors and actuators. The Smart Server has a wired connection with two DACs, with enables it to synchronize the responses activated by different devices. The first DAC (DAC1) controls the traffic of binary information from a tablet inside the room, which contains the building automation control of the system, to the mobile devices. The second DAC (DAC2) notifies the user of the current system status (online or offline). With regard to the performance of the DACs, DAC1 receives a low-voltage signal from the “Control Modules” and sends an HTTPS message to the server integrated into the Information Layer; meanwhile DAC2 is used to receive an HTTPS message from the Information Layer server and sends low-power voltage to the “Control Modules”. The HTTPS message

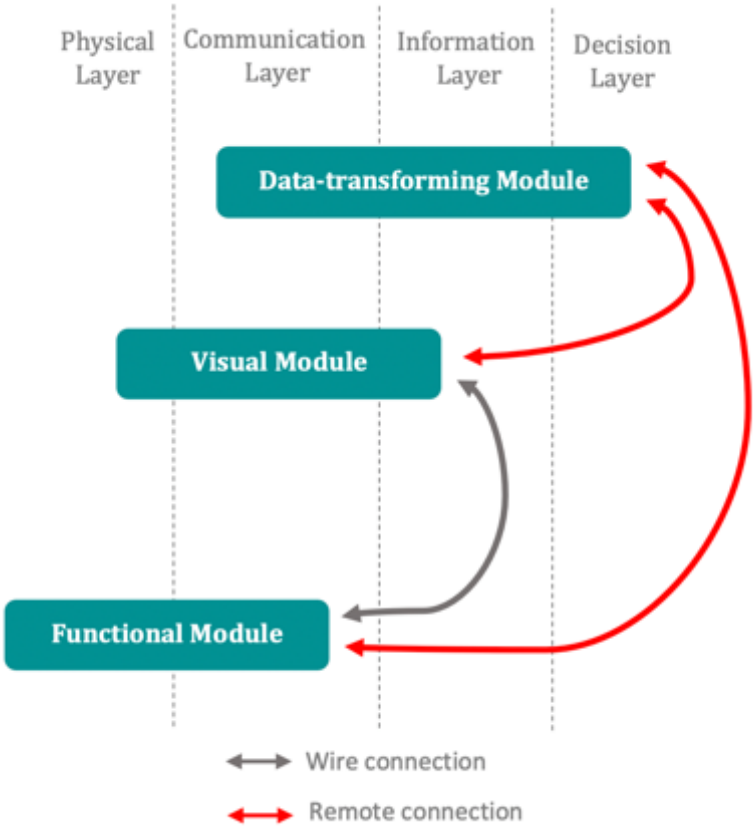


Figure 21. Relationship between the modules of the prototype and the layers of the IoT architecture of the AmI environment.

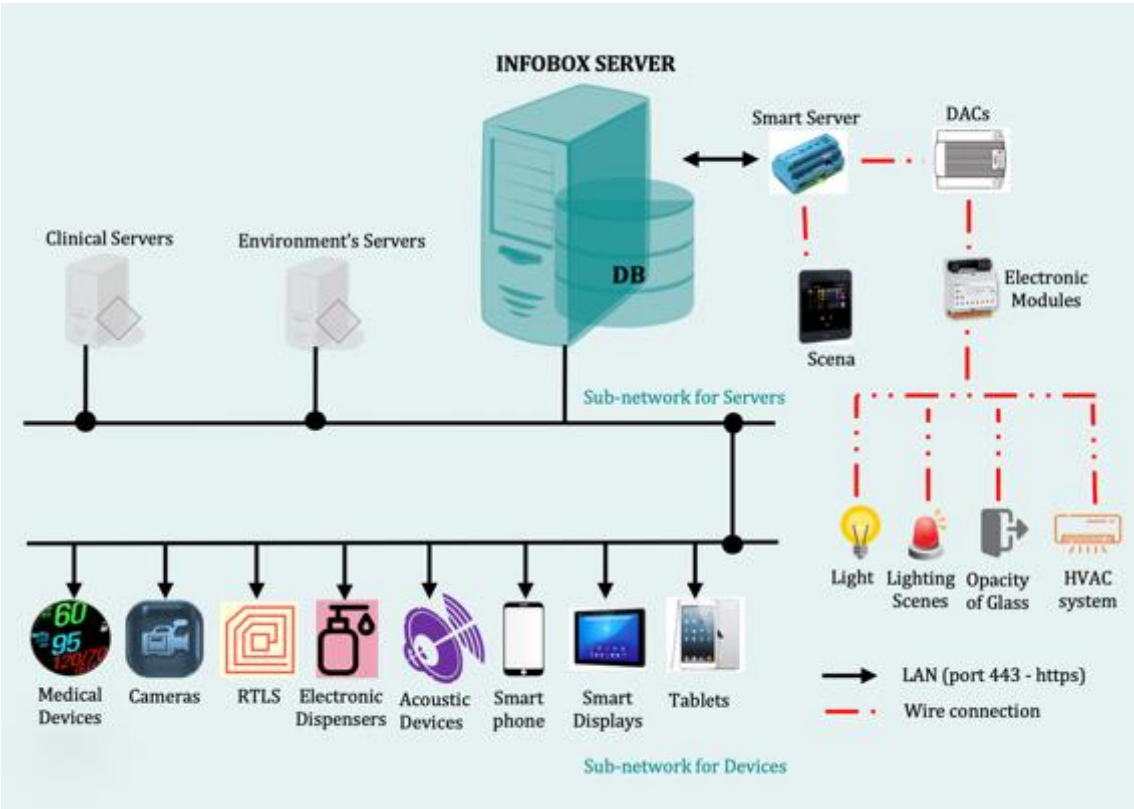


Figure 22. Data-transforming module of the prototype AmI environment for ICU settings.

is a URL that indicates the state of activation or deactivation of the "Control Modules". It returns two Boolean variables, "true" or "false", which are associated with the activation and deactivation of these modules, respectively. In addition, the first sub-network has a control server, called the Infobox, which manages the entire data collection and analysis process as well as the dynamic and adaptative distribution of the useful information generated by the unit. It also generates automated responses in clinical settings. The Infobox server has a large database (DB) containing the data generated over the last month by the AmI environment. The data generated in the AmI environment can originate from medical devices, ambient devices and from the HIS. Annexes 3 and 4 give details of the variables generated from the different sources.

The second sub-network, called the Subnetwork for Devices, establishes remote communications with all the medical devices (medication pumps, medication dispensers, vital signs monitors, mechanical ventilators, etc.), non-medical devices (RTLS, electronic dispensers, acoustic devices, cameras, smartphones, smart displays and tablets) and with the servers in the first subnetwork of the AmI environment. Figure 23 shows a sketch of the AmI environment framework, considering all the foregoing characteristics. Communication between its layers is continuous and in dynamic, to obtain contextual information on the environment at each moment and to adapt the intelligent algorithms to the new reality.

An electronic hand-hygiene monitoring and promotion system was developed and adapted to the needs I observed in the patient room and at the nursing station; it was used mainly in the second sub-network. The system has four main elements: an electronic dispenser for hydroalcoholic gel (HG), the RTLS, HCW identification cards with a chip and smart displays: television screens and tablets (Figure 24). In Figure 26, a tablet is indicated as "Display 1"; it contains dynamic information on the hands hygiene protocol for visitors and is located at the entrance to the unit. Visitors must keep their belongings in a locked cupboard and the key with them while they are in the unit. The key contains an RFID tag.

All habitual HCWs and non-healthcare workers (NHCWs) have a passive RFID tag attached to their hospital identification card. If unusual personnel visit, generic tags will be available in the ICU. These tags are read by antennas located above the hydro-alcoholic solution dispensers at the entrance to the rooms (antenna indicated as "Antenna 1" in Figure 25), in the frames of the access doors (antenna indicated as "Antenna 2" in Figure 25) and inside the rooms (antenna indicated as "Antenna 3" in Figure 25). All these antennas allow the position of HCWs and NHCWs, and monitoring of the hand hygiene (HH) at the entrance of the room (Figure 25). All these antennas allow the positioning of the HW and NHCW and the monitoring of the HH at the entrance of the room (Figure 25). The RTLS registers the movements

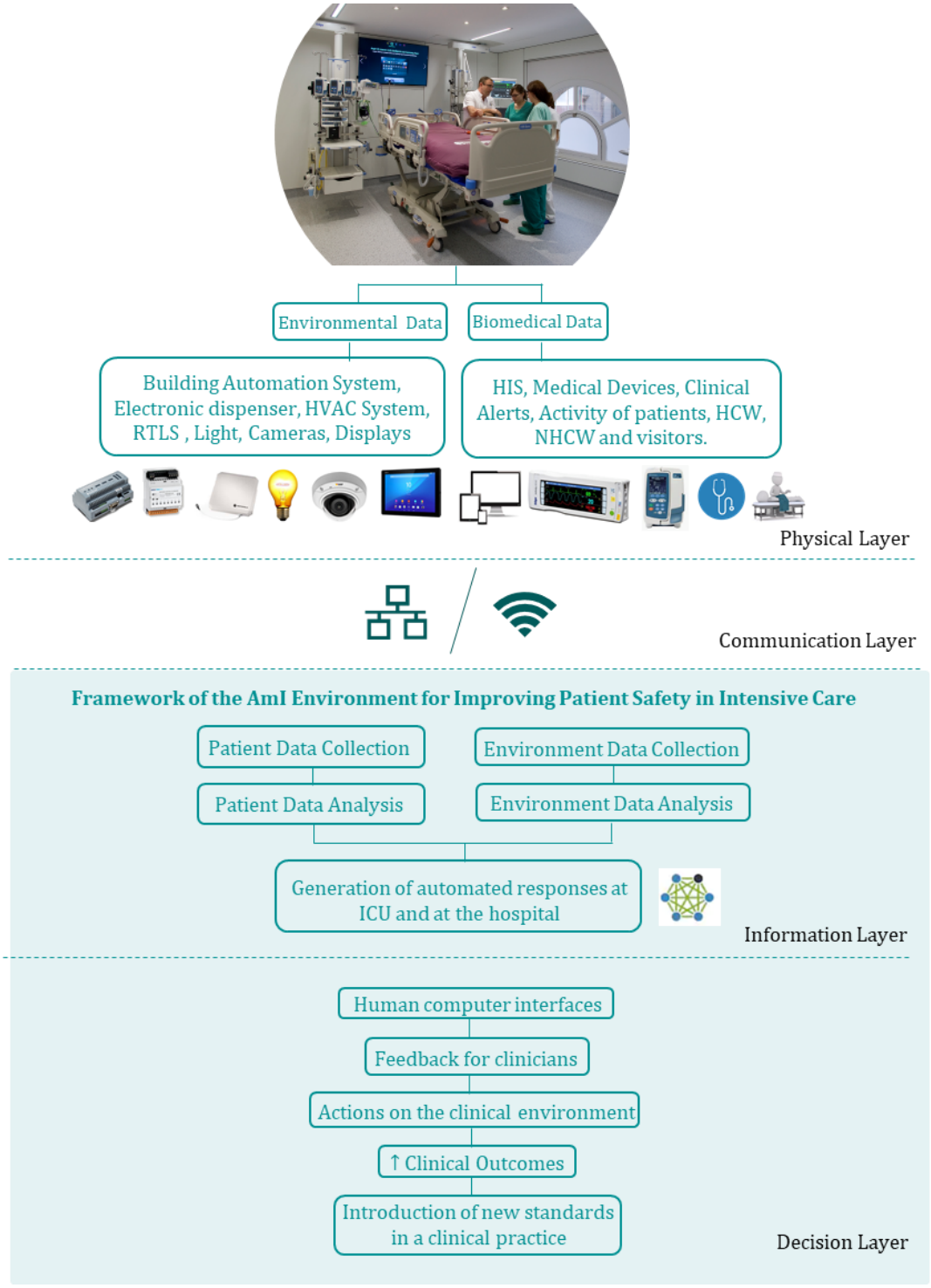


Figure 23. Framework of the AmI environment.

of HCWs and visitors inside and outside of the unit, with it being possible to know if they are inside a room, at the nursing station or outside the unit. “Antenna 4” in Figure 25 indicates the set of antennas installed at the nursing station of the unit, while “Antenna 5” indicates the set of antennas installed outside the unit, in the waiting room.

When HCWs, NHCWs or visitors put their hands near the dispenser, its sensor detects their presence and releases a small amount of hydroalcoholic gel (HG). Then "Antenna 1", located above the dispenser, starts to read the electromagnetic field around them. If the person has an RFID tag in their identification card, then the antenna detects the tag and records the moment and location of the delivery to this person. "Display 2", indicated in Figure 25, will show information about the patients in the room that are closest and the hand hygiene compliance rate for the month. After that, when the person carrying the chip approaches the door to a room, the RFID unlocks the door radar and it opens. If the person does not carry a card with a tag, the system will only record the time and location of the shot: it does not unlock the radar, and the radar will not open the door of patient room. In this case, "Display 2" will show a list of options of professional and visitor profiles. The correct category for each person must be chosen and after that the display will show a question about which patient room the visitor needs to enter. The visitor must choose the patient room they wish to enter, and then wash their hands again and finally, the door will open automatically. In this case, the system will register the category of the person who has entered the patient room. If the person does not clean their hands at the dispenser at the entrance to the patient room, the door will not open. In emergency cases, there is a red button next to the door that can be pressed to open it rapidly. "Display 3" and "Display 4" inside the patient room (Figure 25) display real-time notifications about hand hygiene (HH) habits of habitual workers and visitors, in addition to showing recommendations regarding the 5 moments of HH to professionals and visitors when be necessary. The system only allows monitoring of moment 1 (before direct contact with the patient), moment 4 (after contact with the patient) and moment 5 (after contact with the patient environment) of the 5 HH moments recommended by the WHO.

All the network elements of the AmI environment are monitored through the Nagios application [230], [231]. When the servers or mobile devices are disconnected from the Information Layer for some reason, this application sends a notification to the technicians by email, so they are able to review the alarm history, determine the cause of the incident and address the situation, rapidly. Moreover, they can advise HCWs and NHCWs of the incident.

For cyber security, the following measures were applied to the Information Layer: the access control method; a double authentication process; encryption of credentials and file storage and management; updating of Microsoft security patches, of the web development libraries and of the firmware devices; default passwords changes; the filtering of devices listed on the network communications; changes of the default SNMP community name; activation of the self-signed certificate and communication via HTTPS; and finally, connection to servers using only DNS names.

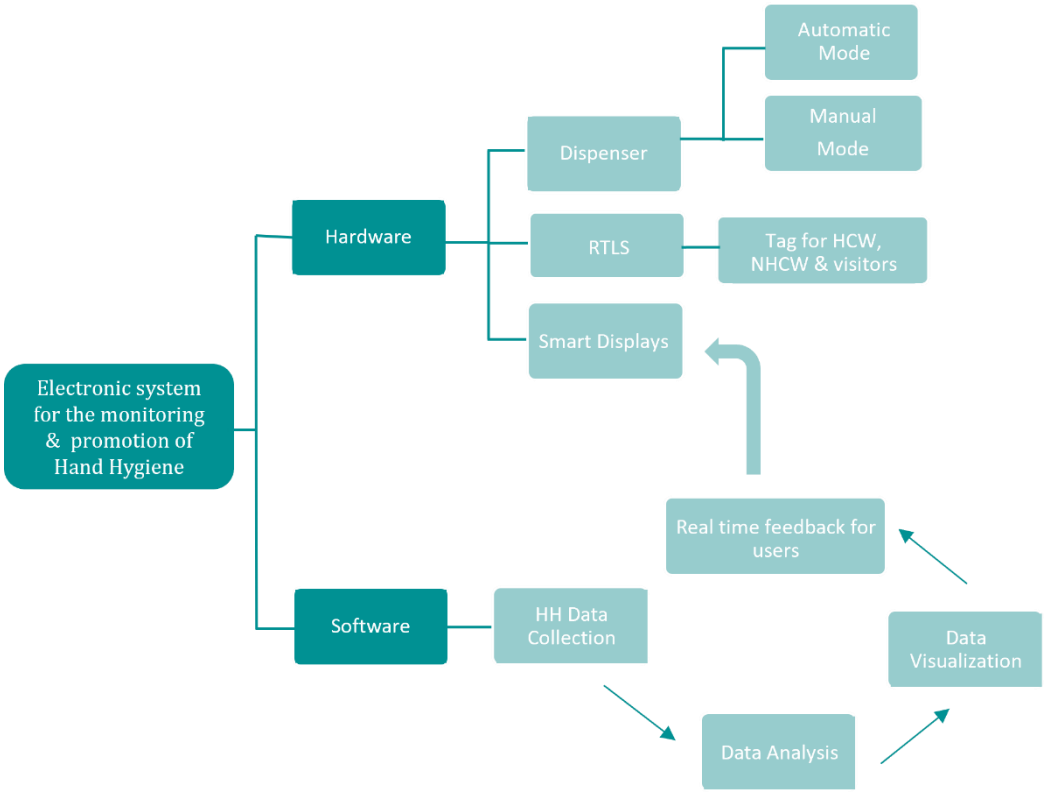


Figure 24. Elements of the electronic system for monitoring and promoting hand hygiene in the AmI environment.

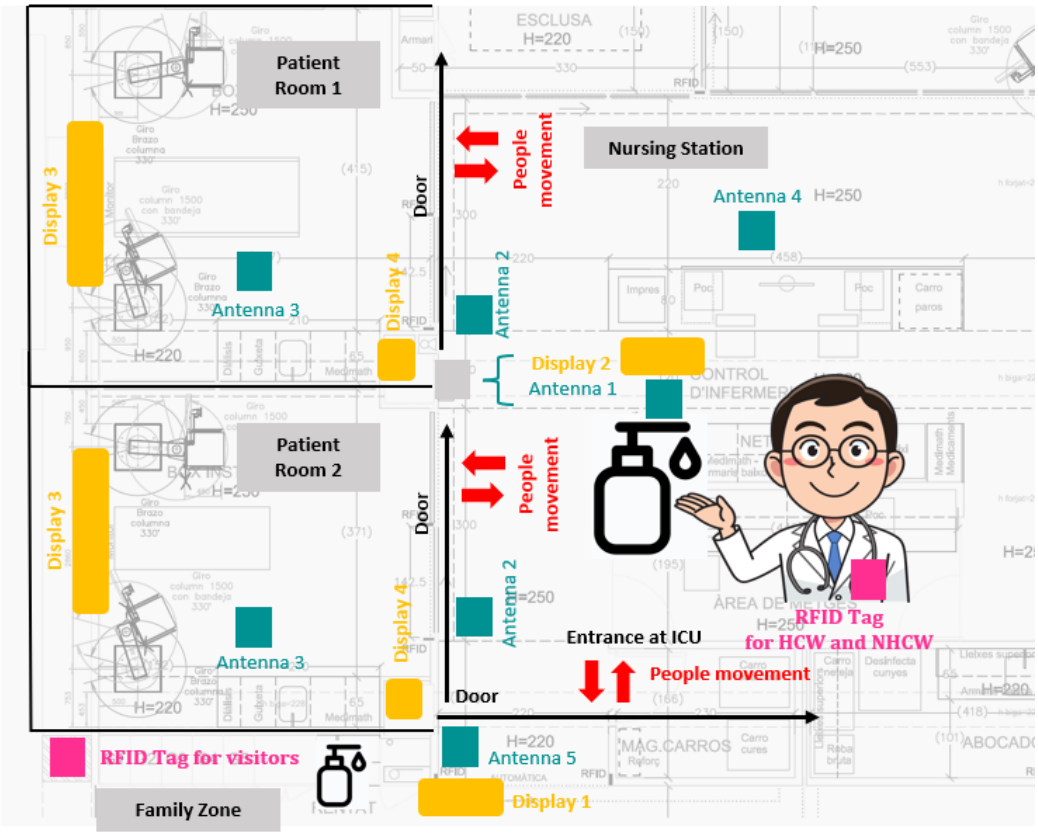


Figure 25. RFID associated with hand hygiene technology developed for the AmI environment.

2.5. Discussions and Conclusions

In this chapter I have presented my needs analysis related to patient safety as I observed in patient rooms and the nursing station of the Smart ICU at HCB. These needs were associated with the increasing complexity of the devices and HIS, as well as the complexity of the protocols used to care for critical patients. Based on these needs, I have elaborated an initial mock-up of my prototype for an AmI environment with the aim of understanding and simulating responses in the clinical environment as well as testing connections with all compute servers, and medical and non-medical devices on a small scale.

The design and manufacture of the AmI environment prototype was carried out in the Bioengineering Office at HCB as a proof of concept of technologies for minimizing unsafe clinical situations detected in the daily practice of the Smart ICU. The prototype framework was composed of four interconnected layers (Physical Layer, Communication Layer, Information Layer and Decision Layer) and the data from patient bedsides as well as from the environment were used to generate responses and alerts for HCWs and NHCWs. I described the data generated by the different sources in detail.

The AmI environment prototype was divided into three main modules (the Functional, Visual and Data-Transforming modules) which enable integration of the information generated at the different layers as well as distribution of the clinical information through the screens at the right time, in a safe way and synchronically.

Finally, the set-up of the electronic hand hygiene monitoring system was designed and built to detect and notify hand hygiene statistics in addition to registering the location of people inside the unit and the time spent in each location.

CHAPTER 3. TESTING THE PROTOTYPE

3.1. Introduction

In this chapter I present the working principles of the prototype. The prototype was developed to work in a baseline case, without events, and in cases of a code blue event, a code red event, a code pink event, a hand hygiene event, a noise event and a medication event. In this chapter, Tablet 1 and Tablet 2 refer to the tablets implemented on the prototype and commented on in the last chapter.

The main objectives of the Chapter 3 are:

- To understand the working principles of the prototype and the main cases it is designed to be used in.
- To present the design of the validation tests which evaluate the performance of the prototype in each of the cases it is used in.
- To explain the clinical need of each case of use at the Smart ICU and the predefined responses which will be generated.

3.2. What are the Working Principles of the Prototype?

3.2.1. Baseline State

In the baseline state, only the room number (patient room number 0, 1, 2, 3 or 4) is shown in the Tablet 1 layout of the prototype. In this case I consider the code of the room of the ICU: E014 (E014001, E014011, E014021, E014031 and E014041).

I prepared an experiment to test the baseline scenario. Throughout the trial I checked the performance of the web application, the data transmission with the physical prototype and virtual servers, the network speed, the use of the central processing unit (CPU), the memory usage and the use of the server disks and the IoT devices (Figure 26). Alerts to monitor the performance of the application were implemented.

The performance of the application was also tested under activation and deactivation of other different scenarios, observing the number of times it presented a failure and the reasons why that happened. The screen on Tablet 2 of the prototype presents the Lights button, previously activated by the users.

Figure 26. Information provided on the monitoring parameters of the application.

3.2.2. Code Blue Actions

According to studies published by the National Institutes of Health, cardiac arrest (CA) is the third most common cause of death in the United States [232]. More than 200,000 cases of in-hospital cardiac arrest (IHCA) are reported in adults annually [233], [234] with survival rates as low as 24.8%. IHCA causes around 100,000 preventable deaths annually, most of which are attributed to medical errors, delays in treatment and a lack of compliance with resuscitation guidelines [235].

Furthermore, approximately 80% of patients who suffer IHCA present demonstrable deterioration prior to the event and so a significant proportion are potentially avoidable [236]. IHCA should be treated as quickly as possible, because the likelihood of survival with good neurological and functional outcomes decreases by around 10% for each minute of CA [237]–[241]. Tertiary hospitals usually use colour codes to indicate emergency situations, and the term “code blue” is commonly used to indicate IHCA. The professionals assigned to respond to this code are generally called the Medical Emergency Team (MET)[242].

In the event of a code blue, when IHCA occurs, there is a sudden, unexpected and potentially reversible malfunction or interruption of the electrical and mechanical activity of the heart [243]–[245]. It can be caused by any of four abnormal electrocardiographic patterns: ventricular tachycardia (VT), ventricular fibrillation (VF), asystole (ASY) or electromechanical dissociation (EMD).

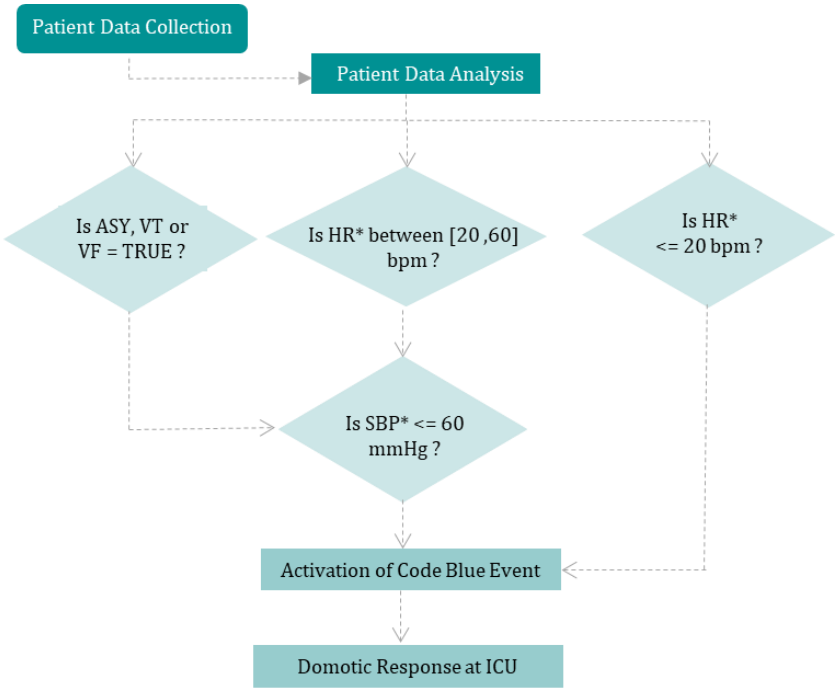


Figure 27. Scheme of code blue algorithm. * Information can be obtained from different sensors. ASY: systole; VT: ventricular tachycardia; VF: ventricular fibrillation; HR: heart rate; SBP: systolic blood pressure; ICU: intensive care unit.

The ensuing medical actions will be in accordance with standard cardiorespiratory resuscitation (CPR) protocols. A vital signs monitor detects these abnormal patterns and generates life-threatening alarms to warn healthcare staff of the abrupt change in patient healthcare status in an ICU. Figure 27 shows the clinical rule used to detect a code blue event clinically. A code blue can be activated and deactivated automatically or manually. If one of the conditions is met, the code blue is activated automatically. False alarms from vital signs monitors are a major concern in the detection of code blue events. Mechanical or physiological artefacts within signals—such as the change of transducer position or damp lines—can generate them [246]. Previous studies indicate that only 15% of alarms in a medical ICU are clinically meaningful [247], [248].

This causes fatigue and may create annoying distractions for medical staff, thereby compromising patient safety. Some authors propose the use of artificial intelligence and statistical approaches to reduce false alarms, and currently some strategies are under study (ANOVA [249]–[251], data mining [107], [252]–[254], machine learning algorithms [255]–[257] and fuzzy methods [182], [258], [259], among others). In contrast, if a HCW detects a code blue event that has not been detected by the clinical algorithm, they can activate the code blue manually by pressing the Code Blue button on Tablet 2 to rapidly inform their colleagues. The screens change, the new layout shows an alert, and a set of actions is triggered in the environment (Figure 28 – 30).

Figure 28. Screens of the Tablets 1 and 2, respectively.

Figure 29. Code blue screens.

CODE BLUE – ON

→ ON Support Lighting
→ ON Medical Examination Lighting
→ OFF Ceiling Lighting
→ OFF Circadian Lightning
→ OFF Floor Lighting
→ ON Door
→ OFF Window
→ ON Adjustable Lightning in nursing station
→ BLUE Color Panel in the Room
→ BLUE Color Panel in nursing station
→ The activation's message will be sent to the Service Management Layer
→ Tablet 1 shows the layout of activation of Code Blue
→ Tablet 2 shows the button "Code Blue" and associated lightning functions ON

CODE BLUE – OFF

→ = Support Lighting
→ = Medical Examination Lighting
→ = Ceiling Lighting
→ = Circadian Lightning
→ = Floor Lighting
→ = Door
→ = Window
→ = Adjustable Lightning in nursing station
→ OFF Color Panel in the Room
→ TURQUOISE/LILAC Color Panel in nursing station
→ The deactivation's message will be sent to the Service Management Layer
→ Tablet 1 shows the layout of the basal state
→ Tablet 2 shows the button "Code Blue" OFF and associated lightning functions in previous state.

Figure 30. Code blue actions. "ON" means that the functionality is active, "OFF" means that the functionality is inactive and "=" means that the functionality has not changed from the previous state.

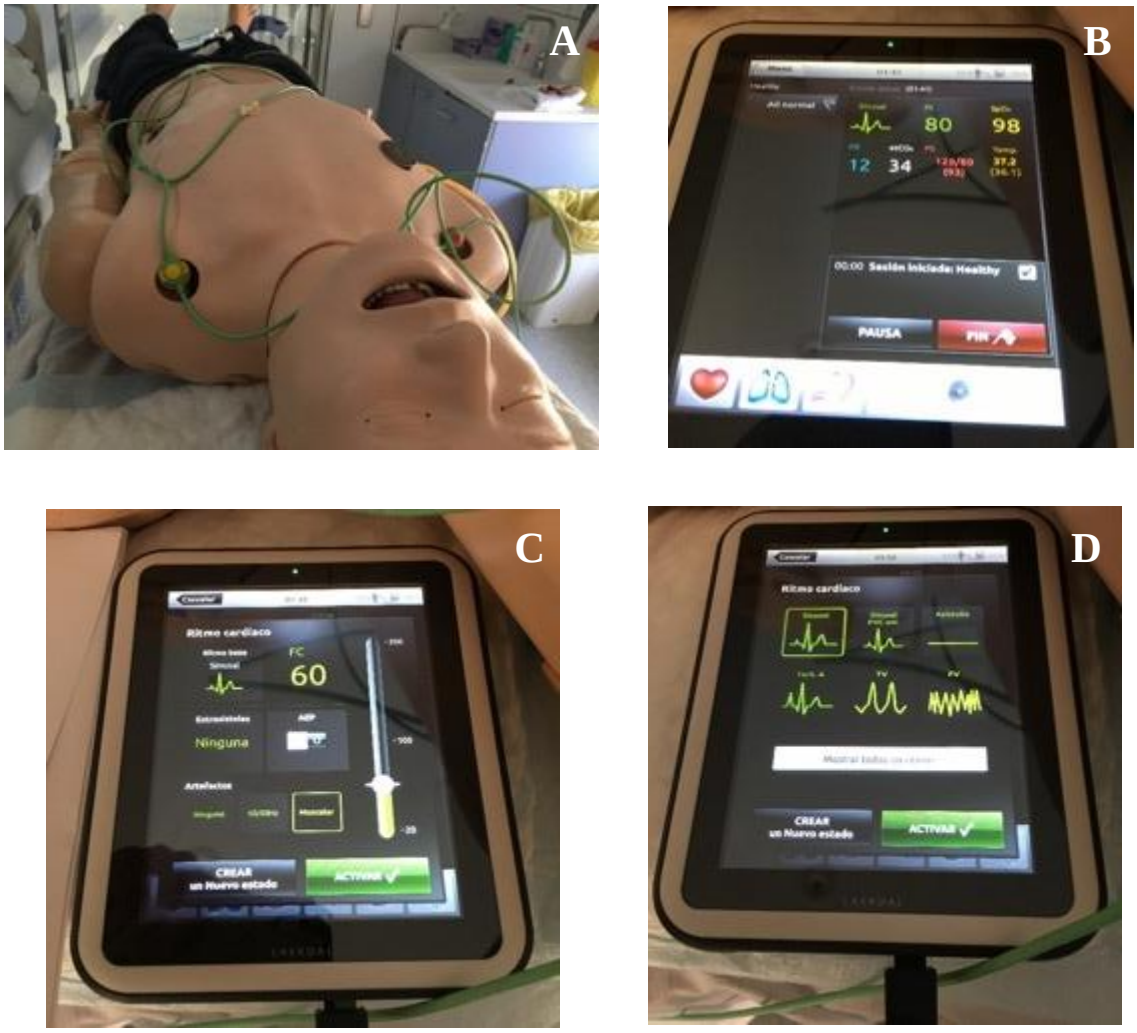


Figure 31. Experimental set-up to test a code blue scenario.

For the video camera, the events recorded are encrypted and only authorized medical staff can watch them later.

An experiment using an adult advanced life support manikin (Laerdal Medical, Norway), a vital signs monitor (Dräger Medical GmbH, Germany), an experimental application of the information layer and physical prototype to test the code blue scenario was also prepared. The manikin was used to obtain simulated patient data from the monitor, the experimental application was used to recover and analyse the data generated as well as the physical prototype being used to test AmI responses.

The manikin was lying in a bed and was connected to the electrocardiogram (ECG) sensors. These sensors were connected to the vital signs monitor (Figure 31A). The manikin was connected to the corresponding control tablet which simulates its vital signs. In sinus mode, this tablet generates normal ECG signals.

In the tests, whenever we finished simulating the arrhythmias and the different values of the heart rate (HR), we returned to sinus mode, to return the constants to normal (Figure 31B) for a healthy subject. The tablet did not allow invasive or non-invasive systolic blood pressure (NI-SBP) or HR from the pulxi-oximeter (HR Pulxi) to be simulated. Estimations of the variables that could not be collected were generated.

Before analysing the tests, it should be noted that the vital signs monitor generates artefacts and false positives due to muscle activity, tremors, respiratory movements, and movements of the patient's limbs [260]. They can also be due to errors in electrode placement and inadequate cleaning of the patient's skin. Artefacts can also be generated by external sources, such as electrical interference, which can occur when an alternating current is present near the patient's bed or when metallic elements are near the electrodes.

It should also be noted that the vital signs monitor itself generates yellow alerts and red alarms with sound, depending on the thresholds of the clinical variables, which are preestablished within the monitor and cannot be changed. Of all these alarms and alerts, 85% are considered to be false according to previous studies.

To simulate patient artefacts, the vibration and percussion system as well as the continuous lateral system of the patient bed (Hill Rom, USA) were used. Considering these factors and the fact that the tests were performed on a vital signs simulation manikin, I carried out the study design I describe in what follows.

1º) Evaluation of arrhythmias (VF/VT/ASY) in the situations described below:

1.1 Manikin at rest.

1.2 Type 1 Manikin undergoing bed vibration and percussion therapy to simulate tremors.

1.3 Type 2 moving manikin: I moved the manikin's upper and lower limbs manually.

1.4 Type 3 moving manikin: continuous bed rotation therapy was activated to simulate torso movements.

2) Simulation of other relevant parameters: HR from the vital signs monitor and apply the conditions of the clinical algorithm.

3) Comparison of results regarding the detection of false positives in all four situations, using only the monitor and when the algorithm is applied.

Another detail that I observed is that the tablet itself allowed me to generate a signal with and without artefacts. I could simulate ECG signals using two types of artefacts: muscular activity and the presence of 50/60 Hz frequencies (Figure 31C). I performed tests to check if the signal shape was affected when there was an artefact, both in the sinus rhythm, and in the presence of arrhythmias and HR variation.

The use the signals without the artefacts was a priority in this case, since the tests already simulated four cases of possible artefacts, due to different situations. Figure 31D shows the different types of arrhythmias that can be simulated on the manikin using the tablet. I used ASY, VT and VF, since they are the types of arrhythmias documented in the international guidelines for cardiopulmonary resuscitation when there is cardiorespiratory arrest. I also tested the AmI responses of the physical prototype once the code blue had been activated.

3.2.3. Code Red Actions

Patient status can suffer potentially reversible deterioration which, if detected early, can be treated and reversed. Early warning system (EWS) scores emerged in 2005 in the United Kingdom to help healthcare staff recognize patients at risk of deterioration, and so that HCWs would be better able to provide patients with the proper and necessary care before and during severe clinical events, such as IHCA, shock [261], and sepsis [262]. The EWS is a scoring system which uses a simple algorithm to evaluate physiological patient parameters during a hospital stay. The parameters evaluated by the EWS are heart rate (HR), respiratory rate (RR), systolic blood pressure (SBP or PAS), temperature (TEMP), oxygen saturation (SpO2), consciousness (CONSC) and the presence of oxygen support (O2_SUP or OX) [106]. In the case of SpO2, NEWS2 presents two scales. The first (Sp02.1) considers patients without chronic obstructive pulmonary disease (COPD) and the second (Sp02.2) those with COPD. NEWS2 scoring is summarized below:

- Addition of 0 points when parameters are within the following ranges:
  - 12<=RR<=20 (breaths per minute)
  - Sp02.1>=96 (%)
  - Sp02.2>=93 (%) if patient has oxygen support or 88<= Sp02.2<=92 (%) if patient does not have oxygen support
  - If there is no presence of O2_SUP
  - 111<=SBP<=219 (mmHg)
  - 51<=HR<=90 (beats per minute)
  - CONSC = alert
  - 36.1<=TEMP<=38.0 (ºC)

- Addition of 1 point when parameters are within the following ranges:
  - 9<=RR<=11 (breaths per minute)
  - 94<=Sp02.1<=95 (%)
  - 86<= Sp02.2<=87 (%) if patient has no oxygen support or 93<= Sp02.2<=94 (%) if patient has oxygen support
  - 101<= SBP <=110 (mmHg)
  - 41<=HR<=50 (bpm) or 91<=HR<=110 (beats per minute)
  - 35.1<=TEMP<=36.0(ºC) or 38.1<=TEMP<=39.0(ºC)

- Addition of 2 points when parameters are within the following ranges:
  - 21<=RR<=24 (breaths per minute)
  - 92<=Sp02.1<=93 (%)
  - 84<=Sp02.2<=85(%) if patient has no oxygen support or 95<= Sp02.2<=96 (%) if patient has oxygen support
  - If there is presence of O2_SUP
  - 91<=SBP<=100 (mmHg)
  - 111<=HR<=130(beats per minute)
  - TEMP>=39.1(ºC)

- Addition of 3 points when parameters are within the following ranges:
  - RR<=8 or RR>=25 (breaths per minute)
  - Sp02.1<=91 (%)
  - Sp02.2<=83 (%) if patient has no oxygen support or Sp02.2>=97(%) if patient has oxygen support
  - SBP<=90 (mmHg) or SBP>=220 (mmHg)
  - HR<=40 or HR>=131 (beats per minute)
  - TEMP<=35.0(ºC)
  - CONSC = confused, voice, pain or unresponsive

After summing all the points, the final NEWS2 score has an associated clinical response, which is explained below:

- For a total of 0 points, the frequency of patient monitoring should be at least every 12 hours. HCWs should continue NEWS monitoring. The colour assigned in this case is grey.

- For 1 to 4 points, the frequency of patient monitoring should be between 4 and 6 hours. HCWs should increase the frequency of patient monitoring or escalate care, if necessary. The colour assigned in this case is also grey. If the patient scores 3 points in a single parameter, the frequency of patient monitoring should be hourly and HCWs should also increase frequency of patient monitoring or escalate care if necessary. The colour assigned in this case is yellow.

- For 5 or 6 points, the frequency of patient monitoring should be hourly. Nurses should inform the medical team and request urgent assessment by the clinician as well as using monitoring facilities if necessary. The colour assigned in this case is orange.

- For a total of 7 or more points, patient monitoring should be continuous. Nurses should inform the medical team and they have to do an emergency assessment of the patient considering whether advanced airway management is necessary. It is necessary to consider transferring the patient to the ICU and the use of monitoring facilities. The colour assigned in this case is red.

Scores for each parameter are added and the final score indicates the patient's level of acuity. Usually, the EWS score is evaluated hourly and depending on the final score, HCWs need to provide more frequent clinical monitoring and clinical review [102],[263].

Recently, new non-vital parameters have been included in this scoring system. These are provided by the electronic medical records, such as clinical data, laboratory results, age, the presence of a specific underlying disease and the presence of an enteral tube, among others [264], [265]. The EWS was designed to evaluate patients in medical or surgical wards and to identify those cases that should be transferred to an ICU, but it could also be useful in identifying deterioration risk in critical patients and improving discharge planning. Furthermore, different versions of an EWS have been shown to be good predictors of mortality and length of stay [266]–[268]. Many clinical studies of different versions of the implementation of an EWS have been carried out in adult and paediatric patients, mostly in hospitals in the United States, the United Kingdom and Australia. Many of them use automated systems to calculate EWS scores and provide fast and efficient feedback for HCWs. Another important scale used in intensive care is the Sequential Organ Failure Assessment (SOFA) score used to predict clinical outcomes and mortality [100], [269]. This score considers the partial pressure of oxygen (PaO_2), the inspiratory fraction of oxygen (FiO_2), the presence of mechanical ventilation, the level of platelets, the level of bilirubin, the presence of hypotension, the Glasgow Coma Scale, the mean arterial pressure, the administration of vasoactive agents, the level of creatinine and urine output. The quick SOFA (q-SOFA) is a simplified version of the SOFA and only considers three parameters: Glasgow Scale, SBP and RR. A q-SOFA score of more than 2 points is able to identify possible cases of sepsis and is easier to calculate than the SOFA score because fewer hourly parameters are checked.

For activation of a code red, I considered the situation in which the EWS accumulates 7 or more points or if q-SOFA accumulates 2 or more points. A code red can also be activated and deactivated automatically or manually. The information layer recovers data every hour from the HIS and medical devices as well as processing them taking into consideration the clinical rules mentioned in Subsection 2.4.2.2.

Meanwhile, if a HCW detects a code red event that has not been detected by the clinical rules, they can activate the code red manually by pressing the Code Red button on Tablet 2 to warn their colleagues rapidly. The screens also change, with the new layout showing an alert, and a set of actions is triggered in the environment (Figure 32-33).

I prepared an experiment to test the code red scenario. I requested authorization from the Ethics Committee of HCB to analyse patient data from the HIS retrospectively (Annex 5) and then studied the evolution of NEWS scores as well as the clinical response at each moment. The AmI responses affecting the physical prototype once a code red is activated were also studied.

3.2.4. Code Pink Actions

More than 50% of patients in the ICU have some pathology related to a multi-resistant pathogen and HCWs need special equipment and clothes to protect themselves and the other patients [129], [270]. In all cases, people should disinfect all the material that is not disposable after it is used and should decontaminate

Figure 32. Code red screens.

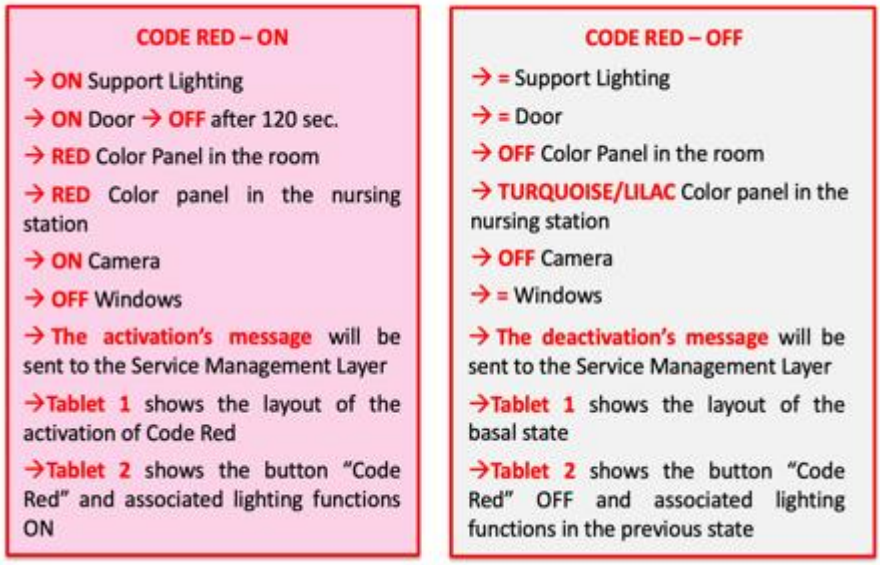


Figure 33. Code red actions. "ON" means that the functionality is active, "OFF" means that the functionality is inactive and "=" means that the functionality has not changed from the previous state.

surfaces with specific products in the environment around of patient. The code pink arose in the Hospital Clinic in Barcelona to indicate the cases of high-level isolation in which HCWs should have specific individual equipment to take care of patients due to the high risk of contagion [271]. In my case, there are two types of code pink that I present in Figure 34. In both cases everyone should wash their hands before entering and after leaving the patient room, the use of double gloves and safety glasses is recommended, as is exclusive use of all clinical material, and the patient room doors should always be closed. No visits are allowed.

In the first case, the isolation is more restrictive and HCWs should have a filter face piece respirator graded as FPP3 (98% filtration efficiency, ambient concentrations up to 50 VLA: high efficiency), impermeable gown and disposable leggings. This level of isolation precaution was used, for example, in patients with Ebola. In the second case, HCWs should use an FPP2 facemask (92% filtration efficiency, ambient concentrations up to 12 VLA: medium efficiency) and an isolation gown. This second level of isolation precautions was used for patients with SAR-CoV-2 infection.

A code pink event can only be activated manually, taking into consideration the clinical procedures established in Subsection 2.4.2.3. When doctors confirm a case for isolation, HCWs can select the right isolation poster by clicking on the hospital logo on Tablet 1. A tab with the different types of isolation protocols will appear. If there a code blue or code red has been activated previously, the layout of Tablet 1 will change image every 4 seconds: first the image of the clinical code will appear and then the isolation poster with the recommendations. If there is not

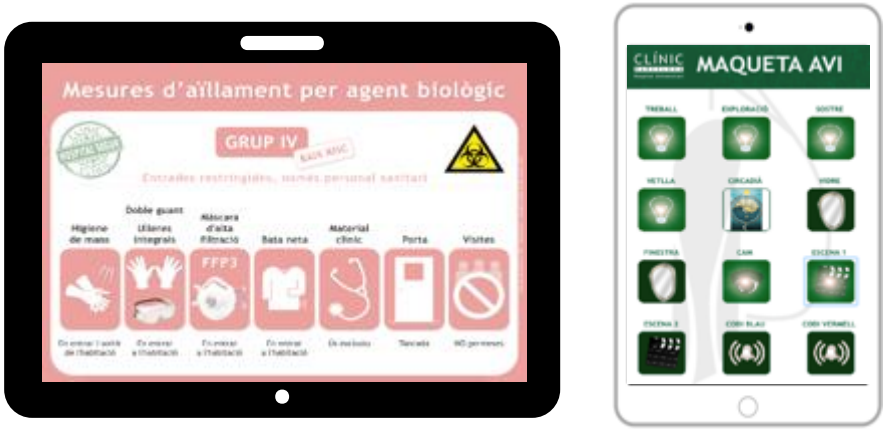


Figure 34. Code pink actions.

Figure 35. Isolation precautions considered in a code pink.

a code blue or a code red activated, then only the image of the isolation protocol previously selected will be displayed on Tablet 1 (Figure 35).

The colour panel at the nursing station and the colour panel in the room will become pink if there is no code blue or code red activated. If a code blue or code red is activated at some moment, then one of these codes will be activated and the colour panels will become blue or red, because the code blue and code red take priority over a code pink. To quit the layout of the isolation state, it is necessary to move the screen to right. The screen will return to the previous state. I tested the code pink scenario by simulating all the cases of isolation protocols and activating the different

options on Tablet 1. I also checked the functioning of the logical rules of the activation of a code blue, a code red and a code pink.

3.2.5. Hand Hygiene Actions

Health care-associated infections (HAIs) are defined as infections acquired by a patient in a hospital setting or in any other healthcare setting [272] – [274]. This definition includes occupational infections contracted by health professionals. According to the European Centre for Disease Prevention and Control, 4.1 million Europeans acquire such infections a year and of these 37,000 die.

On average, 1 in 20 patients receiving healthcare in Europe will be affected by an HAI [275], [276]. Hand hygiene (HH) is one of the most effective practices in reducing the transmission of HAIs. If we also consider its low cost, it is the main element promoted by patient safety systems in clinical settings. However, the rate of compliance with HH among HCWs (doctors, nurses, auxiliaries, and technicians) and visitors is less than 38% of the situations in which it should be performed [277]–[283], mainly due to workload and a lack of awareness of its importance. In 2009, the World Health Organization published a guide entitled "The 5 Moments of Hand Hygiene" with the aim of providing HCWs with a practical tool to teach and monitor the times when HH is required to effectively interrupt HAIs. The 5 moments of hand hygiene are:

- **Moment 1**: HH before touching a patient
- **Moment 2**: HH before a clean/aseptic procedure, such as opening a venous access line, giving an injection, or performing wound care
- **Moment 3**: HH after risk of exposition to body fluid
- **Moment 4**: HH after touching a patient
- **Moment 5**: HH after touching a patient's surroundings

More than one moment of HH can occur together, and in such cases a single HH action will cover the two or more moments for HH. Several authors have found that monitoring the habit of HH and generating reports can encourage compliance. This monitoring can be done both by direct observation and using electronic systems, as explained below.

• In direct observation, the activities of HCWs are followed and all the opportunities to perform HH are recorded (according to the "5 Moments"). However, this method does not provide a reliable number of missed HH opportunities because it encourages HH when HCWs feel they are being observed (the Hawthorne effect). To minimize this behavioural change, many researchers make observations using cameras. In addition, in this way observer bias can be avoided in accounting for HH opportunities [284].

• Electronic systems monitor HH in real time, and can collect and analyse data. These systems allow opportunities of HH by HCWs to be detected, as well as notifications to be sent in real time. This can teach recommendations about HH when necessary and report data on the fulfilment of HH, or even predict if HCWs will not wash their hands through the use of probabilistic models [285]–[288], and thereby be able to establish direct and precise advice. However, previous studies have shown the difficulty of implementing these systems, mainly due to the resistance to change of HCWs and their perception of being controlled. Other factors that do not favour such systems are their high cost of acquisition and maintenance.

Previous studies have not demonstrated clear effectiveness of either direct observation systems or electronic systems in incentivizing HH in the ICU. However, all these studies suffer from being of short duration (with a mean of 24 weeks: 91 weeks, the longest), not having a record of all the moments of HH, and not providing feedback to HCWs. Neither is there any information on the behaviour of non-healthcare personnel (cleaners, porters, maintenance technicians, etc.) and HH.

I discussed different hand hygiene promotion messages with the medical and nursing staff of the ICU, which were then designed, and implemented. Notifications and recommendations were customized according to the professional category of each HCW, NHCW and visitors, as well as according to their most common activities. In addition, a report of the compliance rate of the personal was elaborated monthly. HH notification and incentivization messages were created in collaboration with the designer Seiji Bernabela of the Eindhoven University of the Netherlands for research and academic purposes: https://bernabela.myportfolio.com/.

Figure 36 shows photos of one of the clinical sessions carried out to discuss hand hygiene promotion messages. I present a set of images that resulted from the sessions and were used in the study. The flow of notifications and recommendations are grouped into five cases.

Case 1: When a HCW, NHCW or visitor needs to enter the patient room

Figure 36. Images of the clinical sessions organized to discuss the hand hygiene promotion messages.

- The moment in which the HCW or NHCW uses the electronic dispenser, the RFID identification is activated, and Display 2 will sequentially show the patient's isolation status and the HH compliance rate (target, current month and previous month) (Figure 37-40).

- If the HCW or NHCW has entered without using the electronic dispenser, Display 3 will show an entry warning notification.

- Display 4 will not change from its usual state of building automation control functions.

Case 2: While a HCW or NHCW carries out activities inside the room

- Display 3 will show the following HH recommendations, in a single 10-second sequence, repeatable every 30 min, depending on the HCW or NHCW:

• "Remember to comply with the requirements of patient isolation"
• "Please disinfect your hands before and after touching the patient's bed and devices/tablets"
• "Please disinfect your hands after touching the workstation"
• "Disinfect your hands before and after performing an aseptic clean task"
• "Don't forget to disinfect your hands between different activities"
• "Please wash your hands after risk of exposure to body fluids"
• "Please discard your gloves and disinfect your hands when leaving the room"

- The display 4 will show a "Remember to disinfect your hands in the external dispenser" notification when the door is opened.

Case 3: While visitors are inside the patient room

- Display 3 will show the following HH recommendations, in a single 10-second sequence, repeatable every 30 min (Figures 38-41):

• "Remember to comply with the requirements of patient isolation"
• "Please disinfect your hands before and after touching the patient's bed and devices/tablets"
• "Please disinfect your hands after touching the workstation

Case 4: The HCW, NHCW or visitors leave the patient room

- Display 4 will display the message "Remember to disinfect your hands" when the door is opened.

- If the HCWs, NHCWs or visitors have left without using the electronic dispenser within two minutes, Display 3 will show an entry warning notification.

Case 5: When families are wait for visiting hours outside the unit

I drew up a layout for Display 1 regarding the procedures that visitors have to perform before entering a unit and in a patient room (Figure 40). In addition, a video was made explaining all the steps that people must follow to access the unit. The video is displayed in the family hours together with the recommendation screen. The designer Elia Gil Peña helped design some of the figures for this interface.

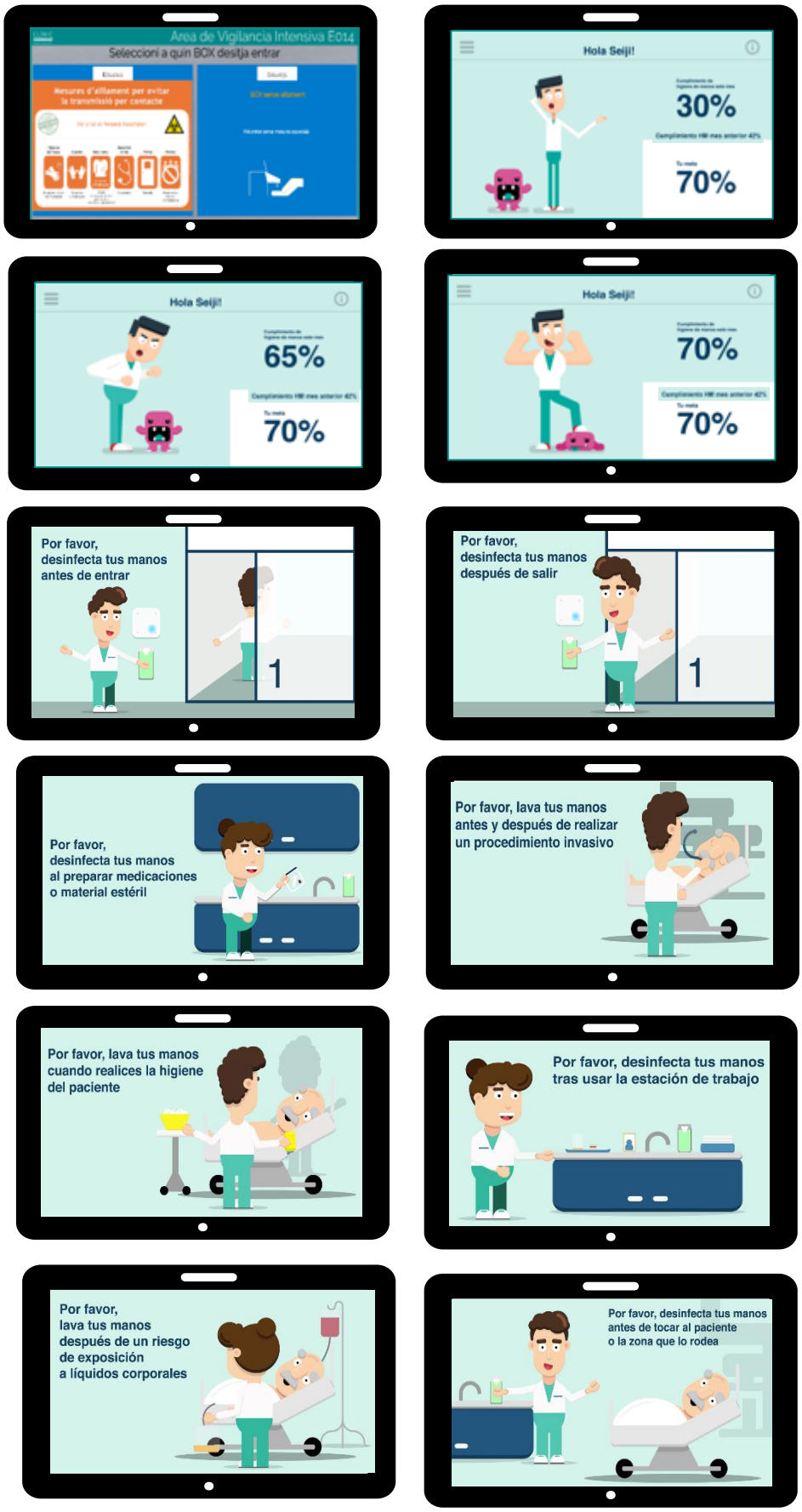


Figure 37. Part I: Recommendations about hand hygiene habits in clinical settings for HCWs and NHCWs.

Figure 38. Part II: Recommendations about hand hygiene habits in clinical settings for HCW and NHCW.

A)

B)

Figure 39. Recommendations about hand hygiene habits in clinical settings for visitors. A) Recommendations designed to be used in patient rooms for visitors (top). B) Recommendations designed to be used at the entrance of medical ICU of HCB (down).

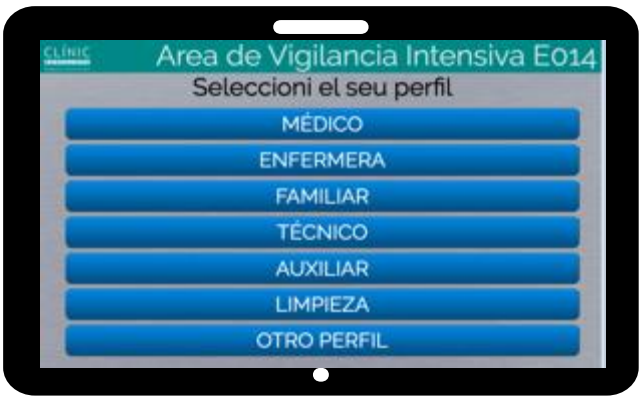


Figure 40. Screens to select the profile for ICU visitors.

I prepared an experiment to test the effectiveness of the hand hygiene scenario using the HCW, NHCW and visitor usability data generated by the system in order to measure the impact of the intervention on patients and daily clinical routines.

I also requested authorization from the Ethics Committee of HCB to analyse the clinical data (Annex 6 and 7). In addition, I tested all the antennas of the system, the electronic dispensers, and the application of the information layer in order to measure the accuracy and the sensibility of the whole system.

3.2.6. Medication Management Actions

Nowadays, medication safety is a priority for healthcare organizations because it is a major indicator of healthcare quality. The medication error (ME) is the most common type of medical error to occur in hospitals [234] and is defined as an error that occurs at any step of the pathway that begins with the prescription of a medication and ends with its administration to the patient [235]. An increase in the length of stay, permanent disabilities and death are consequences that are attributed to incorrect medication management.

In ICUs, 78% of all medical errors which generate adverse effects for patients are errors in medication, and many patients can suffer a potentially life-threatening error during their stay as a consequence if the errors are not detected in time [236]. Moreover, MEs are more serious in ICUs because patients have a complex clinical status, with a high risk of sudden deterioration of their vital functions: they are vulnerable to any incident that affects their health and are exposed to a large number of medications for a long period of time [237].

Medication dosing particularly has been studied in depth [238][239][240][241] to make the correct estimation of a personalized dose of a

medication, considering different dose–response relationships and patient phenotype, as well as to predict future medication doses. In order to decrease MEs in ICUs, some hospitals are developing intelligent monitoring systems to detect MEs in critically ill patients in real time using advanced techniques of data analytics with the aim of identifying potential MEs and creating error alerts on the HIS [242][243]. These new systems can detect, classify, quantify, and issue notifications concerning errors generated in four main stages of medication management: prescription, transcription, dispensing and administration (Figure 41). To make the system more effective, the engagement of a multidisciplinary team—formed of nurses, assistants, managers, physicians, pharmacists, and physiotherapists—is necessary from the development phase until implementation. This disruptive technology will change paradigms in critical care, altering the organizational culture of clinical staff, and improving both patient safety and the management of medication by nursing teams as well as medical diagnosis and treatment of hospitalized patients. Similar systems can be applied for monitoring artificial nutrition (enteral and parenteral nutrition) and metabolism in critical patients.

I collected data from four different sources of medication management (medical prescription and nursing administration from the HIS as well as the tracking of medication dispensation and infusion pumps) to detect discrepancies in some of these steps. Figure 42 shows the data collection I carried out in the medication dispensation of the Smart ICU. The medication dispenser is well-known Pyxis® model [244]. Moreover, I designed new layouts with the information on the infusion pumps in the unit in collaboration with the technician Jordi Montoya from Tecnopixel (S.A., Spain) and I created new alerts concerning manipulation of infusion pumps (Figure 43).

I prepared an experiment to test the medication management scenario. I requested authorization from the Ethics Committee of HCB to analyse the data related to medication from the HIS as well as data generated by the medication dispenser and by the infusion pumps (Annex 5). I also tested the messages about the manipulation of infusion pumps and analysed the discrepancies found in the different steps of medication management.

3.2.7. Acoustic Elements Actions

Environmental noise is a major public health problem and is considered one of the main environmental health risks. It has a negative impact on human health and wellbeing and is a growing concern among the general public and policy makers in Europe [245]-[247]. The WHO recommends that the average sound pressure levels measured over time should not exceed 30 dB in hospital wards and 35 dB in intensive care and anaesthetic recovery units [250][251]. The exposure to noise can

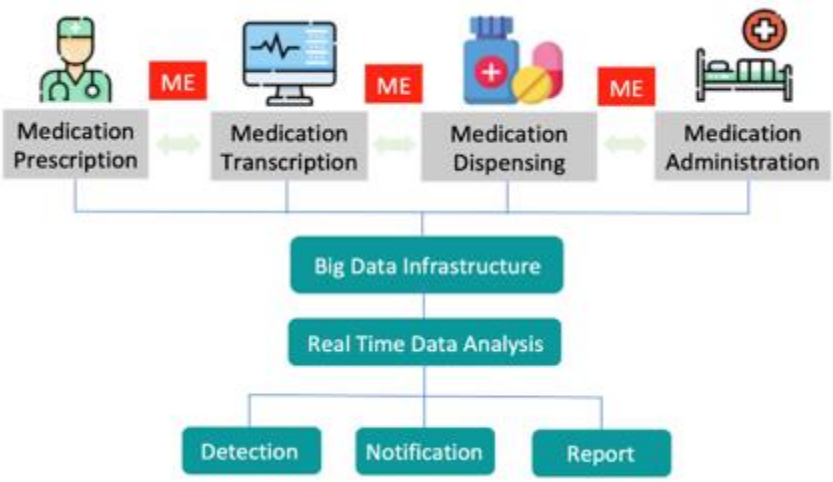


Figure 41. Management and monitoring of medication.

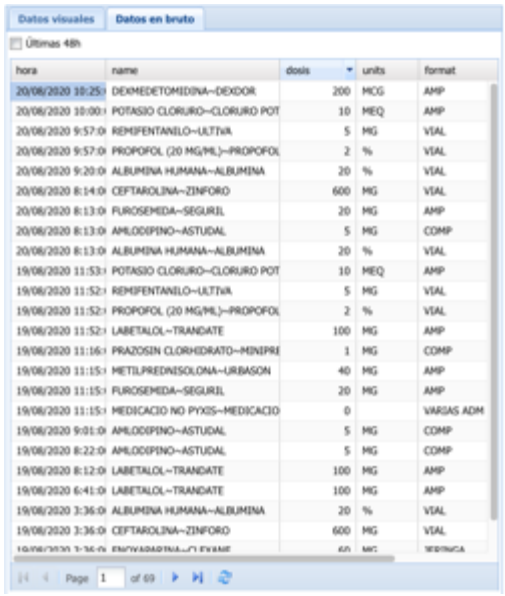


Figure 42. Collection of medication data from Pyxis®.

cause negative effects on the health and wellbeing of patients and health professionals. A lot of effects on the cardiovascular and hormonal apparatus have been described as well as cognitive effects.

This situation is especially striking in the ICUs, where monitoring technology and therapeutic devices are associated with alarms that generate noise [248]- [254]. I collected data related to the sound meter installed at the nursing station and the ceiling speaker installed in the patient rooms at the unit, in order to measure the noise that patients hear and to inform people when the noise surpasses acceptable limits. In addition, I also counted the times the ceiling speaker was used in the unit. I calibrated the acoustic devices and identified the moments when there is more

Figure 43. Different layouts created with the data from infusion pumps.

noise in the unit during daily practices. This study was approved by the Ethics Committee of HCB (Annex 8).

3.3. Discussions and Conclusions

The development of the cases in which the AmI environment prototype is use is based on the main indicators of patient safety for ICUs. All the cases of use were designed with the objective of decreasing preventable adverse events in the ICUs and improving the quality of patient care. In all events, the clinical needs were explained, and the predefined responses of the environment were described.

PHASE II.

IMPLEMENTATION IN A REAL ENVIRONMENT

CHAPTER 4. IMPLEMENTING THE PROTOTYPE IN A REAL ENVIRONMENT

4.1 Introduction

In this chapter, I describe the implementation of the AmI environment in the Smart ICU at HCB. The IoT devices were integrated in an electrical panel outside the unit and a server called Infobox was created in the IT Department of the hospital to manage the data generated by medical and non-medical devices.

The main objectives of Chapter 4 are:

- To present the main phases of the implementation of the AmI Environment in the Smart ICU at HCB.
- To describe the process of installation of the electrical panel and the ambient control interfaces.
- To understand how the Infobox server web application was implemented in the Smart ICU.
- To explain the implementation of a code blue and a code red in the Smart ICU as well as the medication actions and acoustic actions.
- To describe the implementation of the hand hygiene monitoring system in the ICU.

4.2. The Medical ICU at the Hospital Clínic in Barcelona

The medical ICU where I implemented the AmI environment is located on the fourth floor, by stairway number one, of the main building of the Hospital Clinic in Barcelona [255]. This unit was inaugured in March 2014 and has five patient rooms around a nursing station, thus allowing continuous visual monitoring (Figure 44 and 45).

There is a remote control of all medical devices (including the vital signs monitors, infusion pumps and continuous renal replacement machines) and non-medical devices (including nursing call systems, lighting, the HVAC system, polarization of doors and windows as well as the multimedia content of the displays) in the patient rooms, operated from the nursing station.

Figure 44. Medical ICU at HCB. View from the entrance to the unit.

Since its inauguration, the unit has been remodelled each year during the summer vacations to improve the installations, facilities, and technology. The hardware elements were installed in the summer of 2016 and the software has been gradually implemented since January 2017.

The ICU is designed to take care of patients with contagious diseases (such as influenza, Ebola, coronavirus, Lassa fever, yellow fever, meningitis, zika virus and human immunodeficiency virus) as well as immunodeficiency disorders (such as leukaemia, X-linked agammaglobulinemia, lymphocytosis, purine nucleoside phosphorylase deficiency, transcobalamin II deficiency and selective IgA deficiency) [256][257][258][255].

The rooms of the ICU are soundproofed, numbered from 0 to 4, and have sliding glass doors that should be closed while a patient is present in order to avoid horizontal transmission of infections and also to protect patients from contact with other pathogens transmitted by the air.

Patient room number two (Figure 45) has an additional antechamber and a restroom. In this room, it is possible to activate positive and negative pressure, while in the other rooms only positive pressure can be activated. In addition, in all the rooms, patients are connected to vital signs monitoring devices and a large amount of clinical data is continuously generated.

I tested and implemented the integration of data from different IoT devices in the unit in the information layer of this study (Figure 46). The devices presented different communication protocols and programming languages. With the help of the providers, it was possible to integrate all the data generated in the ICU in real time. The Infobox server manages all the processes of data collection and analysis, as well as the distribution of useful information to the displays in the unit.

Support Zone I corresponds to the machine storage area and Support Zone II corresponds to the maintenance and cleaning area. Implementation of the AmI environment was divided into three main phases: implementation of the building

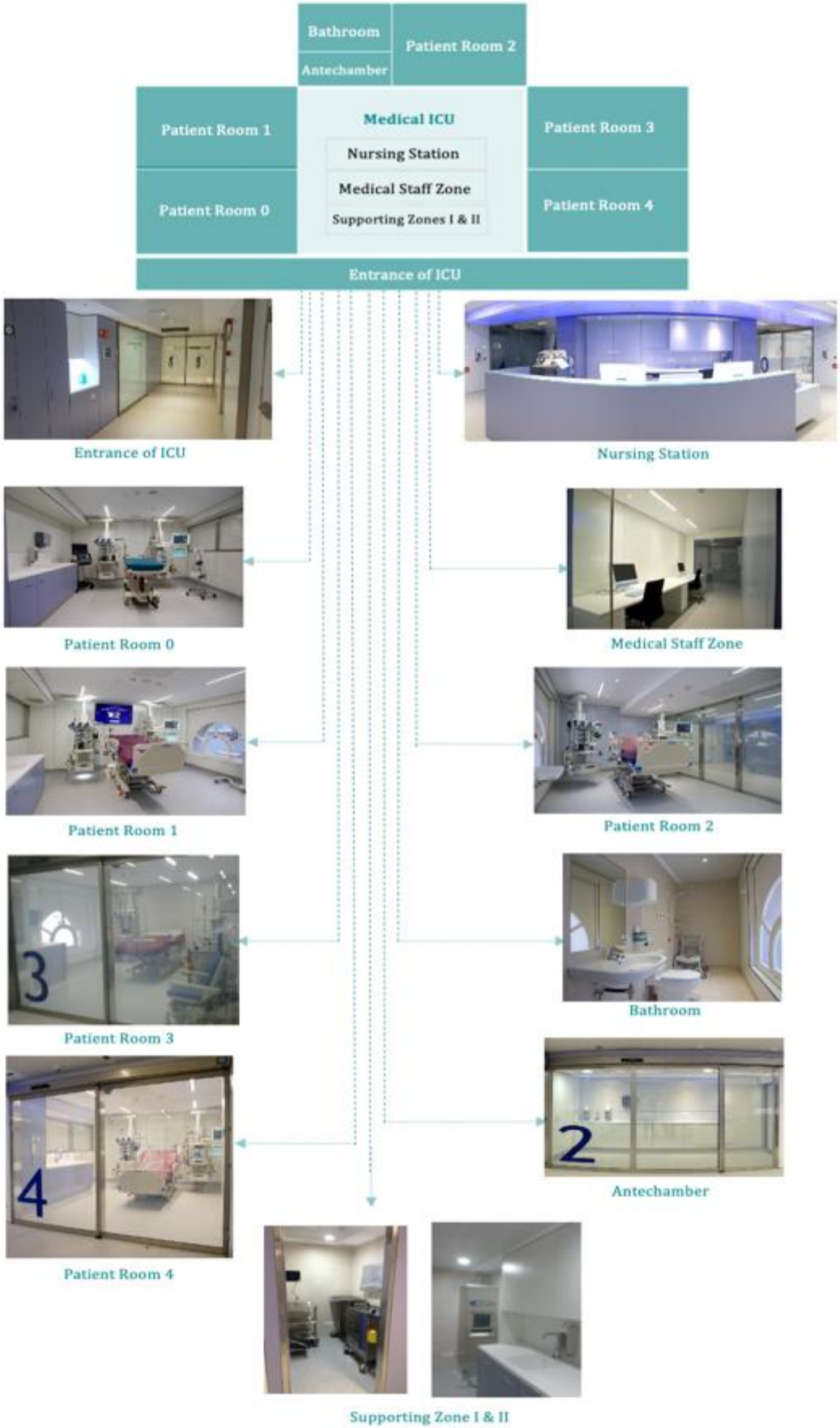


Figure 45. Architectural distribution of the medical ICU at HCB.

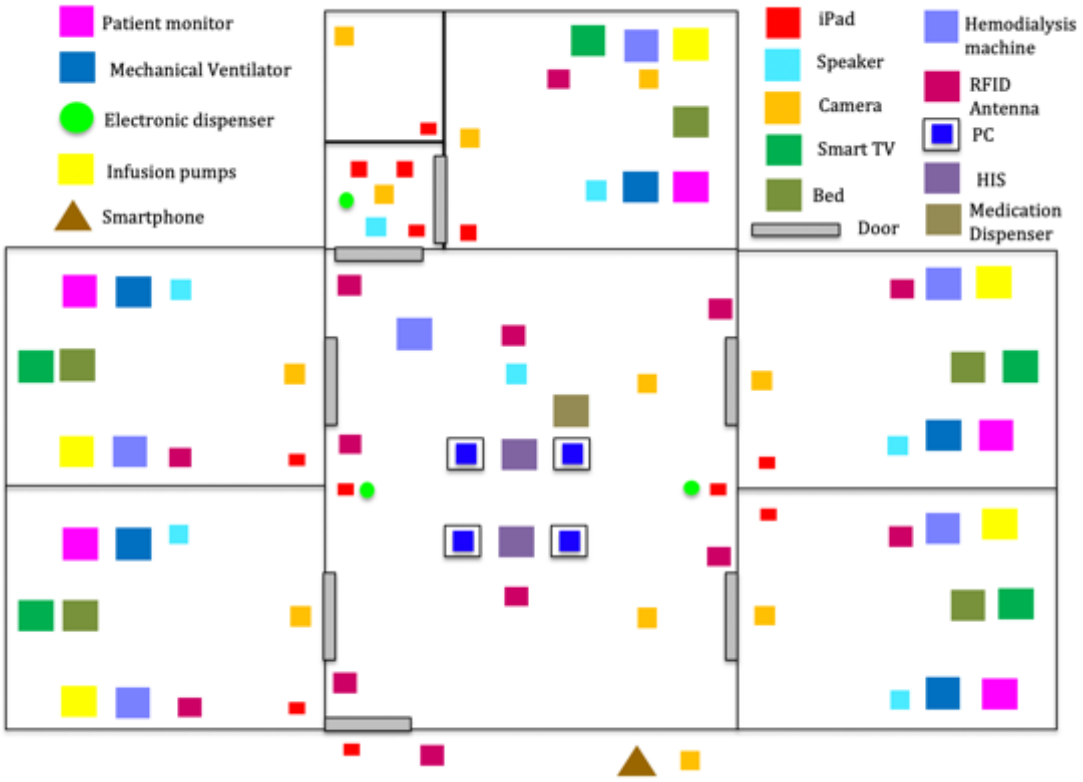


Figure 46. Connectivity of the IoT devices in the medical ICU at HCB.

automation system, implementation of the clinical resources, and implementation of the hand hygiene system.

4.3. Phase I: The Building Automation System

4.3.1. Installation of the Electrical Panel

Once I tested the prototype and checked all the functionalities of the building automation system, an electrical panel was installed at the unit following the same technical requirements as those of the prototype. The electrical and network cables from the ceiling of each room and the nursing station were transported to the electrical panel separately, to avoid electromagnetic interferences.

The electronic modules of the prototype were tested for operation in one patient room and in the electrical panel these modules will be multiplied by five (Figure 47). The first row of the electrical panel corresponds to the electronic modules from the nursing station, the Scena module and two SmartServers. One of the SmartServers functions all time and the other is reserved for possible issues in the network or electrical lines.

If neither SmartServer works, or if there is a problem in an electrical panel, then the lights in the unit can be manually controlled from the machine storage area

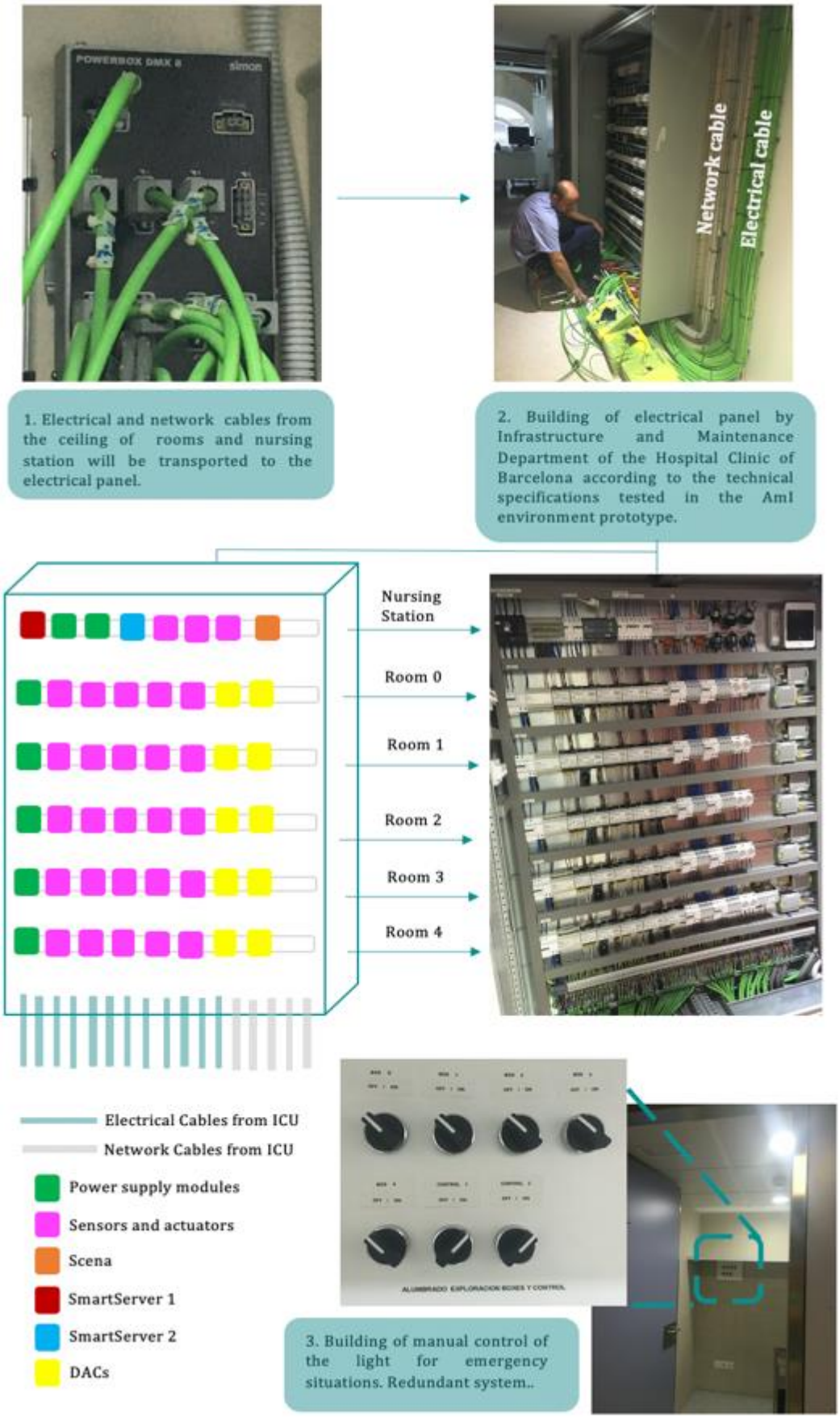


Figure 47. Construction of the electrical panel for the prototype.

of the unit, as a redundant system. From the second and up to the last row of the electrical panel, the modules correspond to patient rooms number 0, 1, 2, 3 and 4, respectively. Figure 48 presents the programming of different colour scenes that can be programmed with the Scena module. In the current implementation, the colours blue, red and pink were used.

In this implementation, a total of 42 new network cables were installed: 13 corresponding to the new iPads; 2 corresponding to the additional cameras (Axis Communications, USA) in room 2; 10 corresponding to the DACs of the electrical panel; 2 corresponding to the SmartServers: 1 corresponding to the Scena module; 2 corresponding to the computers in the medical staff zone; 5 corresponding to the smart displays; and 7 corresponding to the ceiling speakers.

Network communication with the iPads was implemented in two ways in order to guarantee maximum availability of the system. The iPads access the VLAN via a cable (with an ethernet adaptor) or via the Wi-Fi. If the Wi-Fi has a technical issue, the system can notify of the failure and the cable connection can then be activated.

4.3.2. Implementation of Ambient Control Interface in Patient Rooms and the Nursing Station

In each of the five patient rooms and also the nursing station, an iPad was added to control remotely the lights, the polarization of the glass, the music and the multimedia content of the screens (Figure 49). The display at the nursing station presents some direct access to the activation of some functionalities in the patient rooms, because these functions are the most commonly required and important functions. The display has direct access to the buttons “Code Blue”, “Code Red”, “Control”, “Monitor”, “Indicators”,” “Lighting”, “Privacy” and “Night”.

I will explain the buttons “Control”, “Monitor” and “Indicators” in the next subsection, because they involve access to the multimedia content of the patient rooms. The buttons “Code Blue” and “Code Red” indicate automatic activation of these colour codes in the unit, either automatically or manually. The button” Lighting” opens a new tab with control of the lighting in the patient rooms; the button “Privacy” activates the opacity of the patient rooms; and, finally, the button “Night” decreases the brightness of the patient room displays. The button “Night” corresponds to “Scenario 1” of the prototype layout. Moreover, in the layout of the nursing station, the colour of the patient rooms can be turned to blue or orange. A code blue indicates that the patient room is not under any type of isolation protocol, while the colour orange indicates that the patient room is under isolation protocol. In order to know the type of isolation protocol active in a patient room, it is

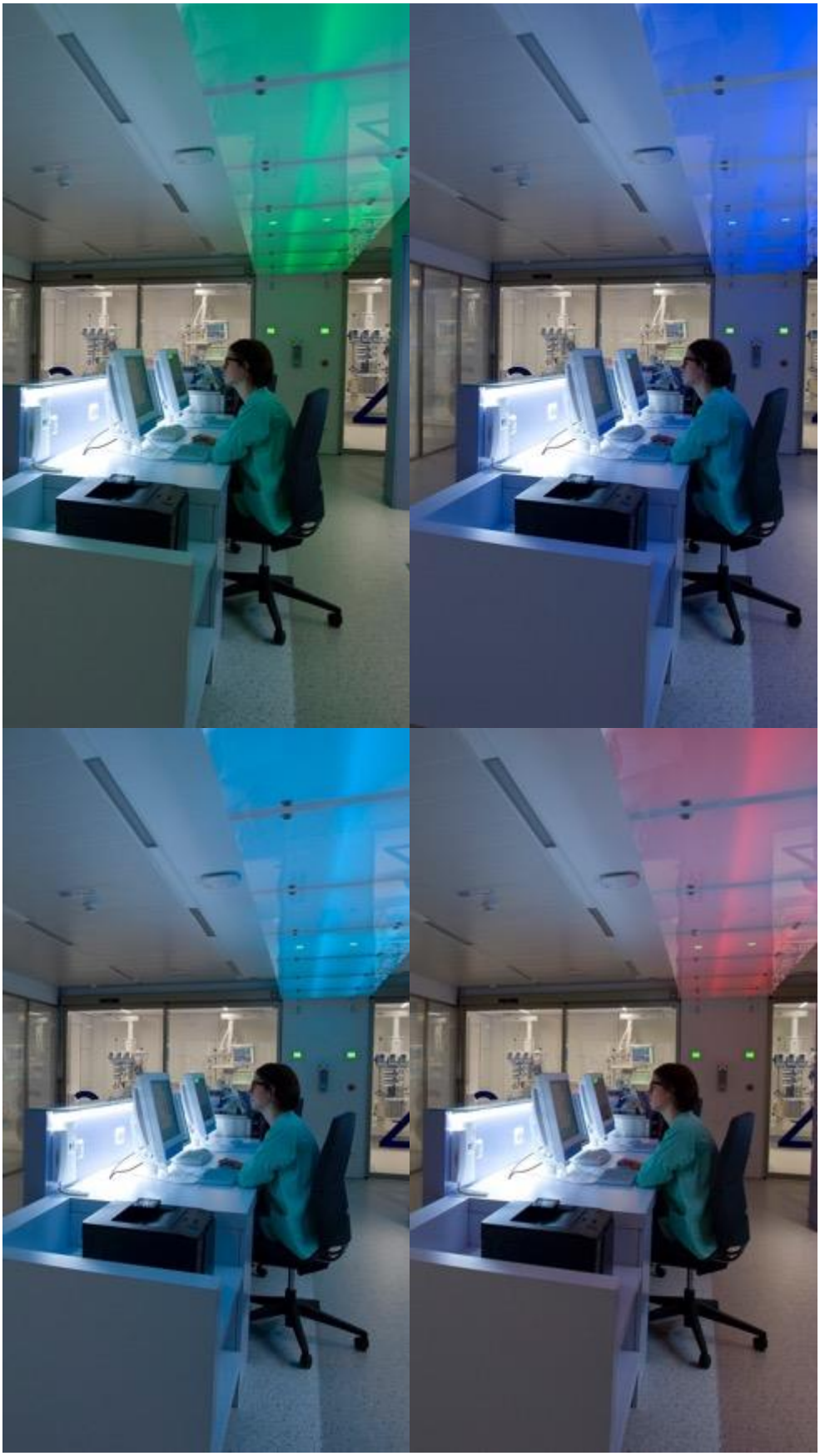


Figure 48. Programming of the Scena Module at the nursing station panel in the ICU.

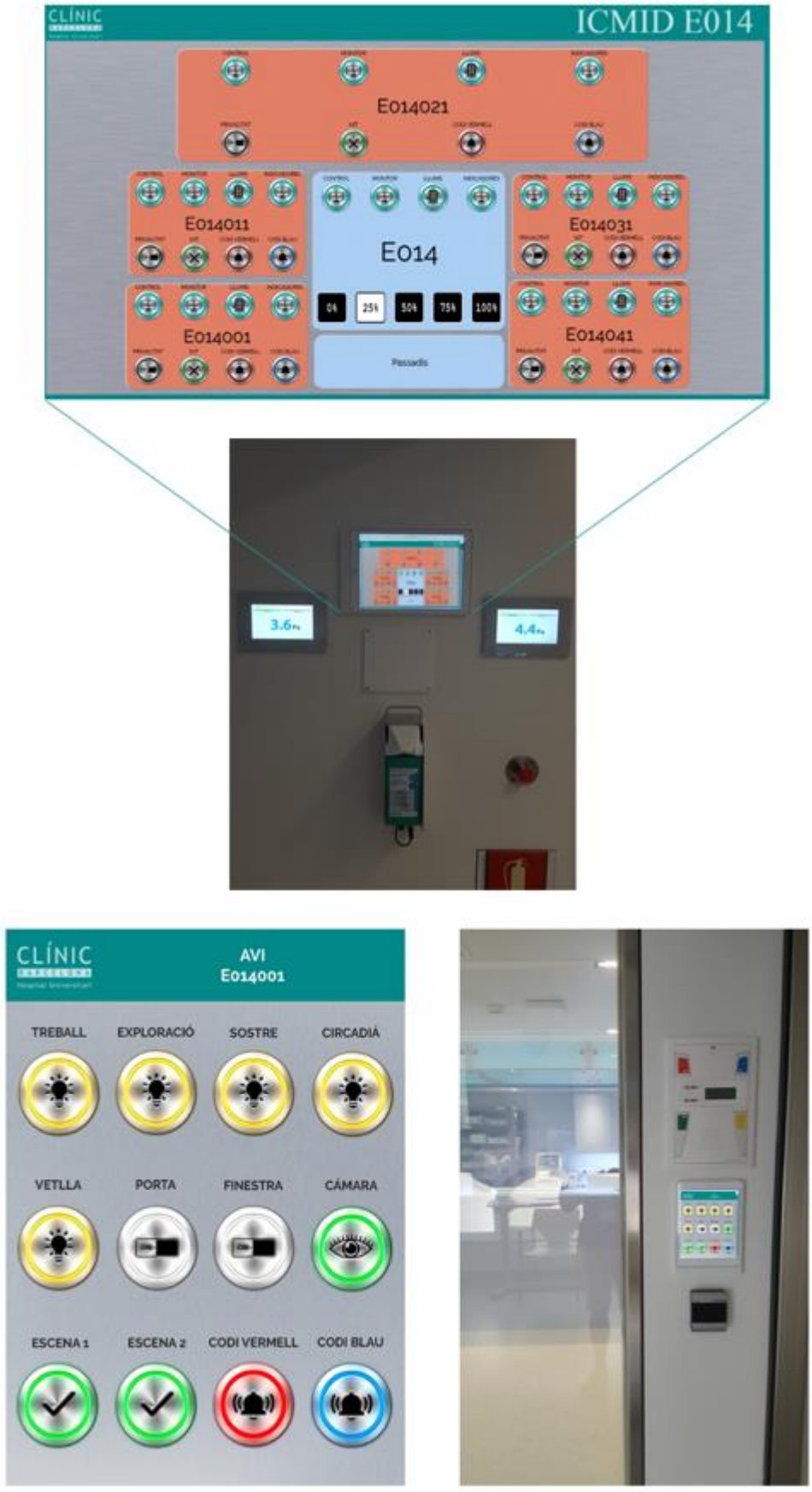


Figure 49. Implementation of the new design of the lighting control and clinical alerts at the nursing station and in the patient rooms, respectively.

necessary to wash your hands; and the layout on the iPad at the nursing station will show the isolation room of all the adjacent rooms.

I updated the design of the light buttons with the help of nurse Isaac Hernandez, who works in this unit on the night shift. He designed all the new buttons and the new icons. The logical rule for a code blue, red or pink in the unit is the same as for the prototype. In other words, a code pink has priority over a code blue and red, for the colour panel in the patient room and for the colour panel at the nursing station.

For the five patient rooms, the colour panel in the patient room will turn to the colour of the activated colour code; but the colour panel at the nursing station will turn to the colour of the activated colour code respecting the priority of the codes. For example, if patient rooms number 0 and 1 have a code red at the same time, while patient room 2 has a code pink and patient room 3 has a code blue, the colour panel at the nursing station will turn pink. Then, if the code pink in patient room 2 is deactivated, the colour panel at the nursing station will become blue; and if there is a deactivation of the code blue, then the colour panel will turn red. Finally, if there is a deactivation of the code red, the colour panel at the nursing station will turn turquoise during the day shift (8:00:00 a.m. until 9:59:59 p.m.) or lilac during the night shift (10:00:00 p.m. until 07:59:59 a.m.).

4.3.3. Implementation of the Video Surveillance System

A bespoke remote video surveillance system was implemented to facilitate access via the cameras for medical and nursing staff in the case of emergency situations (Figure 50). By double clicking on one of the camera streams, the streaming from only one camera can be visualized in more detail and the streaming can be moved in four different directions. This system was synchronized with the camera button of the ambient control interface in the unit.

I registered 50 professionals in the unit and undertook educational training with them. This system was mainly used to visualize the parameters of the medical devices without entering a patient room, due to the high risk of infections contagion. In addition, I applied all the security measures and the staff use their Hospital Clinic email credentials to gain access to this application.

4.3.4. Implementation of Noise Level Management

I implemented a SoundEar device (SoundEar, Norway) at the nursing station and a professional sound meter and microphone in patient room 1 at a distance of 1.5 m from the patient, in accordance with the biomedical regulations,

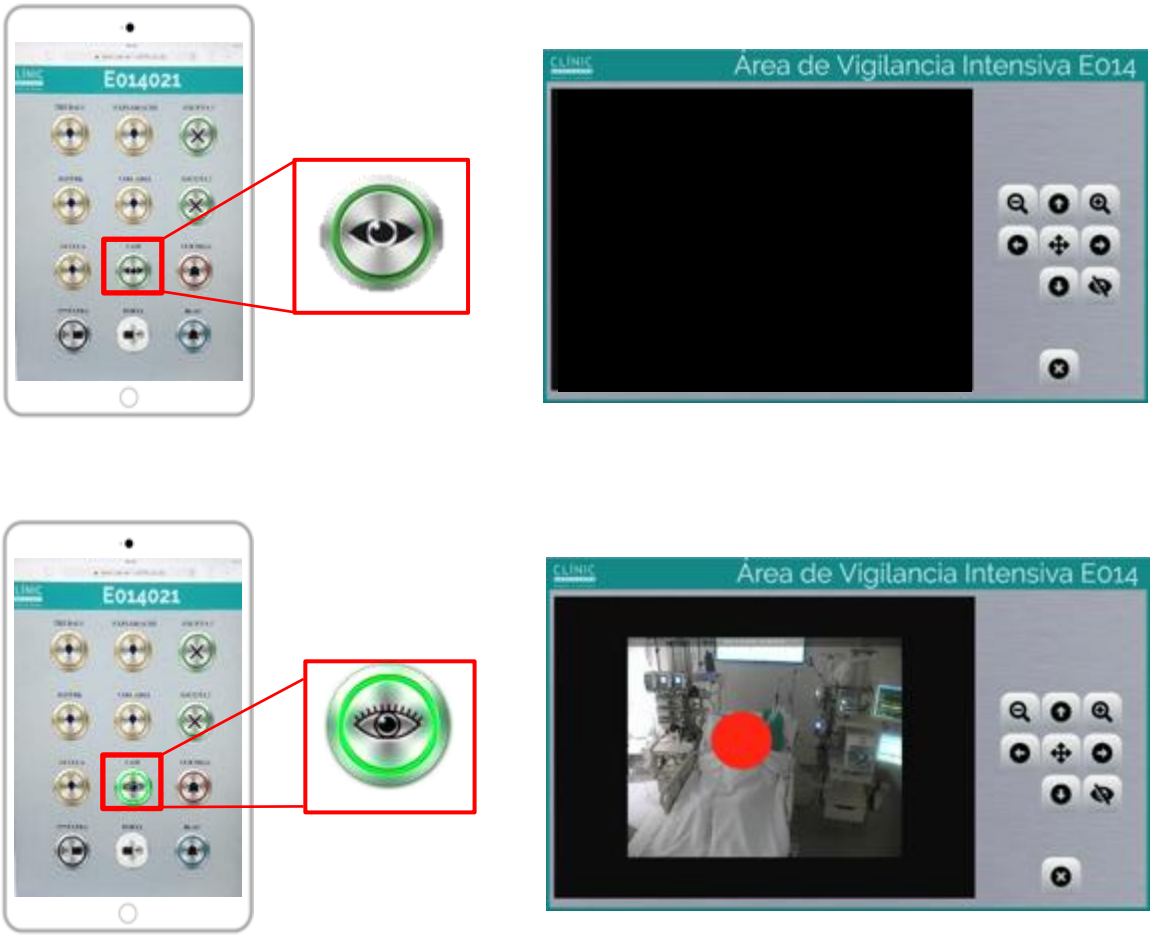


Figure 50. Video surveillance system created as part of the information layer of the AmI environment.

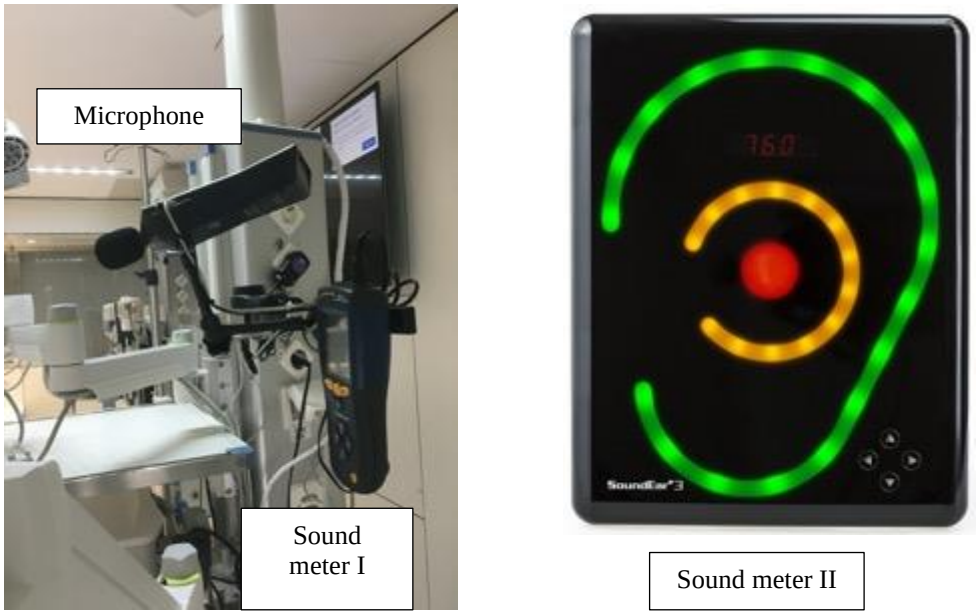


Figure 51. Sound devices in patient room 1 and at the nursing station.

in order to measure the noise generated at the nursing station and the noise that arrives at the patient (Figure 51).

4.4. Phase II: Clinical Resources

4.4.1. Implementation o*f* the Web Application in the Infobox Server

A web application was developed and implemented to register the clinical resources generated in the unit during 2018 and 2019. The web application is chiefly divided into four categories: resources, zones, events and users (Figure 52).

"Resources" contains a large variety of multimedia files such as videos, web files, collections of images, layouts, clips of information, URLs, pdfs, controllers and widgets. All this media content was used to design the display screens for the Smart ICU. The widgets form an automated part of the application which analyses each dataset separately and shows the results on a predefined dashboard. I used the widgets to construct the logic for the code blue, code red and code blue alerts, as well as to monitor hand hygiene in the unit. Moreover, the controllers were used to design the ambient control interface and the clinical resources control interface.

"Zones" was used to build a structure that included all the devices and the architectural elements of each unit. It is also key for the design and distribution of the IT devices in each patient room and at the nursing station. Zones includes a list of remote connections with the IoT devices and servers to provide online access to

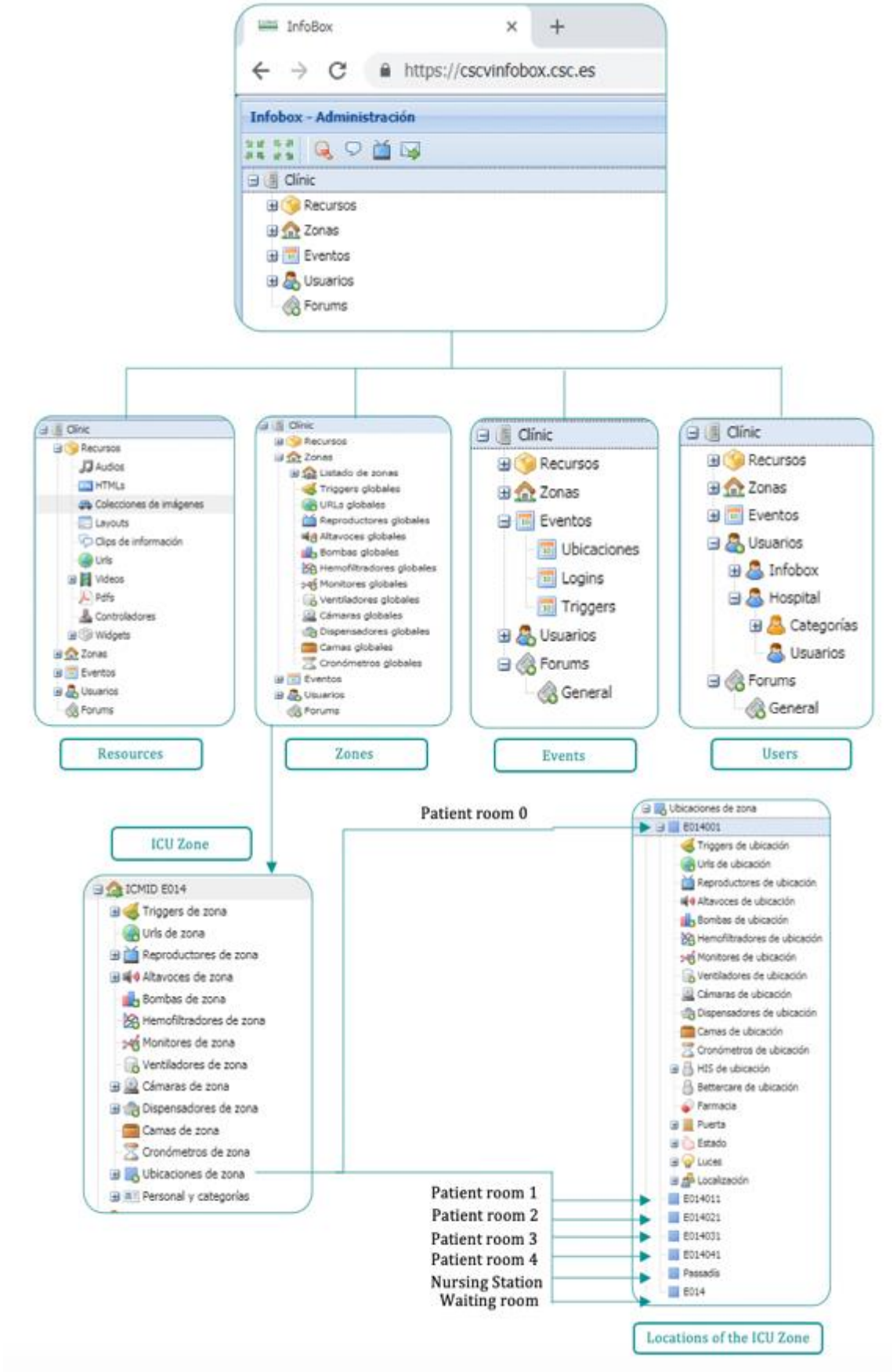


Figure 52. General structure of the Infobox web application.

Figure 53. Clinical resources control interface in a patient room.

the triggers, URLs, displays, ceiling speakers, infusion pumps, haemodialysis machines, lists of locations, cameras, electronic hand hygiene dispensers, drug dispensers, vital signs monitors, ventilators, beds and the movements collected by the RTLS. In addition, for a specific zone, there is a list of locations where monitoring of ambient parameters, such as light, doors, windows, state of the chronometer and the state of the pressure, takes place.

"Events" houses a register of all the activities that occur inside a specific area, as well as all the register of the logins and triggers activated by the users. Finally, "Users" contains registers of all the users who can access the web application with different types of access permissions.

4.4.2. Implementation o*f* the Clinical Resources Control Interface

The clinical resources control interface was developed in the Infobox server in order to manage all the clinical information on the displays in the unit (Figure 53 - 54). The interface works the same way a TV remote control does: if you touch a button, the TV screen in a patient room will display the layout associated with this function. The button "Resting State" is automatically activated when a patient is discharged from the unit. The button "Privacy" is used to indicate situations in which it is not allowed to enter a patient room for a certain reason, for instance, during family visiting hours or an X-ray test.

Figure 54. Examples of the layouts that the clinical resources control interface can display on the screen in a patient room.

The buttons “Vital Signs Monitor” and “Infusion Pumps” display the information on these devices in real time. The button “Patient Data” recovers data from the HIS and displays the latest information generated by this system, such as microbiological results, laboratory results, validated vital signs data, medication prescriptions or medical and nursing instructions. The button “All Patients” displays the latest data for all the patients on the medical devices; and the button “Isolation State” has a list of isolation states and staff can select the most suitable one for the patients.

When a level IV isolation state (either IV.A: state of low risk; or IV.B: state of high risk) is activated, the colour panel at the nursing station turns pink. The code pink was only implemented for these two cases; for other isolation cases, the colour panel at the nursing station does not change colour. In addition to this AmI response, the sensor at the door of the ICU entrance was blocked and the layout of the tablets in the unit changed in order to inform the healthcare workers of the extraordinary measures.

The buttons “Music Therapy” and “Background Music” have a pre-programmed list of songs, which are played for one hour. The button “Patient Lighting” opens the lighting layout of the patient room, as presented in Figure 53. The button “Turn off TV” is used to turn off the TV display when necessary. The TV display is automatically turned off from 10 p.m. to 7 a.m. in all patient rooms.

4.4.3. Implementation of a Code Blue and a Code Red in the ICUs

I collected the clinical data from the vital signs monitors in the unit using Visual Studio and the data libraries from the provider. I implemented the code blue clinical algorithm presented in Figure 27, and tested the AmI responses in the real environment (Figure 55).

For the code red, firstly, I collected the clinical data from the HIS and organized the data into four different categories: administrative data, validated vital signs data, medication information and laboratory results. The administrative data presented in Figure 56 take into account any limitation of therapeutic effort (LTE), the patient’s age, length of ICU stay, length of hospital stay and the presence of an isolation protocol. The validated vital signs data include all the vital signs validated by the healthcare staff.

A clinical decision rule was created for each vital sign, in order to select the proper parameter (Figure 57-58). For example, for heart rate (HR), the clinical decision rule established by the ICU doctors first considers the HR obtained by electrocardiography. If this parameter cannot be evaluated at a given moment,

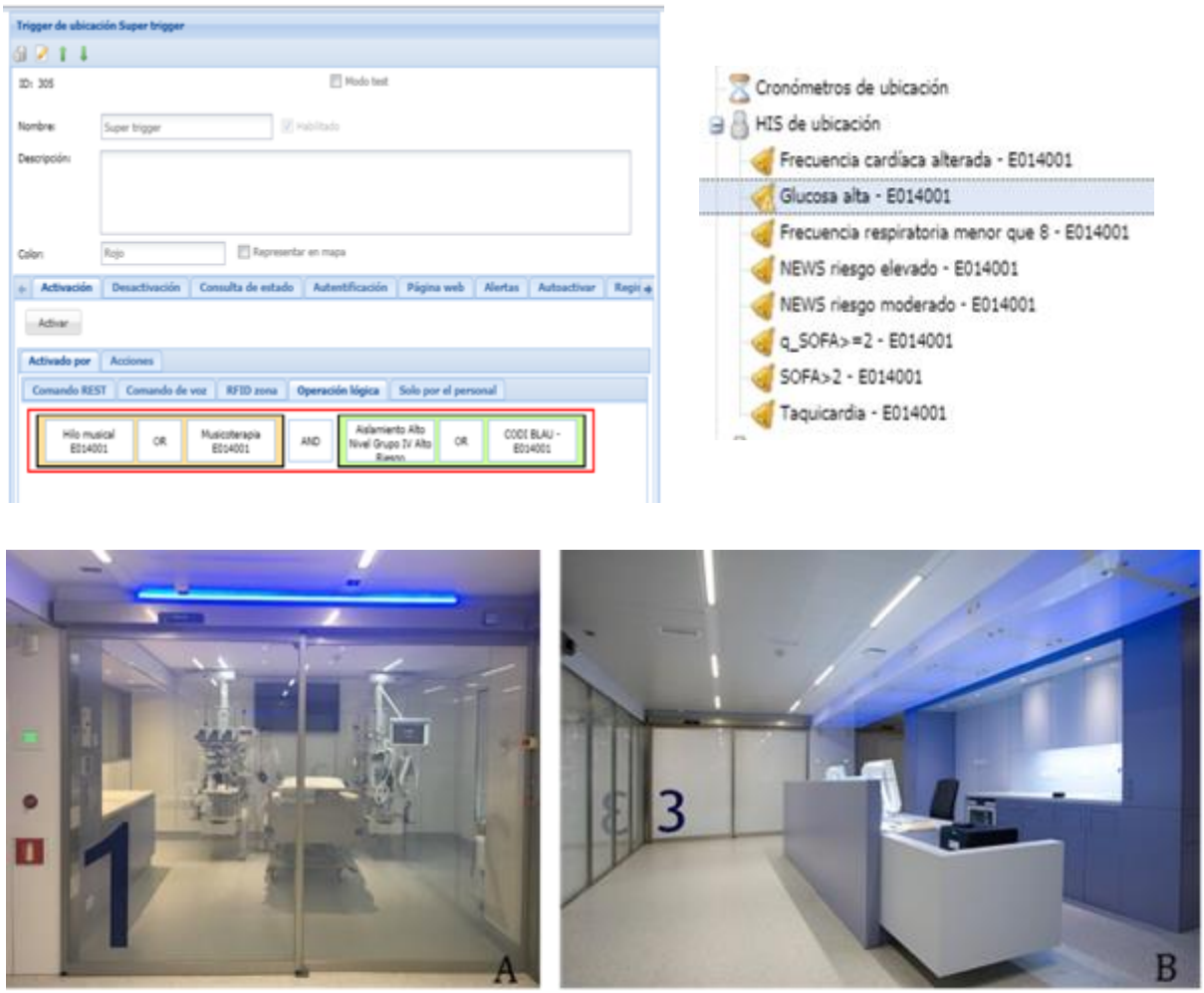


Figure 55. Construction of the code blue algorithm in Infobox, and the AmI responses in the ICU.

Figure 56. Administrative data collected by the Infobox web application.

the HR obtained from the blood pressure waveform is considered. If this parameter is not available, then the availability of HR provided by plethysmography, oscillometry, auscultation and pulse is checked, in this order. If one such parameter is available, that specific parameter is used in the calculation of the clinical indicators. If no HR value is available, then this parameter is not used in the

Figure 57. Logical rules for vital signs parameters: Part I.

Figure 58. Logical rules for vital signs parameters: Part II.

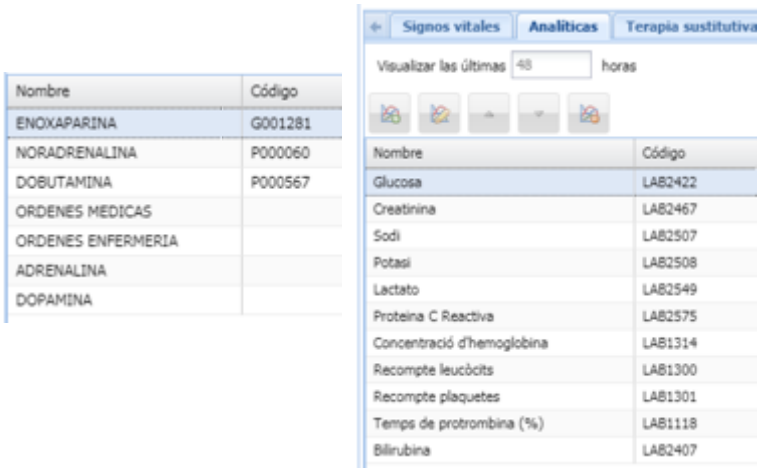


Figure 59. Selection of the main medication and laboratory results to be used in the logic for clinical indicators.

calculations, and the clinical indicators which dependent on it cannot be calculated for a time.

A message is displayed to the clinical team indicating that the parameter was not found. This can be because errors associated with human factors sometimes occur and the value of a given parameter is not available in the HIS. The data on medication prescriptions and administration retrieved from the HIS as well as the laboratory data selected for use in the clinical indicators are presented in Figure 59. Figures 60-64 present the clinical indicators that are used in the ICU, some indicators have only one clinical parameter and others have multiple parameters.

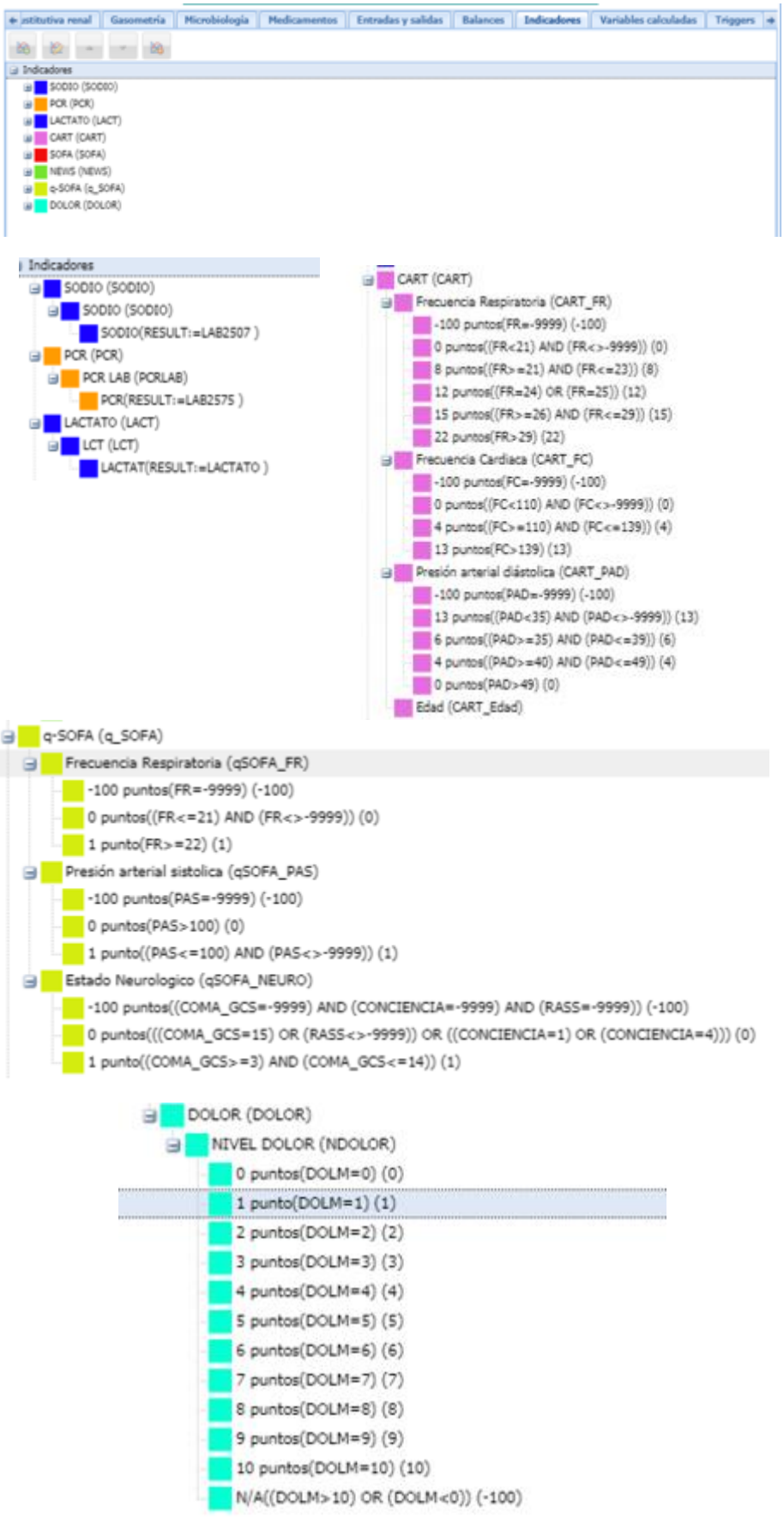
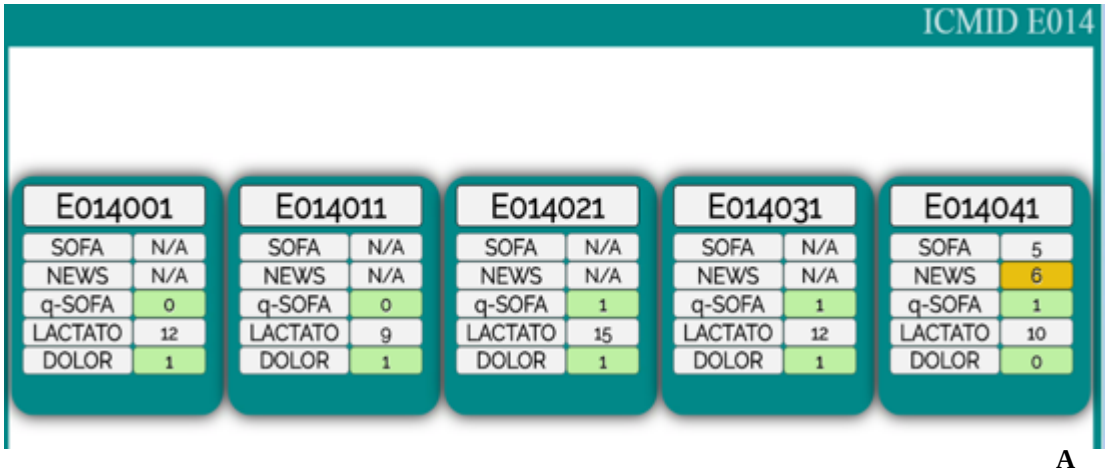


Figure 60. Construction of the code red algorithm in Infobox: Part I.

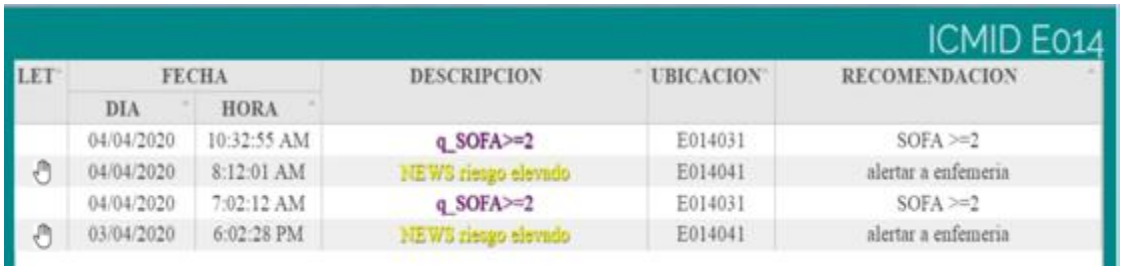
Figure 61. Construction of the code red algorithm in Infobox: Part II.

Figure 62. Construction of the code red algorithm in Infobox: Part III.



A

B



C

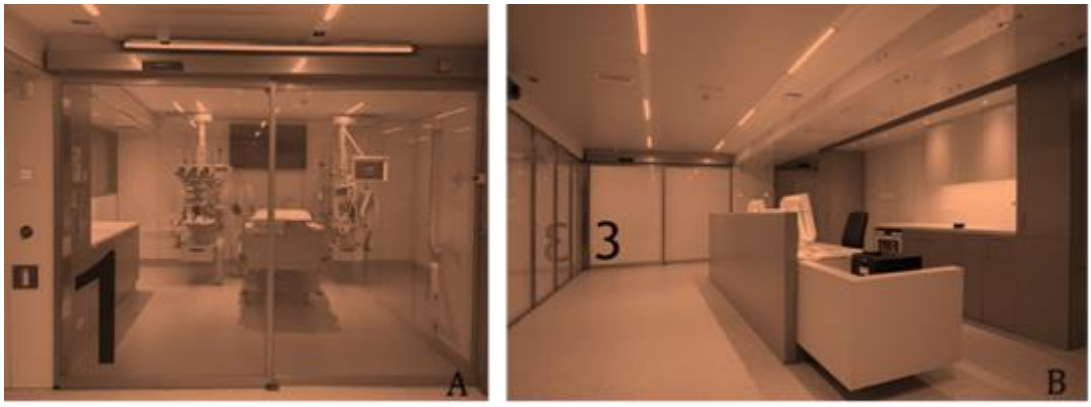


Figure 63. Visualization of the main patient clinical indicators in the Smart ICU. A) Visualization of clinical indicators generated over the previous hour. B) Trends in the main clinical indicators. C) List of active alerts and notifications of clinical indicators. D) Code red activation in a patient room and the nursing station of the ICU.

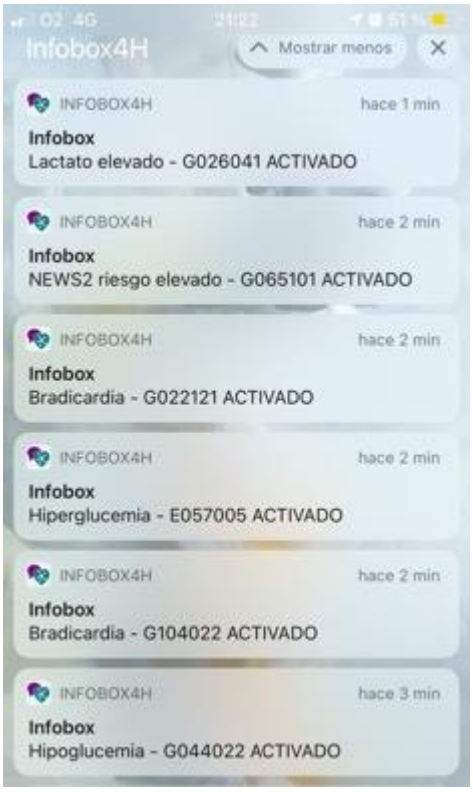


Figure 64. Information on the parameters recovered over the previous hour by the Infobox web application and the notifications received on smartphones.

These indicators help the medical team take clinical decisions at a daily clinical meeting and the help to summarize the clinical information given by the HIS. The first indicator, “Sodium”, takes into consideration only the latest laboratory result for the sodium level. Abnormal sodium values indicate some medical condition (such as kidney disease, diabetes mellitus, dementia, liver cirrhosis, hypertension, metastatic carcinoma or coronary heart disease [259]) and patients who exhibit hyponatraemia (serum sodium <135 mmol/L) have a greater probability of have more mobilities and generating higher direct medical costs over the next 6 months or year.

The second indicator, “C Reactive Protein”, is an important predictor of the presence of multi-resistant pathogens, because a high value here indicates the presence of inflammatory processes in the body [260]. It is an important parameter to evaluate critical patients as microbiology results can take up to two weeks to complete. If this parameter is high, medical staff can use it to prescribe some treatment against infection before the arrival of the latest microbiology results.

The third, “Lactate”, is a predictor of a poor clinical outcome and a high risk of mortality [260]. Patients with severe hyperlactataemia (defined as a lactate level >10 mmol/L) have a greater probability of developing medical complications and of dying[261]. The fourth, “Cardiac Arrest Risk Triage (CART)” score, is a multiparameter scoring system that predicts the risk of cardiac arrest in the ICU [262][263]. The higher this value, the more probable it is that the patient suffers a cardiac arrest at a given moment.

The fifth indicator, “Sequential Organ Failure Assessment (SOFA)” score, is a multiparameter scoring system, which evaluates the dynamic level of acuity and the mortality risk of critical patients in the ICU. The sixth, “q-SOFA”, is a variation of the SOFA score which considers some of the values included in SOFA. If the value of q-SOFA is greater than or equal to 2 for a long period of time, then there is also a high probability of a poor clinical outcome and a hight risk of death. The seventh, “NEWS”, is also a multiparameter score and it indicates the level of deterioration of a patient and the need for continuous care in the ICU if the score is more than 7. The eighth, “Pain”, is a single parameter that express the level of pain experienced by patients.

In order to facilitate the visualization of the different clinical indicators generated over the most recent hours, three interfaces were constructed for the medical team (Figure 64). These interfaces can be programmed to appear when a member of the medical staff enters a patient room or on their smart phone. The first layout is a summarized view of the latest results of the indicators of the ICU patients.

The second layout corresponds to the trends of the layouts over the last 12 hours, and the up and down arrows indicate the increasing or decreasing trend

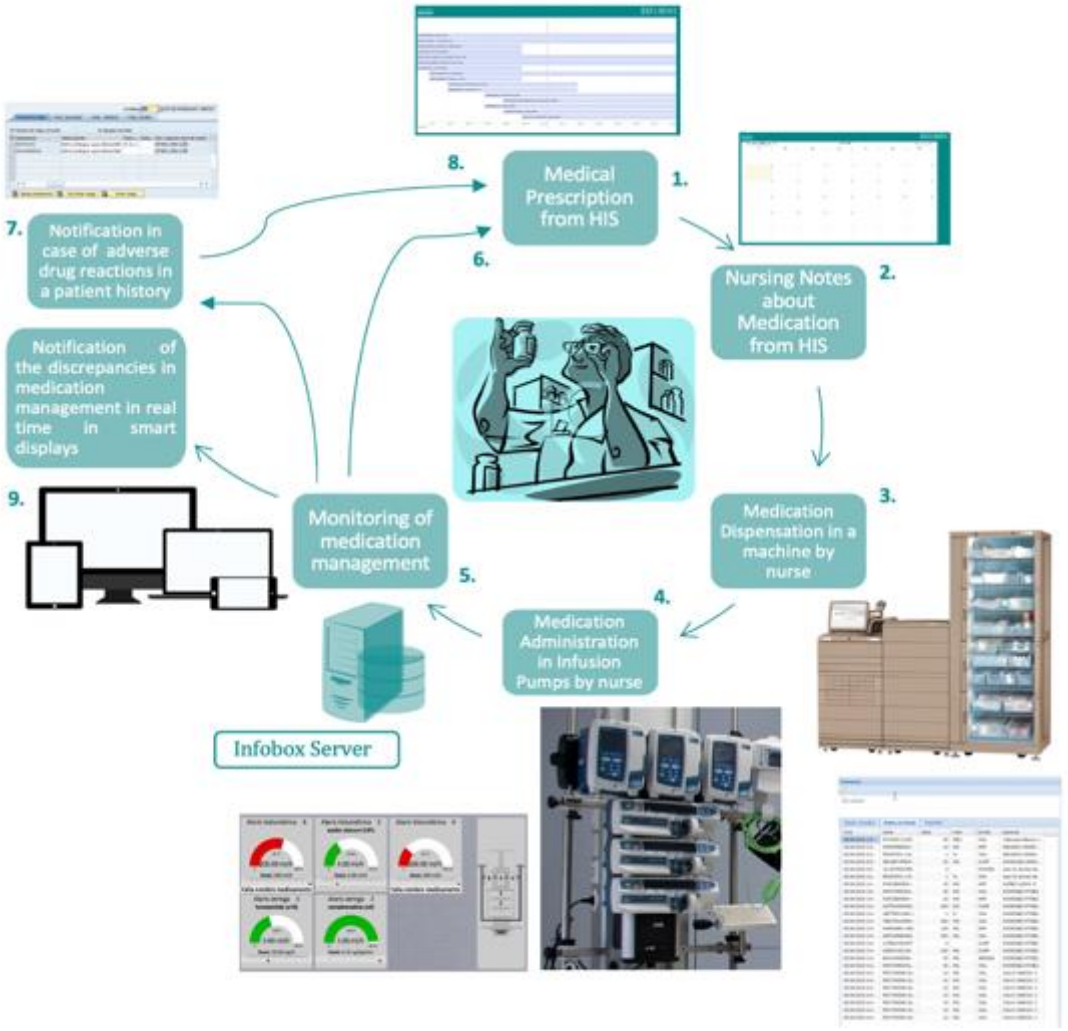


Figure 65. Detection of medication discrepancies at different steps of medication management.

of the indicators over this period, respectively. The third and last layout corresponds to a list of the active alerts and notifications of the clinical indicators. If the LTE is activated it means that there is some restriction on the medical interventions, as instructed by patients or their families, and in some cases no clinical intervention is possible.

4.4.4. Implementation of Medication Actions

The Infobox web application collects data from different sources on medication, analyses them to detect discrepancies in the medication chain and, finally, generates a notification for users (Figure 65). At HCB, the first step of the medication chain is drug prescription by a doctor, as reflected in the HIS. The second step is the registration of medication infusions by nurses in the HIS. Nurses register the medication in the electronic system and then they attach it to the drug machine (step 3). In sequence, nurses prepare medications at the nursing station and then go to the patient rooms (Figure 70).

In a patient room, the nurse prepares the medication, placing it in an infusion pump in the cases of intravenous medications. The infusion pumps start working, and the medication is delivered to the patient's body (step 4). The Infobox web application analyses all the information generated in this chain and when it detects some discrepancy, it sends alerts to the clinical teams in the ICU (steps 5 and 9). If there are no alerts for a given medication cycle, the application returns to collecting drug data and turns to analyse again (step 6 and 8).

Moreover, the application is also able to detect if there is some annotation about adverse drug reactions in the HIS (step 7) and reminds HCWs about this possible reaction through the smart displays. It also incentives the professionals to make a note in the HIS if there is a possible new case of adverse effects due to the medication.

4.5. Phase III: Hand Hygiene System

4.5.1. Installation of the Hand Hygiene System

The RTLS and three electronic dispensers were implemented in the unit. Two electronic dispersers were installed at the nursing station and one in the antechamber of patient room number 2. The RFID antennas were distributed inside and outside patient rooms, as well as above the doors to the unit. I performed a set of tests in order to guarantee accuracy in detecting staff and visitors correctly.

Figure 66 presents the part of the web application developed in the Infobox server to register all the data from medical and non-medical devices, including real-time data from RTLS and data from the electronic hand hygiene dispersers. In the figure we can observe the presence of two people (Ágata and Sandra) at the nursing station and the presence of one person (Rosa Maria) at the entrance to the unit. I selected the area of patient room 2 and the registers presented in this figure correspond to the flow of people at this location.

4.5.2. Implementation of the Hand Hygiene Real-Time Feedback

If HCWs need to enter a patient room, first they must disinfect their hands at one of the electronic dispensers in the unit (Figure 67). After that, it is necessary to wait for three seconds so the antenna above the dispenser can read the RFID tag. Meanwhile, the blue light of the antenna flashes, and when the antenna has read the tag, the light stops flashing. During this time, the HCW should distribute the hydroalcoholic gel over their hands. After a correct reading, some content will appear on a tablet above the antenna. These multimedia contents are detailed in Subsection 3.3.5 above. Once the HCW has disinfected their hands, they can approach the door

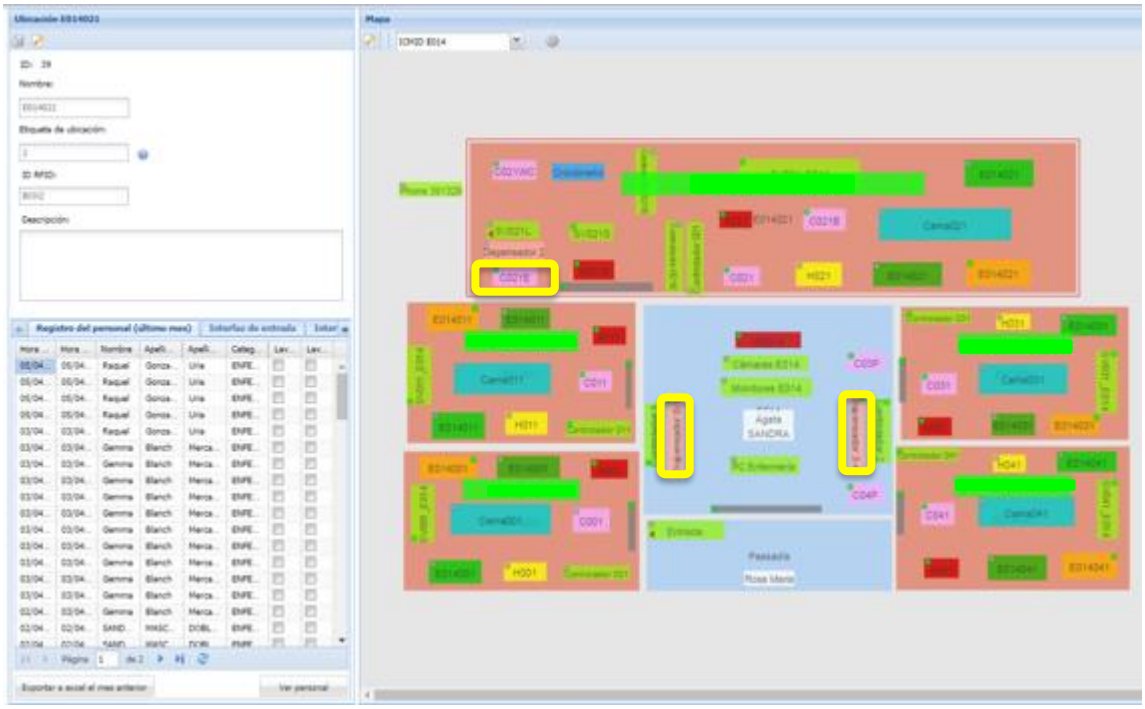


Figure 66. The Infobox web application with the RTLS software and the location of the electronic dispensers highlighted in yellow.

1. Dispenser activation

2. Reading of RFID tag by the antenna

3. Display with personalized information

Figure 67. Workflow of the use of the electronic dispensers at the nursing station.

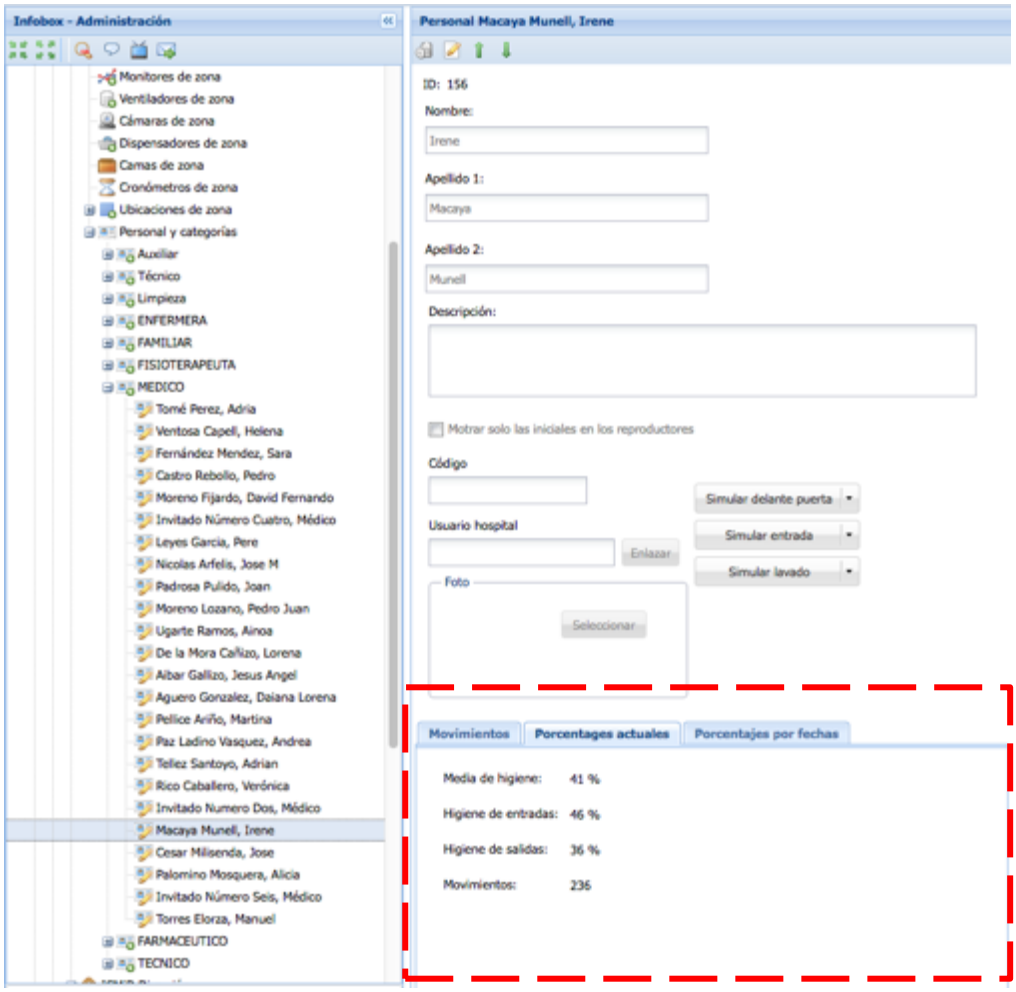


Figure 68. Registers of the number of opportunities for and compliance with hand hygiene for a given HCW.

and it will open if the antenna above the door detects their tag correctly. In an emergency or if a HCW needs to enter with healthcare material on their hands, they can press the red button located at the side of the door.

The Infobox web application registers the moments when people change location and whether they disinfect their hands or not at one of the electronic dispersers before and after moving (Figure 67 and Figure 68). It is possible to calculate hand hygiene compliance at the entrance and exit of the patient rooms and we can show hand hygiene compliance in real time together with personalized recommendations about hand hygiene on the smart displays for each person. The proposal of a monthly email on hand hygiene education is presented in Figure 69.

¡Hola Sergi Campos!

¡Vamos a luchar juntos contra la transmisión de patógenos!

Te enviaremos este email una vez por mes para recordarte las buenas prácticas de higiene de manos y para informarte sobre las estadísticas de uso de los dispensadores electrónicos por el equipazo de la AVI E014.

¿Por qué la higiene de manos es tan importante para combatir la transmisión de patógenos?

Las manos son responsables de transportar los patógenos (bacterias, hongos, virus, parásitos…) de un lugar al otro, o de un paciente a otro. Las infecciones causadas por los patógenos pueden ser provocadas bien por patógenos que ya estaban presentes en la piel/mucosa del paciente o por patógenos procedentes de otro paciente, del profesional sanitario o del entorno.

La forma más efectiva de prevenir las infecciones es realizar la higiene de manos con frecuencia durante todos los momentos del cuidado del paciente.

Los 5 momentos de higiene de manos

Momento 1
Recuerda lavarte las manos antes de tocar al paciente.

Momento 2
Recuerda lavarte las manos antes de realizar un procedimiento séptico/limpio.

Momento 3
Recuerda lavarte las manos después del riesgo de exposición a fluidos corporales.

Momento 4
Recuerda lavarte las manos después de tocar al paciente.

Momento 5
Recuerda lavarte las manos después de tocar al entorno del paciente.

Los 3 dispensadores electrónicos de la AVI E014 contabilizan un uso total de:

76.543 veces
Septiembre 2020

55% Sin tarjeta RFID	5% TCAIs
15% Enfermería	5% Camilleros
10% Doctores	5% Técnicos
5% Limpieza	5% Familia

Clica **aquí** para obtener la información completa sobre las buenas prácticas de la higiene de manos propuestas por la Organización Mundial de la Salud.

Clica **aquí** si no deseas volver a recibir este e-mail de forma mensual.

Puedes dirigirte a **bcorrea@clinic.cat** para cualquier aclaración, sugerencia, queja y/o reclamación.

Figure 69. Proposal for monthly email about hand hygiene education.

4.6. Discussions and Conclusions

The implementation of the AmI Environment in the Smart ICU at HCB was divided into three main phases. In the first phase, the building automation system was implemented. The electrical panel was installed, and ambient control of the interfaces was achieved considering the number of patient rooms and the nursing station in the unit as well as the configuration of the ambient elements. In the second phase, the clinical resources control interface was implemented. The Infobox web application was built with the aim of collecting and distributing the clinical information from the unit when necessary. In the third phase the hand hygiene monitoring system was implemented with all its hardware and software elements.

PHASE III.

DATA ANALYSIS

CHAPTER 5. CRITICAL CARE DATA ANALYSIS AND MANAGEMENT

5.1. Introduction

The critical care data generated at the Smart ICU during this doctoral thesis is analysed in this chapter and enables me to quantify the use of digital tools by professionals and visitors. The data collection was carried out using the web server *InfoboxforHealth*, installed at HCB, respecting all the principles of data quality, data privacy, data security and ethics. Thus, the objectives of Chapter 5 are:

- To analyse and interpret the ambient data generated by the building automation system.

- To analyse and interpret simulated clinical data generated by vital signs manikins for detecting code blue events using an automated trigger.

- To analyse and interpret clinical data from critical patients in order to build code red prediction models.

- To analyse and interpret data related to hand hygiene generated by the electronic hand hygiene monitoring system.

The data from the AmI environment, code blue and code red data, were analysed using descriptive statistics techniques because my objective is to quantify these events and understand the critical care data generated by professionals and patients. I analysed the hand hygiene data using more advanced statistical techniques because the hand hygiene monitoring system generated more than 2 million recordings of use of the system by professionals and visitors, and it was possible to elaborate prediction models for hand hygiene compliance in this unit. I used two free desktop software packages, called RStudio®[289] and Waikato Environment for Knowledge Analysis (Weka®)[290], for data analysis and the free desktop software Tableau®[291] for data visualization. I also used the libraries lubridate, tidyr, caret, devtools, dplyr, ggplot2 and RcmdrMisc from RStudio® and standard libraries from Weka® in the development of the data management.

5.2. AmI Environment Data Analysis and Management

5.2.1. Characterization of Data Collected from the AmI Environment

I collected the environment data generated in the Smart ICU over 200 patient days, between 26th October 2019 and 13th May 2020, and saved them in a secure database. A total of 20918 anonymous registers of the use of the functions of the building automation system GUI were generated on tablets located in the 5 patient rooms and at the nursing station. The objectives of my collection and analysis of data from the AmI were:

- To evaluate the usability of the building automation system in a clinical environment.
- To quantify the use of each function of the building automation system GUIs.
- To understand the use pattern of the building automation system between HCWs and visitors during the period of study.
- To associate the daily clinical tasks of HCWs with the use of specific functions inside patient rooms.

The Smart ICU had a manual lighting control system before implementation of the building automation system. The use of the previous system did not allow the usability of its functions to be quantified. For this reason, daily quantification of the functionalities was important to discover its use patterns, and to propose an optimized lighting scenario for each time of day which is sensitive, responsive, and adaptive in addition to creating awareness of the behaviour of HCWs and visitors.

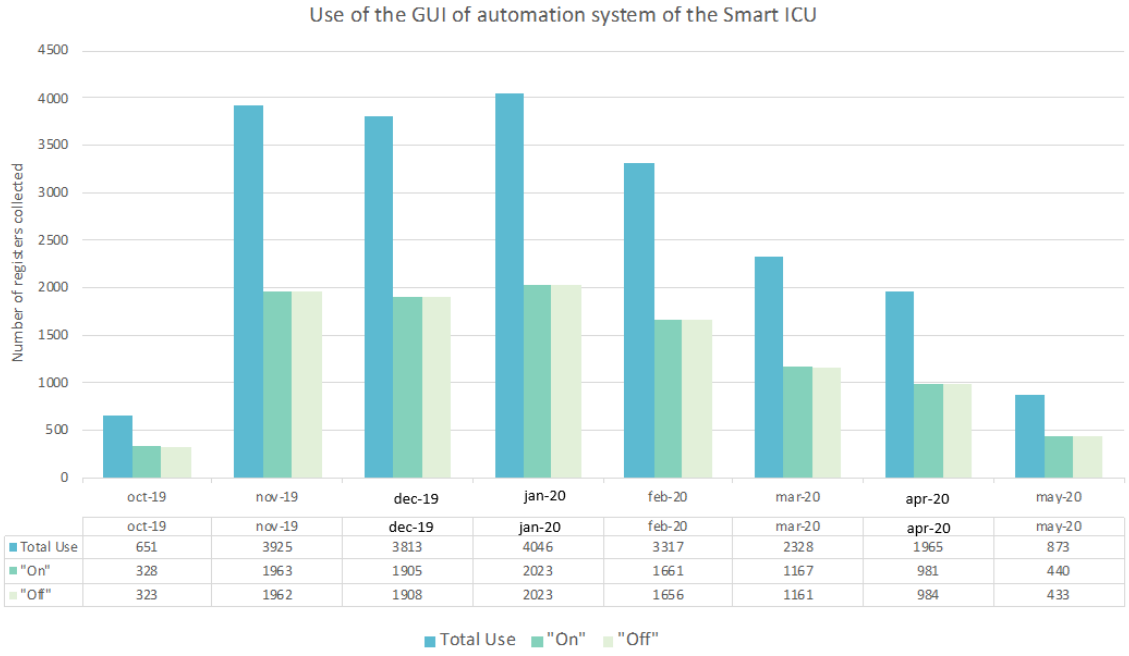
5.2.2. Global Evaluation of AmI Environment Data

I quantified use of the building automation system and use of all functionalities via two values: 0 (switched off) and 1 (switched on). The total monthly use of the automation building system GUIs in the smart ICU compared with the total use of the function “on” and the function “off” is presented in Figure 70. The values for the two functions were very similar. This indicates that the clinical environment is a very dynamic location in which clinical personnel touch the lighting configuration frequently to change the state of the lights, in addition to other functions. During the month of January 2020, the global use was more elevated (4046 times) due to the overload of patients and the nursing workload in the winter period. During February 2020, the first patients with Covid-19 arrived at the unit. The use of the automation system decreased from February 2020 to May 2020, although the unit remained busy every day, because people left the function “on” for long periods and changed to “off” less frequently.

The distribution of the use of the building automation system GUI hourly is presented in Figure 71. The hour with most registers was 10 a.m. (1625 registers) and the period with the greatest number of registers was between 9 a.m. and 12 noon (a total of 5761 registers). This is due to the high rate of clinical activity that is usual in this time frame. Such activities are patient hygiene, realization of X-rays 'in situ', wound dressing, biological fluid extractions for analysis, sessions of physiotherapy, sessions of dialysis and medical visits by other physicians from the hospital, among others. The hour which registered the least use was 4 a.m. (233 registers) and the period with the smallest number of registers was between 2 a.m. and 5 a.m. (a total of 1089 registers). The early morning is the period in which there is the least record of light activity, as patients are usually sleeping and because there are no activities planned in these hours.

There are 3 shift changes in the Smart ICU. The morning shift starts at 8 a.m., the afternoon shift at 3 p.m., and the night shift at 10 p.m. The distribution of GUI use according to the different working shifts is presented in Figure 72. This figure and the last one show that in the morning shift there was more activity and during the night shift there was less activity in patient rooms. The difference in registers between the afternoon shift and night shift was not significant globally because in both shifts there were peak hours with a large spike in the number of registrations. For example, one hour before all shift changes (7 a.m., 2 p.m. and 9 p.m.), there was an important peak hour and in all cases the sum of registers was over 1000. Globally, this can be explained by the nursing workload and because during the last hour the nurses check all clinical tasks pending are carried out.

I also studied the distribution of GUI use during the different days of the week. Figure 73 presents the use of the system on each day. Wednesday was the day with most records (3524 records) while Sunday (2335 records) was the day with least. The days at the weekend (Friday, Saturday and Sunday) were the days with fewest registers because during these days there are less daily clinical tasks, and activity is greatly reduced compared with during the week, mainly because there are no medical visits from other departments or medical and nursing students. Between Monday and Thursday there is no significant variation in the number of records, and this means that the activities in a patient room remain constant over these days.



	oct-19	nov-19	dec-19	jan-20	feb-20	mar-20	apr-20	may-20
Total Use	651	3925	3813	4046	3317	2328	1965	873
"On"	328	1963	1905	2023	1661	1167	981	440
"Off"	323	1962	1908	2023	1656	1161	984	433

Figure 70. Monthly use of the automation system GUIs in the Smart ICU.

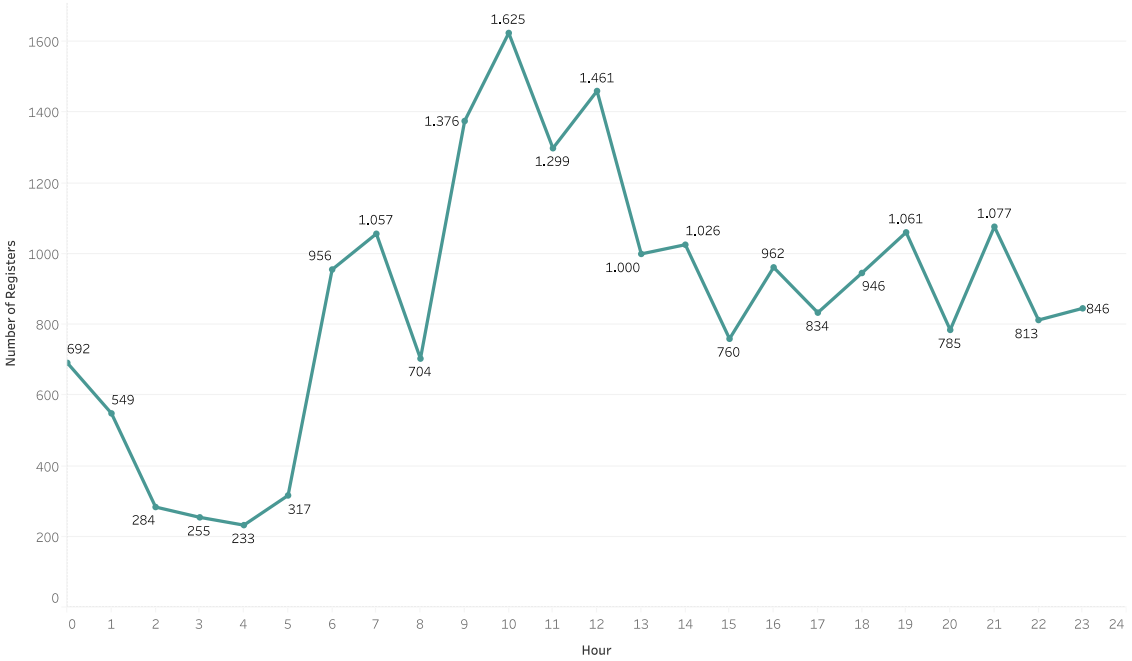


Figure 71. Distribution of the use of the automation system GUIs by hour.

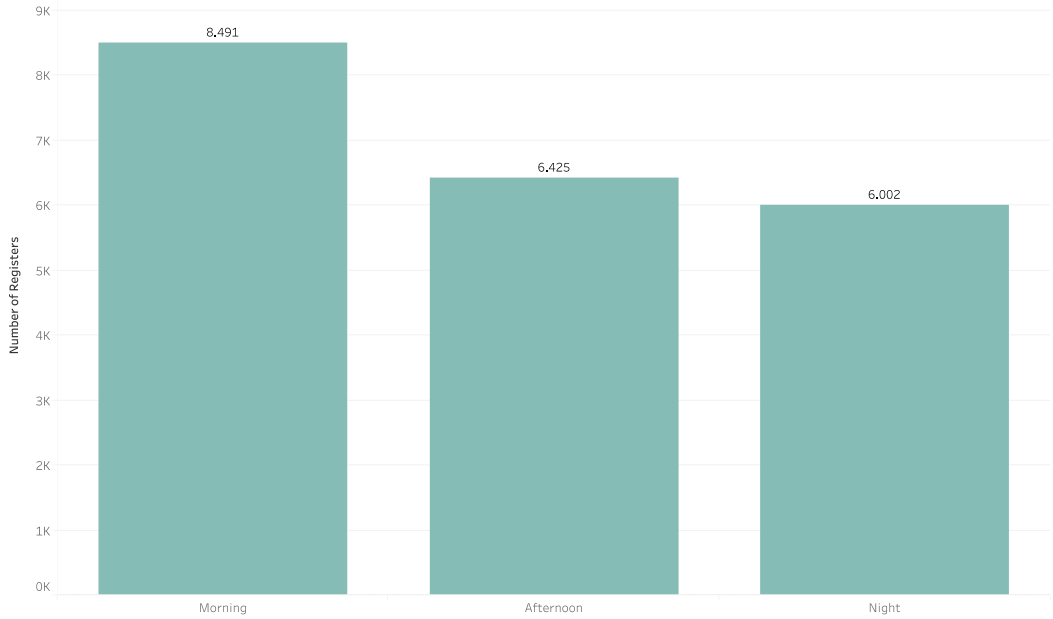


Figure 72. Distribution of the use of the automation system GUIs according to work shifts.

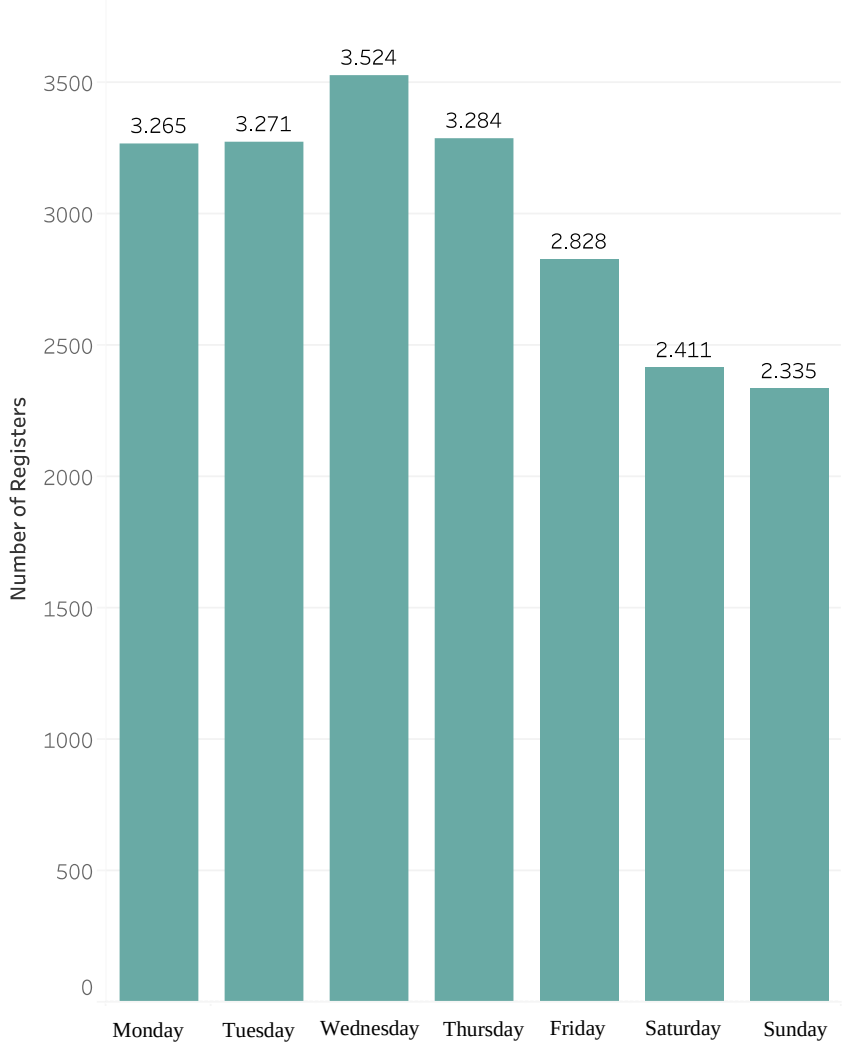


Figure 73. Distribution of the use of the automation system GUIs by day of the week.

5.2.3. Usability Evaluation of Functionalities of the Building Automation System

The functionalities presented in the GUIs are: Support Lighting, Medical Examination Lighting, Ceiling Lighting, Floor Lighting, Circadian Lighting, Door, Window, Camera, Scenario 1, Scenario 2, Code Blue, Code Red, Nursing 0%, Nursing 25%, Nursing 50%, Nursing 75% and Nursing 100%. All the functions, except the nursing functions, are replicated for the five patient rooms. During the period of my study, the number of times that each of the functions was used in every month is presented in Table 2 and in Figure 74. Some functionalities were not used in some patient rooms, particularly: Camera, Code Blue, Code Red, Scenario 1 and Scenario 2. This is because these functionalities were only implemented manually and many of them are not extensively used. In the future, these functionalities should be activated automatically when the AmI environment detects that HCWs need them. The table and figure show that the most commonly used functionality was the Door of patient room number 1 during the month of November 2019 with a total of 181 registers.

Between the month of November 2019 and February of 2020, the functionalities Door, Support Lighting, Medical Examination Lighting and Ceiling Lighting were the most commonly used and represented a total of 81.2% of all uses (16,995 records). These functionalities were also the most used globally during the period of my study, as shown in Figure 75. The common characteristic shared by all of them is that all these functionalities are used in the direct care of patients and they are in close proximity to them. The Door was used daily at the moment of performing patient hygiene, during family visiting hours and for medical visits. Generally, Support Lighting is always switched on because nurses need to prepare medication, supplies and equipment on the table under these lights. The Medical Examination Lighting is used during medical visits and for patient hygiene, when wounds are being dressed, and during intubation, weaning, medication administration and non-invasive procedures. The Ceiling Lighting can be used for the same purposes as the Medical Examination Lighting. Occasionally, two or more functionalities are used at the same time in order to improve the level of lighting in a patient room. Moreover, the use of the Support Lighting in patient room 0 and patient room 4 was greater than in the other patient rooms because in these two rooms there is no natural lighting and it is necessary to have this light switched on. In patient rooms 1,2 and 3, there is natural lighting and during the day it is often possible to switch off the Support Lighting.

The two most commonly used nursing buttons were the 0% and 25% nursing station lighting intensity options. This is because during the night, the nurses switched off this light in order to decrease the artificial lighting for patients, and

Function	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20
0 % - E014	5	32	26	29	25	29	35	16
25 % - E014	7	39	40	41	32	31	40	14
50 % - E014	1	5	3	15	5	5	10	2
75 % - E014		2	1	7	2	2	4	2
100 % - E014	1	10	9	9	9	7	8	2
CÀMERA - E014001				2				
CÀMERA - E014011				1	10	1	6	1
CÀMERA - E014021		1		5			2	3
CÀMERA - E014031		3		3	2		1	1
CÀMERA - E014041		1		3	1		4	0
CIRCADIÀ - E014001	2	4	21	18	6	4	2	1
CIRCADIÀ - E014011	1	11	23	21	6	6	3	2
CIRCADIÀ - E014021	2	9	12	23	6	8	9	3
CIRCADIÀ - E014031	2	23	19	12	5	5	8	1
CIRCADIÀ - E014041		24	23	23	10	5	10	6
CODI BLAU - E014001		1	1		1	2		
CODI BLAU - E014011		1	1	1	2	1		
CODI BLAU - E014021		2	4	2	1			
CODI BLAU - E014031		5	2	2	1	2	2	2
CODI BLAU - E014041	1	4	1	2	1	1		
CODI VERMELL - E014001		2	4					
CODI VERMELL - E014011	1	3	3	2		1	1	
CODI VERMELL - E014021		1	2	1		1		
CODI VERMELL - E014031	1	5	1	1	3	6		2
CODI VERMELL - E014041		2		1	2	2		
ESCENA - E014001						1		
ESCENA - E014011	1	1		1				1
ESCENA - E014021	1			3	1	1	1	
ESCENA - E014031	5	1		1	1			
ESCENA - E014041					2		2	
EXPLORACIÓ - E014001	12	41	48	41	31	34	15	7
EXPLORACIÓ - E014011	19	68	61	45	40	38	35	8
EXPLORACIÓ - E014021	2	21	28	40	27	37	25	13
EXPLORACIÓ - E014031	6	42	44	35	28	33	31	17
EXPLORACIÓ - E014041	12	76	47	47	44	28	34	19
FINESTRA - E014001	5	12	12	11	19	6	0	
FINESTRA - E014011	5	27	14	11	18	8	4	4
FINESTRA - E014021	2	28	24	54	39	9	14	3
FINESTRA - E014031	4	10	10	19	24	7	9	4
FINESTRA - E014041	3	22	10	21	21	6	4	3
NIT - E014001	1		2		1	2	1	
NIT - E014011		2	1	2				1
NIT - E014021	1	1	3	3	1	2		
NIT - E014031	4	2	4	1	2		1	
NIT - E014041			5	1	2		1	
PRIVACITAT - E014001	28	151	146	124	149	59	18	9
PRIVACITAT - E014011	35	181	166	177	130	90	46	11
PRIVACITAT - E014021	2	76	61	123	93	56	52	20
PRIVACITAT - E014031	34	136	146	148	116	99	65	30
PRIVACITAT - E014041	15	127	137	143	139	74	53	22
SOSTRE - E014001	4	29	21	36	27	27	12	4
SOSTRE - E014011	16	105	108	93	91	72	58	24
SOSTRE - E014021	3	21	17	42	23	32	22	7
SOSTRE - E014031	7	34	40	34	19	22	23	13
SOSTRE - E014041	5	44	43	40	36	21	33	25
TREBALL - E014001	16	103	119	111	91	70	35	22
TREBALL - E014011	16	90	89	75	87	54	52	18
TREBALL - E014021	2	30	34	55	38	29	18	6
TREBALL - E014031	21	103	94	71	71	60	67	32
TREBALL - E014041	8	118	112	117	89	50	87	41
VETLLA - E014001	2	11	18	17	9	2	4	2
VETLLA - E014011	5	7	13	12	6	5	3	4
VETLLA - E014021	1	10	6	14	6	6	4	2
VETLLA - E014031	1	17	10	13	5	3	2	2
VETLLA - E014041		26	16	18	5	5	5	8

State

0 181

Suma de State desglosado por Datetime mes vs. Function. El color muestra suma de State. Las marcas se etiquetan por suma de State.

Table 2. Use of the different buttons on the GUI during my study.

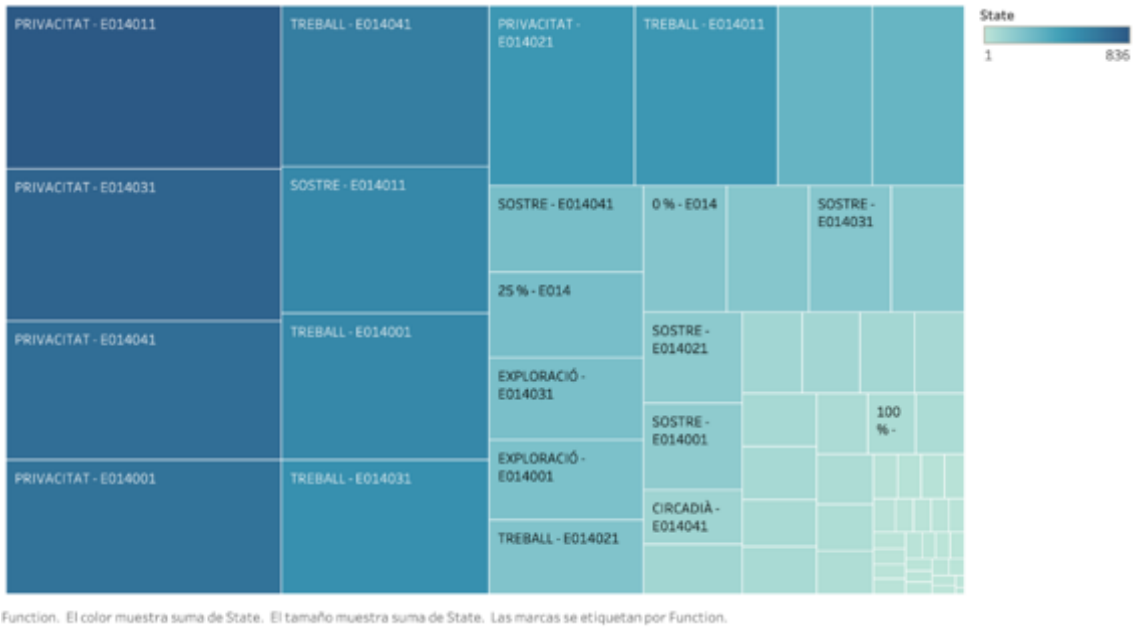


Figure 74. Tree map of the use of different GUI buttons of the automation system in the Smart ICU.

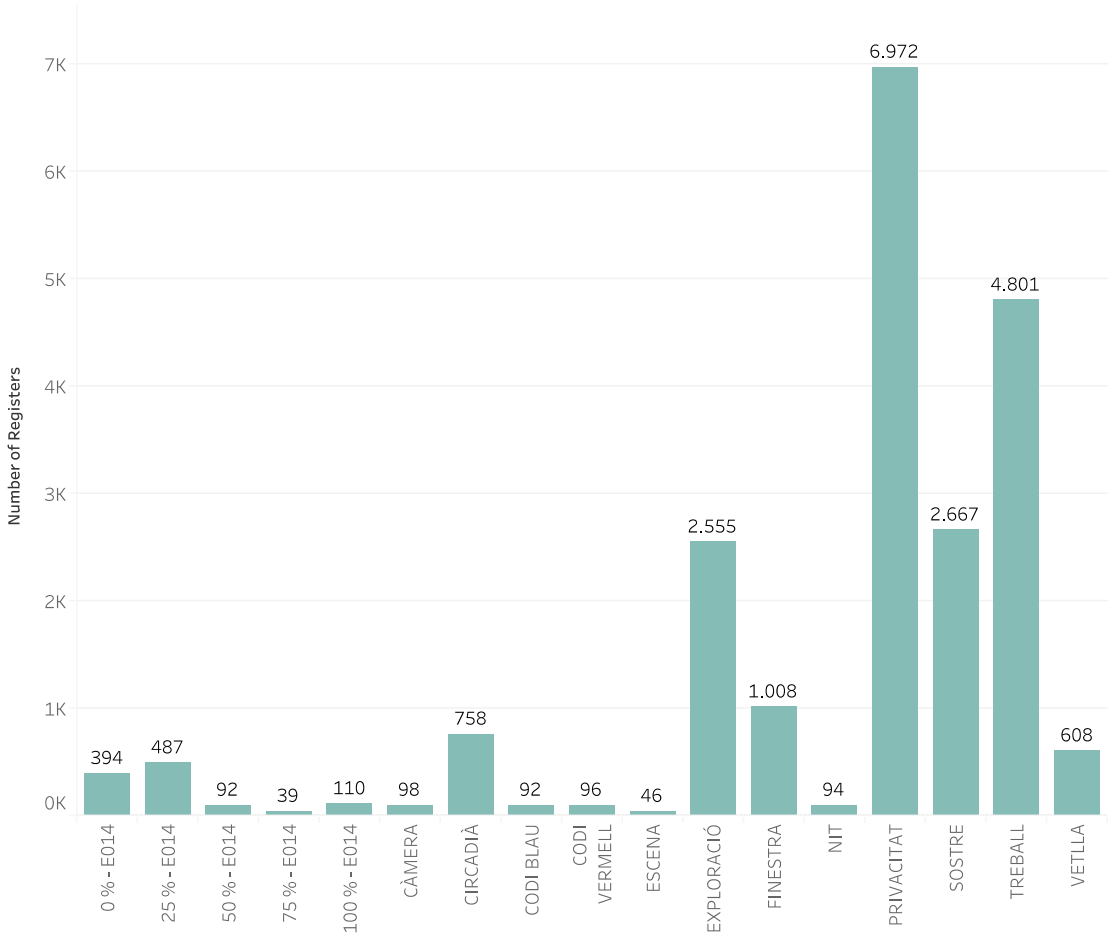


Figure 75. Total use of all the functions of the automation system GUIs.

consequently, to improve the quality of their sleep. In the same way, during the first hour of the morning, nurses tended to switch on 25% lighting in order to avoid an excessive lighting.

5.2.4. Time Series Analysis of the Functionalities of the Building Automation System

The functionalities of the building automation system can be activated from the nursing station or directly from inside a patient room. During the period of my study, the number of activations and deactivations of the functionalities of the GUIs, classified according to different locations, evolved not only in terms of the number of registers but also in terms of use at different locations (Figure 76). Between October 2019 and November 2019, the registers classified by location increased globally, but after November 2019 the use of each location was different. In all cases, the records decreased significantly until the end of study. This could be seen as a predictive factor of epidemics, given that people avoided touching the GUI, and only did so when totally necessary, despite the number of patients in the unit remaining stable. It is also important to highlight that from February 2020, the beginning of Covid-19 in the unit, the number of people who entering the unit reduced dramatically and the clinical protocols for taking care of patients changed (obligatory use of double gown, gloves, masks, and hair and foot protectors).

From the nursing station, the number of registers varied slightly during my study and remained constant between February 2020 and March 2020. This indicates that the clinical team used the lights at the nursing station following the same pattern both before and during the Covid-19 period. Patient rooms 0, 1, 3 and 4 saw a constant reduction in the number of registers, with some small peaks. In contrast, patient room 2 had an important peak during the month of January 2020, and this could be explained by the use of this location for patients with suspected Covid-19. At that moment, patients in the other rooms had no suspected Covid-19 infections. At the end of February 2020, the first case of Covid-19 was confirmed at hospital and the patient was located in patient room number 2. From that day on, and up to the time of writing, all the patients with confirmed Covid-19 occupied the rooms in this unit.

During the period of my study, I evaluated the use of each functionality weekly (Figure 77) and the most commonly used functionalities (Door, Support Lighting, Medical Examination Lighting and Ceiling Lighting) experienced many variations that can be attributed to the different activities carried out in the patient rooms, with peaks possibly corresponding to the period when nurses saw most activity inside the patient rooms. There are no previous studies that quantify the use of ambient elements in a similar clinical setting to compare my analysis with.

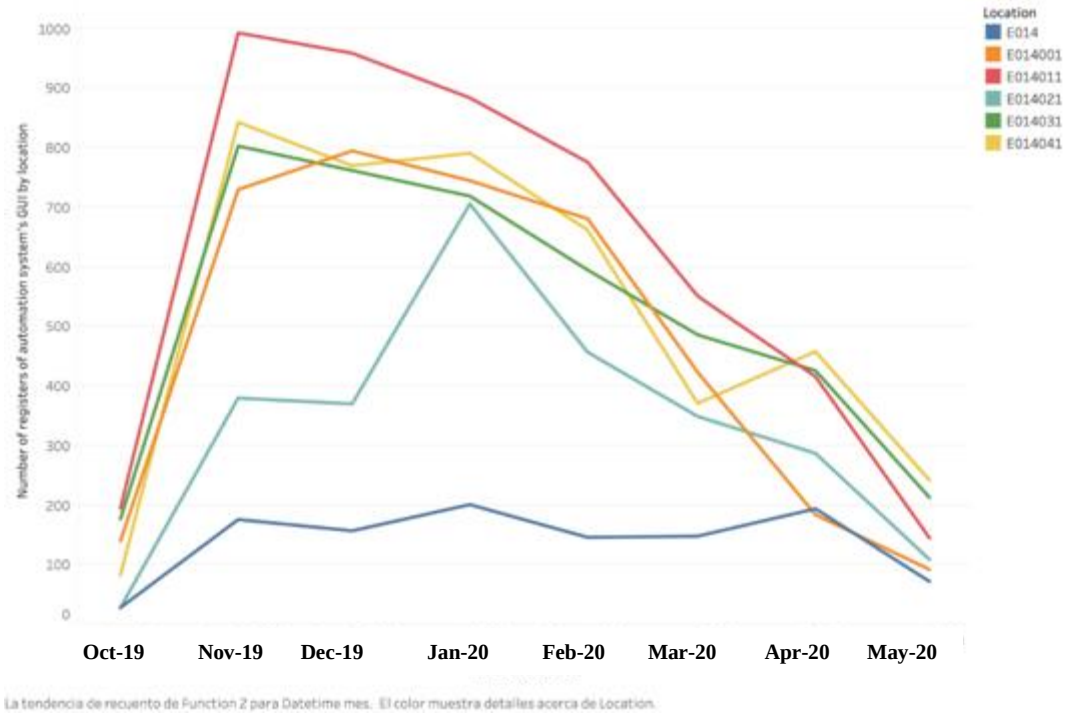


Figure 76. Use of the automation system GUIs classified by location during the period of my study.

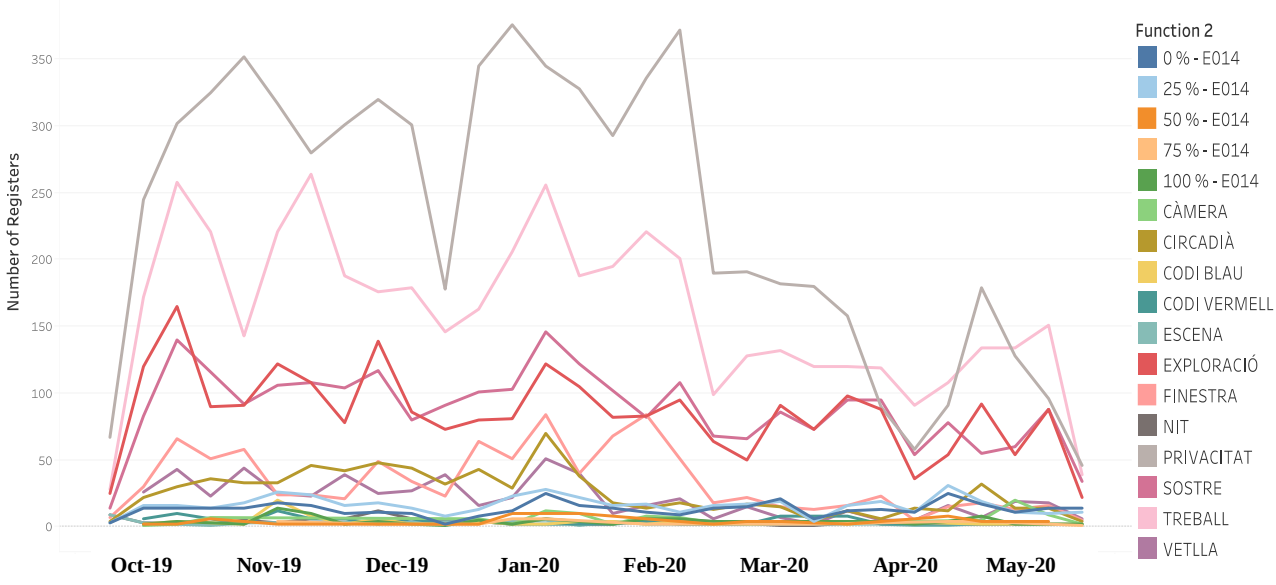


Figure 77. Global use of the different functionalities of the automated system during the period of my study.

5.3. Code Blue Data Analysis and Management

5.3.1. Characterization of the Simulated Clinical Data Generated by the Manikin

I collected the vital signs clinical data simulated using a manikin that were generated in the Smart ICU on 2 consecutive days: 16th and 17th November 2017. I saved them in a secure database on a hospital server. A total of 1000 tests of Code Blue events were performed using the experimental setup described in Chapters 2 and 3. In all cases, the Code Blue event was correctly activated in the experimental software and in the physical prototype. My objectives derived from the simulated data collection and analysis were the following:

- To simulate life-threatening arrhythmias (ASY, VF and VT) using the manikin under different conditions and to determine the number of true positive cases and of artefacts, and to estimate the number of false positives.

- To use the manikin to simulate two different ranges of HR (20, 60 beats per minute and 0,20 beats per minute) under different conditions, and to determine the number of true positive cases and of artefacts, as well as estimating the number of false positives.

- To estimate the total number of false positive cases of a Code Blue event under different conditions, using the manikin, and also globally, considering the previous measurements as well as the Code Blue algorithm (Figure 27, Chapter 3).

- To compare the global results with the results obtained in previous studies which used different approaches.

In this study, true positive cases are those in which there was a correct detection of an alarm from vital signs monitor. For example, the occurrence of an arrhythmia was simulated in a manikin when the manikin was at rest and the vital signs monitor detected this event. A false positive case is when the manikin did not have a simulated arrhythmia, but for some reason the vital signs monitor detected arrhythmia (due to some types of manikin movements or artefacts in the signal processing). In this case, false positive cases were estimated to be 85% of all true positive cases, based on the large number of previous studies and real experiments to detect these cases [292]–[295]. The artefacts were generated in each of the different conditions due to the movements of the manikin and the incapacity of the

Figure 78. Simulation of ASY in the manikin and its visualization in the vital signs monitor in the ICU.

vital signs monitor to discriminate the waveforms when the manikin body is moving.

The number of false negative cases cannot be detected in this setting because the internal status of the vital signs monitor (working mode) cannot be measured and the consequences for the health of the manikin cannot be measured, as occurs in the case of a real patient. In the same way, the true negatives cannot be detected or measured because the number of non-existent potential alarms cannot be quantified with the manikin.

5.3.2. Analysis of the Life-Threatening Arrhythmias under Different Conditions

ASY is the absence of electrical activity in the heart and it always appears as a flat line (Figure 78). VT and VF are two very serious types of arrhythmias that can lead to sudden death or cardiac arrest. In both cases, the heart rhythm begins in the ventricles, without the protective mechanisms of the heart acting to prevent very fast frequencies. The basic difference between VT and VF is that VT is rhythmic, and the ventricles beat in coordination, but too fast, so it does not have time to fill and loses its effectiveness. In contrast, VF is a fast frequency but with a lack of coordination in the contraction of the ventricles. Figure 79 shows the image of the vital signs in a monitor: sinus, VT and VF, respectively, all of them simulated with the manikin. The vital signs monitor is less sensitive at differentiating VT and VF because these waveforms are polymorphic and many times the arrythmia alarm occurs, but VT and VF are not differentiated correctly, mainly in the presence of artefacts or patient movements.

All the devices generated flashing red alarms and yellow alerts on the monitor and generated the characteristic audible alarm. The 50 most recent yellow alerts and red alarms were recorded in the history section of the monitor. In all cases, a colour alert/alarm was triggered on the monitor with the corresponding sound. An apnoea "APN" alert

a)

b)

c)

Figure 79. Evaluation of ECG curves: a) sinus mode, b) VT, c) VF.

appears on the vital signs monitor because the 5th lead is not connected (Figure 80): the manikin only has 4. This does not influence the tests because the minimum number of leads to detect arrhythmias is 3.

I used 200 activations of ASY alarms with the manikin to evaluate detection in each of the four conditions. I recorded the number of artefacts and estimated the number of false positive cases to be 85% as many as the true positive cases (Table 3). I carried out the same tests for VT and VF, including 200 activations of each of them. Detection of the alarms was not specific for these two types of arrhythmias given that VT and VF are not very well discriminated by the monitor. Detection of one of these three types of arrythmias represents one of the rules that is evaluated on the Code Blue algorithm (Figure 27, Chapter 3).

Upper and lower limb movements generated most of the artefacts for the three types of arrhythmias. This could be because this is the type of movement with the greatest opening angle, and the ECG sensors move more frequently. ASY has fewer artefacts as it is a characteristic curve, unlike VF and VT. Limb movement is a very frequent patient movement in ICUs because the clinical staff need to perform it to maintain patient hygiene once each working shift. During this activity, nurses should

	ART	**ASY**	FP
E1	0 (0 %)	**200**	170
E2	6 (3%)	**194**	165
E3	8 (4 %)	**192**	163
E4	6(3%)	**194**	165

a)

	ART	VF	**VT**	FP
E1	0(0%)	82(41%)	**110**	94
E2	14(7%)	88(44%)	**98**	83
E3	16(8%)	90(45%)	**94**	80
E4	8(4%)	94(47%)	**98**	83

b)

	ART	VT	**VF**	FP
E1	0(5%)	90(45%)	**100**	85
E2	20(10%)	98(49%)	**82**	70
E3	28(14%)	112(56%)	**60**	51
E4	12(6%)	106(52%)	**82**	70

c)

E1= Evaluation 1 – mannikin at rest.
E2 =Evaluation 2 – mannikin under bed vibration and percussion therapy.
E3 = Evaluation 3 – mannikin under upper and lower limbs' movements.
E4 = Evaluation 4 – mannikin under continuous bed therapy.
ART – number of artefacts detected.
ASY – number of asystole detected.
VF – number of ventricular fibrillations detected.
VT – number of ventricular tachycardia detected.
FP – number of false positives estimated.

Table 3. Tables of life-threatening alarms: a) ASY tests, b) VT tests, c) VF tests. ART = artefacts, FP = false positives. ART and life-threatening alarms are obtained experimentally while I estimated the number of FPs.

temporarily silence alarms generated by artefacts and false positives because they are very disturbing while nurses are at the bedside.

5.3.3. Analysis of the HR under Different Conditions

The normal sinus rhythm of the heart is characterized by having HR between 60 and 100 beats per minute (bpm). The HR values were simulated within two threshold ranges ([20, 60] bpm and [0, 20] bpm) using the manikin tablet. Each one of these two threshold ranges represents one of the four rules that is evaluated in the Code Blue algorithm (Figure 27 Chapter 3). Table 4 shows the results obtained for the threshold ranges under the four different conditions. The upper and lower limb movements also generated the largest number of artefacts for both HR threshold ranges, for the reason explained above.

The number of artefacts generated by the HR, in both cases, was also smaller than the number of artefacts detected in the cases of VF an VT because the monitor is also more sensitive at detecting this waveform. The second threshold HR range, [0, 20] bpm, is not frequently observed on the ICU because when a patient presents

	ART	**HR [20, 60]**	FP
E1	0(0%)	**200**	170
E2	4(2%)	**196**	167
E3	8(4%)	**192**	157
E4	2(1%)	**198**	168

a)

	ART	**HR < 20**	FP
E1	0(0%)	**198**	168
E2	6(3%)	**194**	165
E3	10(5%)	**190**	162
E4	6(3%)	**194**	165

b)

E1= Evaluation 1 – mannikin at rest.
E2 =Evaluation 2 – mannikin under bed vibration and percussion therapy.
E3 = Evaluation 3 – mannikin under upper and lower limbs' movements.
E4 = Evaluation 4 – mannikin under continuous bed therapy.
ART – number of artifacts detected.
HR – number of heart rate detected.
FP – number of false positives estimated.

Table 4. HR ECG tests for a) threshold 1 and b) threshold 2, respectively. ART = artefacts, FP = false positives. ART and HR ECG were obtained experimentally while I estimated FP.

values of HR within the first threshold, [20, 60 bpm], the monitor also emits life-threatening alarms. However, both rules were considered separately in the Code Blue algorithm because they are considered important for the physicians to classify the medical reasons for the possible case of CA.

5.3.4. Global Evaluation of Code Blue Algorithm

I evaluated the Code Blue algorithm to detect potential avoidable CA in the Smart ICU under four separate conditions and globally. The three rules of the Code Blue algorithm (Figure 28, Chapter 3) were evaluated using the experimental data previously reported. The number of true positives, false positives and artefacts for the first condition of the algorithm were calculated as the mean of the three values obtained for ASY, VT and VF (Figure 80). For the second and third conditions of the algorithm, I also considered the two HR threshold ranges. For each four conditions, the application of the Code Blue algorithm decreased the number of false positives detected. Globally, the reduction of the false positive alarms using Rule 1, 2 and 3 was 30%, 42% and 39%, respectively (Figure 81). The global reduction in false positive alarms was 37.1%. This result means that detection of CA using the algorithm can decrease the number of false positives currently registered by almost 40 percent.

In a real scenario, the number of false positive alarms obtained using this algorithm remains very high and the activation of the Code Blue scenario can occur in many unnecessary situations, thereby causing extra stress for the clinical team. Other ambient variables could be considered to decrease the number of false positives.

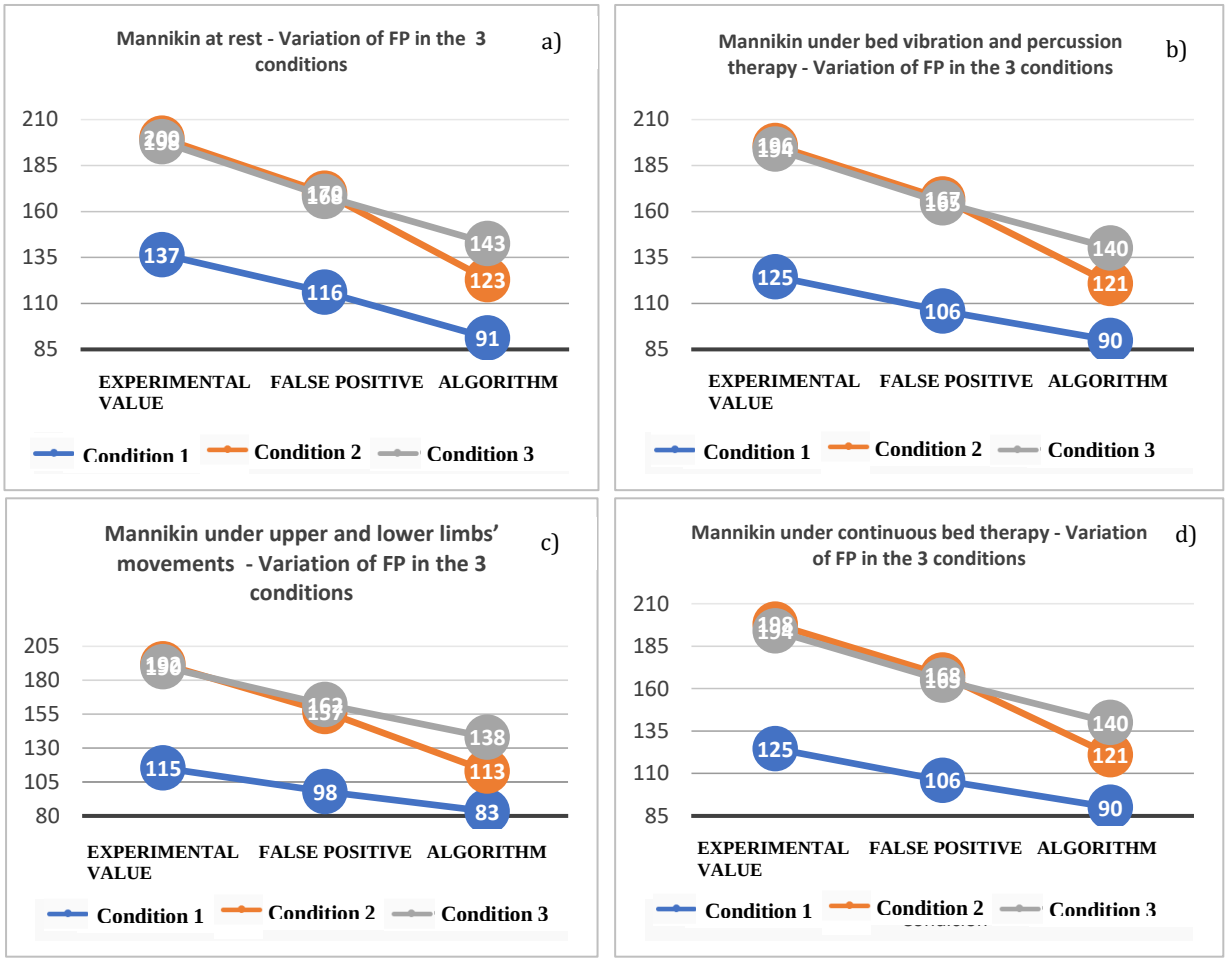


Figure 80. Evaluation of false positives at rest (a), under vibration (b), with limb movements (c) and with rotational movement (d); and considering the detection of condition 1 (life-threatening alarms), condition 2 (HR between 20, 60 bpm) and condition 3 (HR between 0, 20 bpm).

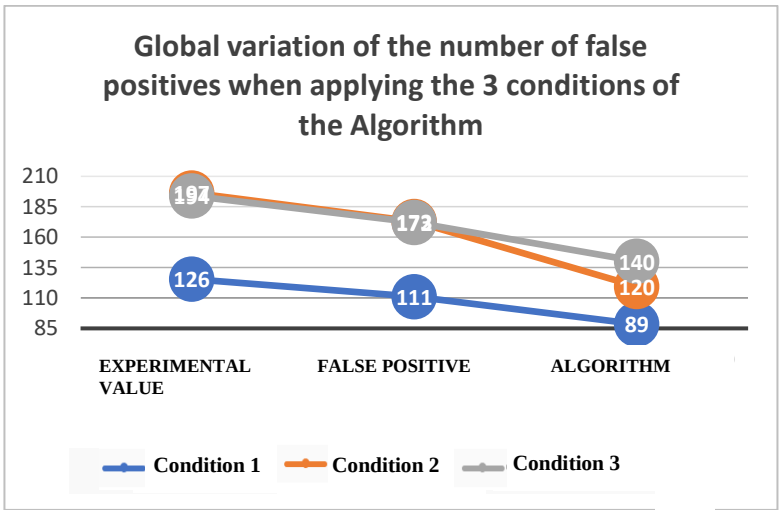


Figure 81. Global variation of the number of the false positives in the code blue algorithm considering the detection of condition 1 (life-threatening alarms), condition 2 (HR between 20, 60 bpm) and condition 3 (HR between 0, 20 bpm).

Studies [296]–[304] have considered other monitoring and clinical parameters in order to activate an automated Code Blue Alert, such as temperature, oxygen saturation and laboratory results. These data were modelled, and machine learning techniques were applied to predict a code blue better in the units. In addition, the analysis of waveforms from ECG and SBP, for example, were also considered in other studies. The diminution of false positive CAs detected in other studies was not reported in detail and the number of patients included in those studies was low. In addition, the frequency of monitoring data was very low, and data with a greater frequency are necessary for a significant estimation of real CAs.

5.4. Code Red Data Analysis and Management

5.4.1. Characterization of the Clinical Data from Critically Ill Patients

I collected clinical data from nine patients who were admitted to the Smart ICU during the months of January and February 2018, according to the study protocol approved by the Ethics Committee (Annex 5). I logged a total of 3,024 records and considered a total of 126 patient-days for my code red analysis. I obtained the NEWS2 score from the parameters RR, SpO2, OX, SBP, HR, CONSC and TEMP, in addition to recording demographic data as well as the main comorbidities registered in the HIS. I saved these data in a secure database on a hospital server hourly. The objectives of my critical care data collection and analysis were the following:

- To make an exploratory analysis of the clinical data obtained retrospectively.
- To calculate the NEWS2 score hourly and the ΔNEWS2 score over 24 hours for all patients.
- To evaluate the prognostic value of high risk hourly NEWS2 scores and of a high risk 24-hour ΔNEWS2 score in predicting a prolonged ICU stay.
- To compare performance between high risk NEWS2 scores and a high risk ΔNEWS2 score over 24 hours to predict a prolonged ICU stay.

In previous studies, a prolonged length of stay (LOS) is considered equal or superior to 14 days [305]–[308]. I present a summary of the main demographic patient data in Table 4. Only 2,210 records (73%) from the total of 3,024 for the physiological variables (RR, SpO2, OX, SBP, HR, CONSC and TEMP) were used in my code red calculation due to the lack of data compliance or bad compliance in the HIS by HCWs. It is very important that HCWs fill in the clinical data in HIS correctly because if correct data is not recorded each hour, it is not possible to calculate the NEWS2 score. Only a small part of the lack of compliance of HIS data can be justified by the situation at the moment of patient ICU admission, when nurses and doctors must receive records and evaluate patient health, and not all the data are correctly captured by medical devices and sent to HIS. In the case of these data, only 82 empty records (3.7%) can be justified by the previous reason. Then, I divided the 2,210 completed verified data records into 58 intervals of 24 hours and calculated the mean value of NEWS2 daily. A major part of these data represented a high risk NEWS2 score calculated hourly (67%) and daily (63%), evidencing the high risk of deterioration of the majority of patients during their stay in the ICU and reflecting the highly severe state of their health. For this reason, I only analyse the high risk NEWS2 data obtained hourly and daily to predict a prolonged ICU stay.

Age(mean)	54.3 YEARS
Gender (n Male, [%])	5, [56]
LOS (mean in days)	16
Main comorbidities	Arrythmia, heart failure, chronic obstructive pulmonary diseases, sepsis, renal failure, cirrhosis, vascular disease
NEWS2 at admission (mean)	9,5
Number of records with NEWS2 between 1 and 4 - low risk (n, [%])	132, [6]
Number of records with NEWS2 between 5 and 6- medium risk (n, [%])	685, [31]
Number of records with NEWS2 equal or more than 7 - high risk (n, [%])	1393, [63]
NUMBER OF 24-HOUR ΔNEWS2 SCORES BETWEEN 1 AND 4 - LOW RISK (N, [%])	1, [2]
NUMBER OF 24-HOUR ΔNEWS2 SCORES BETWEEN 5 AND 6—MEDIUM RISK (N, [%])	18, [31]
NUMBER OF 24-HOUR ΔNEWS2 SCORES EQUAL TO OR MORE THAN 7—HIGH RISK (N, [%])	39, [67]

Table 5. Summary of demographic data from patients included in the Code Red Data Analysis Study.

The univariate distribution of the values of the NEWS2 variables is presented in Figure 82. The HR and the RR present asymmetric histograms leaning to the left. The SpO2, TEMP and SBP present symmetric histograms shifted to the right. In both cases, the peaks represent the most frequent values. The CONSC and OX are nominal variables and have a bar plot with the quantity of each category variable. In the case of CONSC, the values are very well distributed between the different categories. In contrast, in the case of OX, there is a very pronounced peak value for the oxygen support category.

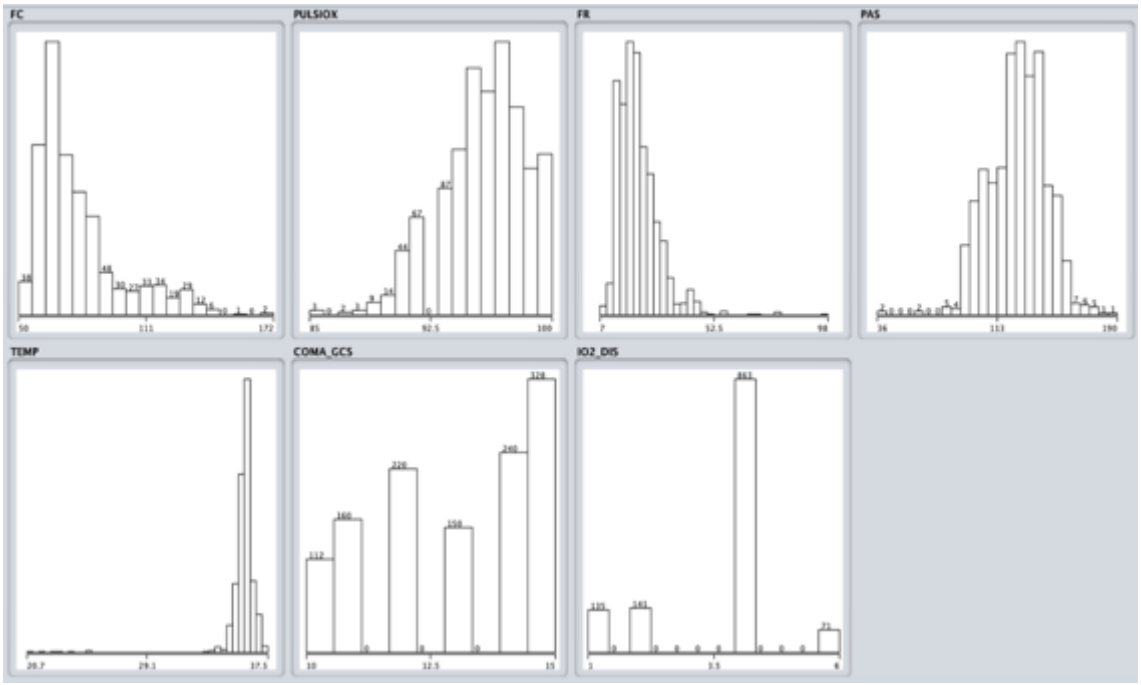


Figure 82. Distribution of variables included in NEWS2.

5.4.2. Relationship Between High Risk NEWS2 Score and a Prolonged Stay in the ICU

I used Pearson's chi-squared test to evaluate the relationship between a NEWS2 score of more than 7 (high risk) and a prolonged LOS, considering the relationship significant when the p value was more than 0.05 (Table 6). I applied the functions *'chisq.test().residuals'* and the function *'chisq.test().stdres'* in RStudio® to perform the calculations [309]–[311]. In this table, the value of Pearson's chi-squared test was statistically significant (p value>0.05). I calculated the odds ratio, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) and they are presented in Table 7. The odds ratio indicates that it is 3.3 times more probable to have a prolonged stay when there is a high risk NEWS2 score. The high risk NEWS2 score has low values of sensitivity and specificity, and so this parameter is not a good estimator of a longer ICU stay. The PPV indicates that out of every 100 patients who have NEWS2>=7, 67 patients will eventually have a prolonged stay and their NPV indicates that out of every 100 patients who had NEWS2>=7, 64 patients are still likely to have a prolonged stay.

	N (%)	LOS>=14 days	LOS<=14 days	χ^2 Pearson TEST
NEWS2>=7	1393(63%)	836(60%)	557 (40%)	0.136

Table 6. Relationship between a high risk NEWS2 score and a prolonged stay at ICU.

	Odds Ratio (95% CI)	S	e	PPV	NPV
NEWS2>=7	3.312(1.001-6.982)	52.2%	59.7%	66.9%	63.7%

S = Sensitivity
E = Specificity
PPV = positive predictive value
NPV = negative predictive value

Table 7. Odds ratio, sensitivity, specificity, positive predictive value, and negative predictive value from NEWS2 scale considering a prolonged stay in the ICU.

5.4.3. Relationship between 24-Hour ΔNEWS2 Score and a Prolonged Stay in the ICU

I also used Pearson's chi-squared test to evaluate the relationship between the mean NEWS2 over 24 hours being equal to or more than 7 and a prolonged LOS, considering the relationship significant when the p value was more than 0.05 (Table 9). The p-value in this case was also significant (Table 7). I calculated the odds ratio, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) and they are presented on Table 8. When the variation of NEWS2 over 24 hours was equal to or more than 7, it is 9.1 times more likely that the patient will experience a prolonged stay based on the odds ratio. ΔNEWS2 is not specific for a prolonged stay (19.7%); however, it has a high sensitivity (92.1%) for detecting this case. Their PPV indicates that out of every 100 patients who had a ΔNEWS2>=7, 58 patients will eventually have a prolonged stay and their NPV indicates that out of every 100 patients who had ΔNEWS2>=7, 88 patients are still likely to have a prolonged stay. The specificity of NEWS2 is greater than that of ΔNEWS2 (59.7%), but it has a lower sensitivity (52.2%), which is counterproductive as it does not cover all patients who will have a prolonged stay. The PPV for NEWS2 >=7 is higher than for ΔNEWS2 (66.9%) but the NPV is lower (63.7%), and a considerable number of patients could still have a prolonged stay with NEWS2 >=7.

	N (%)	LOS>=14 days	LOS<=14 days	χ^2 Pearson TEST
24-HOUR ΔNEWS2 >=7	39(67%)	25(63%)	14 (37%)	0.109

Table 8. Relationship between the high risk NEWS2 score and the prolonged stay at ICU.

	Odds Ratio (95% CI)	S	e	PPV	NPV
24-HOUR ΔNEWS2 >=7	9.123(4.277-17.876)	92.1%	19.7%	57.8%	89.7%

S = Sensitivity
E = Specificity
PPV = positive predictive value
NPV = negative predictive value

Table 9. Odds ratio, sensitivity, specificity, positive predictive value, and negative predictive value from NEWS2 scale considering a prolonged stay in the ICU.

5.4.4. Comparison of Performance between High Risk NEWS2 and 24-Hour ΔNEWS2 Scores

I analysed the receiver operating characteristic (ROC) curve and the area under the curve for the NEWS2 and 24-hour ΔNEWS2 scores, with regard to a prolonged stay in the ICU, considering p-values lower than 0.05 as indicating a significant value. The area under the curve for ΔNEWS2 over 24 hours was 0.792, with p = 0.003 and a 95% confidence interval of 0.624 - 0.88 (Figure 83). For NEWS2, the area under the curve was 0.590, with p = 0.005, a 95% confidence interval of 0.53 - 0.70. Both values are statistically significant and evidence an AUC ≥ 0.7, which is a value that indicates a good predictive capacity. I obtained the Youden index from the coordinates of the curve to find the cut-off point of NEWS2 and ΔNEWS2 over 24 hours, in which their sensitivity and specificity are optimal for discriminating those who would have a prolonged LOS from those who would not. The cut-off points for ΔNEWS2 over 24 hours was 14.5 days, with 84.2% sensitivity and 45.3% specificity. For NEWS2, the cut-off point was 9.5 days, with 81.2% sensitivity and 40% specificity. So, the high risk ΔNEWS2 score over 24 hours is a better predictor of prolonged length of stay than the high risk NEWS2 score collected hourly.

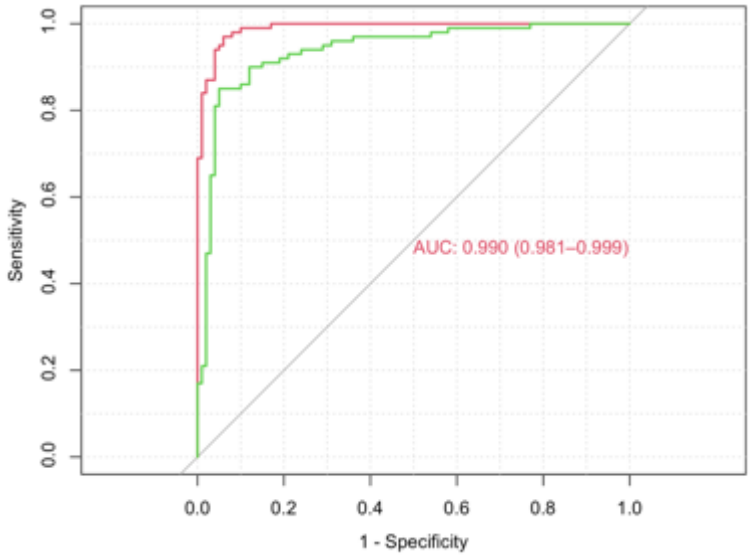


Figure 83. ROC curve for NEWS2>=7(green line) and variation of NEWS2>=7 over 24 hours (red line).

5.5. Hand Hygiene Data Analysis and Management

5.5.1. Characterization of the De-Identified Data from Healthcare Workers and Hand Hygiene Data

The hand hygiene data was generated and I collected it for the Smart ICU during the period from June 2018 to March 2020. I saved it in a secure database. The hand hygiene practices of HCWs and NHCWs were registered by the three hydroalcoholic gel dispensers and the RTLS system installed in the unit. The objectives of my analysis of the data collected from the hand hygiene devices were the following:

- To evaluate the usability of the whole hand hygiene monitoring system in a clinical setting.
- To quantify the use of the whole system during the period of my study and to understand its use patterns.
- To calculate hand hygiene opportunities and compliance rates for professionals and visitors to the unit using the RTLS system.
- To predict hand hygiene compliance using mathematical models.

The sociodemographic data of the 51 professionals who worked in the ICU and who accepted to participate in my study of the effectiveness of the hand hygiene monitoring system implemented over the time of development of this thesis are shown in Table 10. All the participants signed the informed consent form shown in Annex 7, thereby authorizing the use of their data for my research during the period of the study. The nursing team was the professional category with the most participants in this study (n=29/51). Most of the participants were women (n=38/51) and most had a master's degree or above (n= 36/51). The data were de-identified in all cases before I performed the data analysis, and the data recovered by the electronic dispensers in the unit is summarized in Table 11. In addition to the professionals who agreed to participate in the study, 5 generic RFID tags were distributed at the entrance to the ICU for family members, as were 20 generic cards with generic tags for non-habitual professionals who work in the unit, such as medical and nursing students. These tags cannot identify a specific person, they only identify professional or family. My study received a good reception and acceptance from all the professional categories and the permanent clinical team at unit (nurses, assistants, and doctors) made a great effort so that all non-permanent professionals who are not from the unit and family members could use the generic cards in a systematic way and comply with all the protocols established for the performance of hand hygiene when necessary.

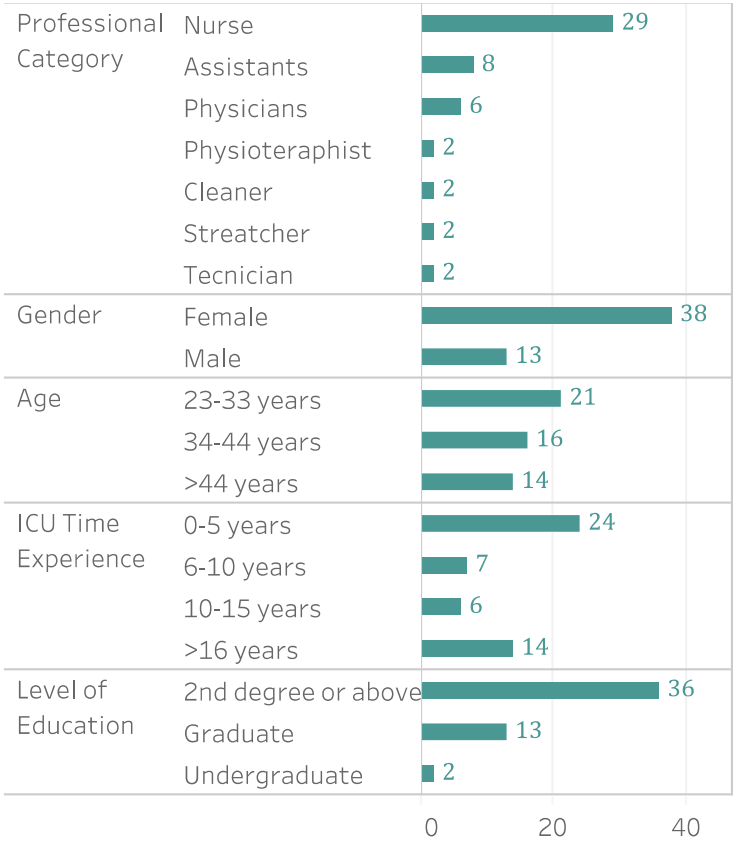


Table 10. Sociodemographic data of ICU professionals who participated in the study.

VARIABLE	FUNCTION
DATETIME	Register of the day, month, year, hour, minute and second when the record of the hand hygiene was registered with the format='%m/%d/%Y %H: %M: %S'
RFID	Boolean variable that indicates whether the RFID antenna above dispenser detected an RFID tag or not.
ID	Identification code of the people (and generic tags) registered on the system when they were detected.
CATEGORY	This variable indicates the following categories: • Doctor • Nurse • Technician • Assistant • Cleaner • Relative • Stretcher • Physiotherapist • No tag
DISPENSER	Identification of the dispenser used (Dispenser 1, 2 or 3).

Table 11. Type of data collected by electronic dispensers for hydroalcoholic gel.

5.5.2. Analysis of the Use of Electronic Dispensers for Hydroalcoholic Gel in the Unit Classified According to Professional Category

A total of 232.987 moments of use of alcoholic dispensers for hydroalcoholic gel were registered during the period of this study. In the year 2018, a total of 42,593 moments of use of electronic dispensers were registered; in 2019 a total of 147,434 moments of hand hygiene were registered; and in 2020, a total of 42,960 were also registered. It is important to highlight that some considerations concerning the data collection should be taken into account. Successive uses of a dispenser carried out during a period of 30 seconds are grouped, because some people use the dispensers more than one time and, consequently, they use more alcoholic solution each time they clean their hands. Another important thing to consider in the data analysis is that clinical professionals from other units visit the ICU at certain moments during medical consultations. These people do not have an RFID tag and so in these cases they cannot be identified. For this case and for the cases when people are not identified, the moment of dispenser use was registered with the label of "No tag".

A representation of the quantification of the monthly use of the electronic dispensers is presented in Figure 84. The month of November 2019 was the month with the most registers; this can be explained by the high workload for nurses and doctors as well as by the number of serious cases due to the influenza virus season [312], [313]. The same occurs for the months of October 2018 and March 2019, in which there are two local peaks of use of the electronic dispensers compared to the other months. The month with the fewest registers was August 2018, because in this month the unit was closed due for disinfection processes. In the month of August 2019, the unit was not closed but the registers were fewer than usual in other months, because members of the permanent clinical staff were on holiday and non-permanent professionals worked in the unit during this period.

The three categories with the most registers of hand hygiene (nurses, assistants and "No tag") can be observed in Figure 85 together with the other categories of professionals and visitors registered by the devices. During the period from October 2019 to February 2020, there was a significant increase in the use of the dispensers by nursing staff, due to the overload of nurses during this period. During the months of November 2019 and December 2019 the number of registers of assistants was greater than the category "No tag" and this can be explained by the reduction in external professionals and students who entered the unit during this period. On the other hand, in the month of March 2020 the data for nursing staff decreased and the "No tag" category saw a large increase due to the beginning of the coronavirus disease epidemic. In the month of March 2020, all HCWs had to use protective equipment and they did not use the identification card frequently. The data for the category "No tag" in this month include the data for all categories.

Figure 84. Analysis of the use of electronic dispensers by all workers and visitors between June 2018 and March 2020.

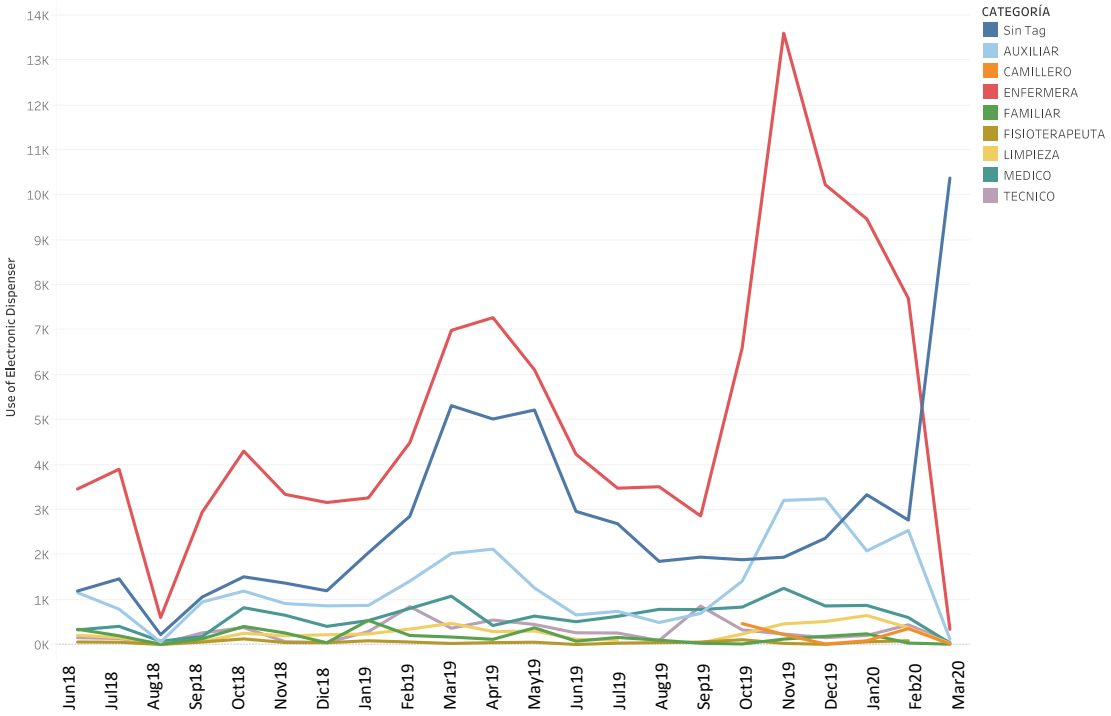


Figure 85. Analysis of the use of electronic dispensers classified by category between June 2018 and March 2020.

I calculated the hourly frequency of hand hygiene to understand the patterns of use of electronic dispensers and the frequency of hand hygiene by the healthcare professionals in more detail. Figure 86 presents the histogram of the use of electronic dispensers per hour by all workers and visitors. This histogram shows that there are six well-defined branches. The branch in which there was use of the electronic dispensers between 5 and 10 times per hour and that for use between 20 and 25 times per hour represent 56% of the total use of the dispenser. The branch in which there was use of the electronic dispensers between 0 and 5 times per hour and a use of between 25 and 30 times per hour represent 9% of the total use of the dispenser. The branch in which there was use of the electronic dispensers between 10 and 15 times per hour represents 23% of the total use of the dispenser and the branch in which there was use of the electronic dispensers between 15 and 20 times per hour represents 12% of the total use of the dispensers. The mean use of the dispensers was 14.7 times per hour and the 95% quantile for use of the system is 24.4 uses per hour.

The distribution of hand hygiene disinfection with hourly frequency among different professional categories is presented in Figure 87. The large size of the boxplots indicates that there was heterogeneous behaviour among people within the same category. The interquartile range is between 9 and 21 hand hygiene events per hour in a large part of the professional categories, except in the cases of porters. In this professional category, use of the electronic dispensers is concentrated between 16 and 27 times per hour. This can be explained by the fact that porters enter the unit only when nurses call them at specific moments, for example when patients must be moved to the radiology department, when patients are to be discharged, or when nurses need extra help to move patients during their hygiene or more complex clinical procedures. Moreover, in almost all cases, some people from different categories fall outside of the interquartile ranges, they can be classified as 'outliers' at both extremes of the boxplot, and this means that there are people who disinfect their hands more or less frequently than the majority of their colleagues.

Considering that one dose from a dispenser represents 1.5 ml of hydroalcoholic gel and that 500 ml bottles were used in the electronic dispensers in the unit, I calculated the number of bottles used during the period of study (Figure 88). The mean number of bottles per month was 31. It is interesting to associate this graph with the graph in Figure 84 to check that the months in which there were most registers of hand hygiene events correspond to the months in which the number of bottles was greater.

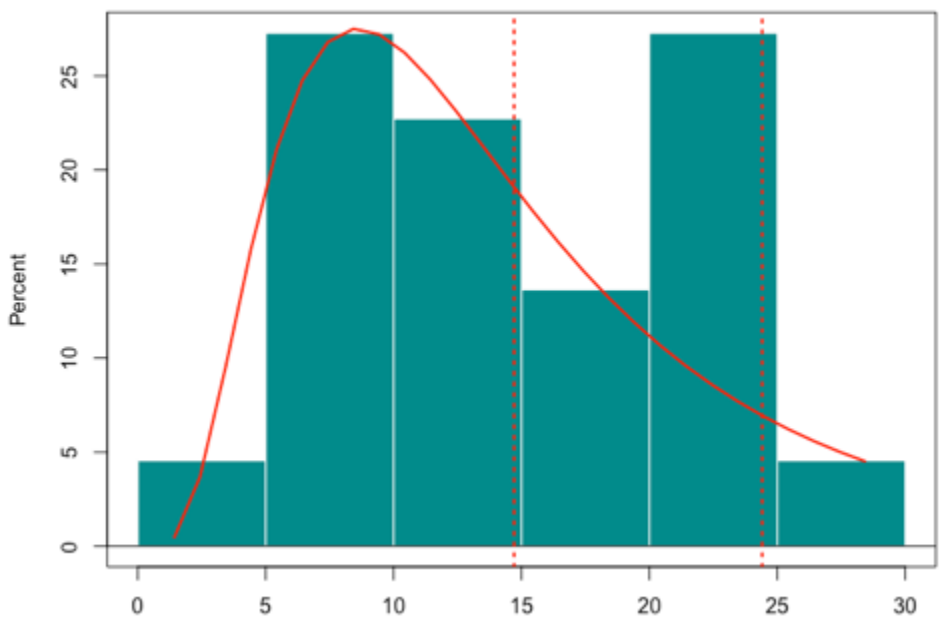


Figure 86. Distribution of the use of the electronic alcoholic dispensers per hour for all workers.

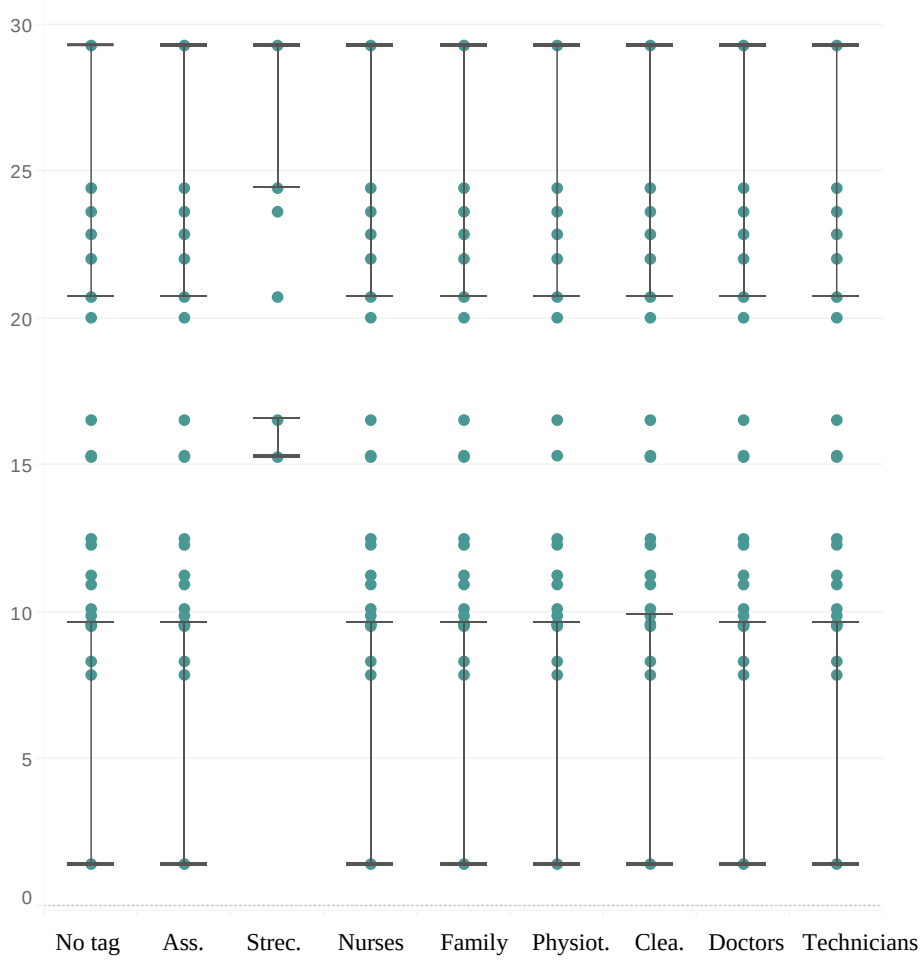


Figure 87. Distribution of the use of the electronic alcoholic dispensers per hour classified according to professional category. Ass.=Assistants. Strec.= Streatcher. Physiot.=Physioteraphist. Clea.= Cleaner.

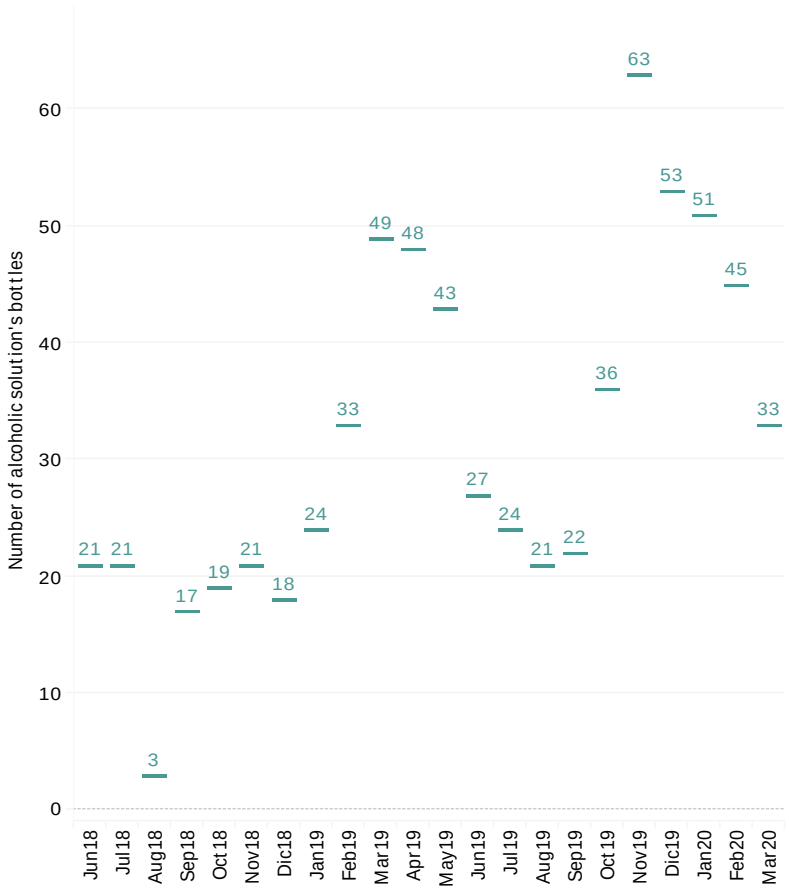


Figure 88. Number hydroalcoholic gel's bottles used during the period of my study.

Figure 89 shows the use of the three different electronic dispensers in the ICU separately. Dispenser 0-1 and dispenser 3-4 were always used more than dispenser 2, because they were in the nursing station and the patient room number 2 was used less than the others. Many professionals enter the unit and only go to the nursing station: they do not enter patient rooms. The time series graph of dispensers 0-1 and 3-4 also follows a similar pattern to the time series in the previous figure and Figure 85.

During the weekends, the use of the dispensers was lower because the most important clinical procedures, which require contact with patients, are carried out during the week (Figure 90), and there is a higher flow of professionals into the patient rooms. During the week, the day with most registers was Tuesday and the day with least was Friday. Monday, Wednesday, and Thursday had a very similar number of records of hand hygiene events. Moreover, the use of dispensers was more intensive during the morning shift and was reduced during the night shift for the same reason (Figure 91). The main activities related to patients are usually carried out during the morning and afternoon. During the night, the clinical staff prioritize rest and sleep for the patients, and the staff try to perform a minimum of actions so as not to wake them up. The period with most use of the dispenser was

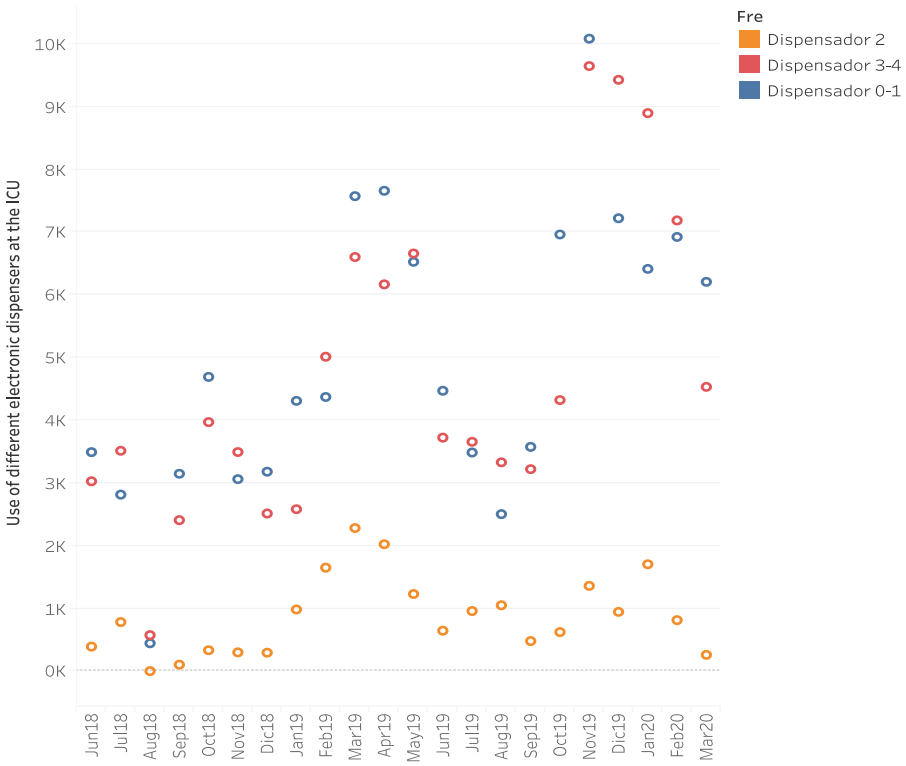


Figure 89. Use of the three electronic dispensers in the ICU during the period of my study.

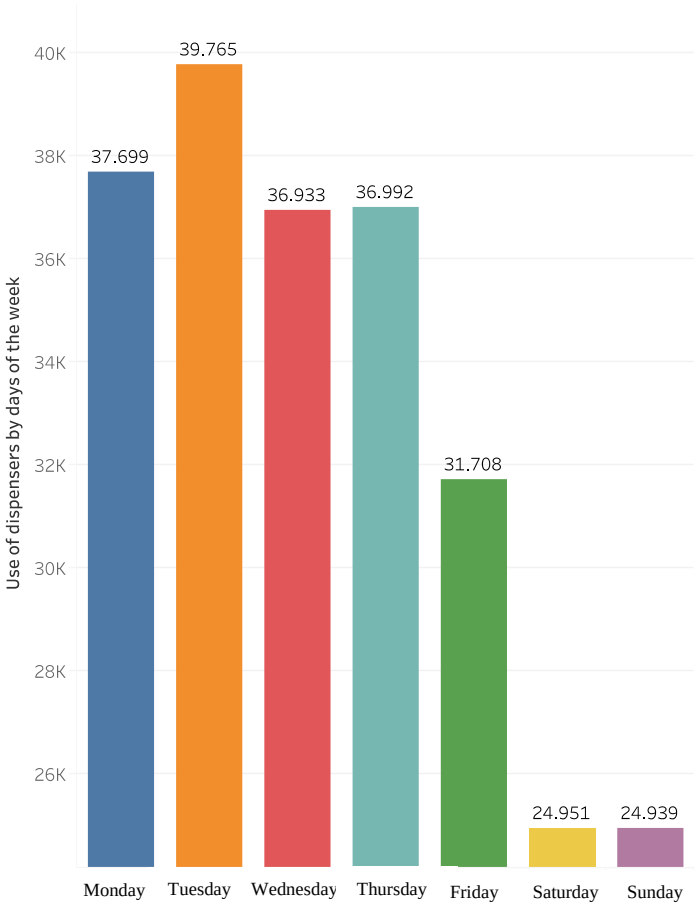


Figure 90. Use of the dispensers by days of the week.

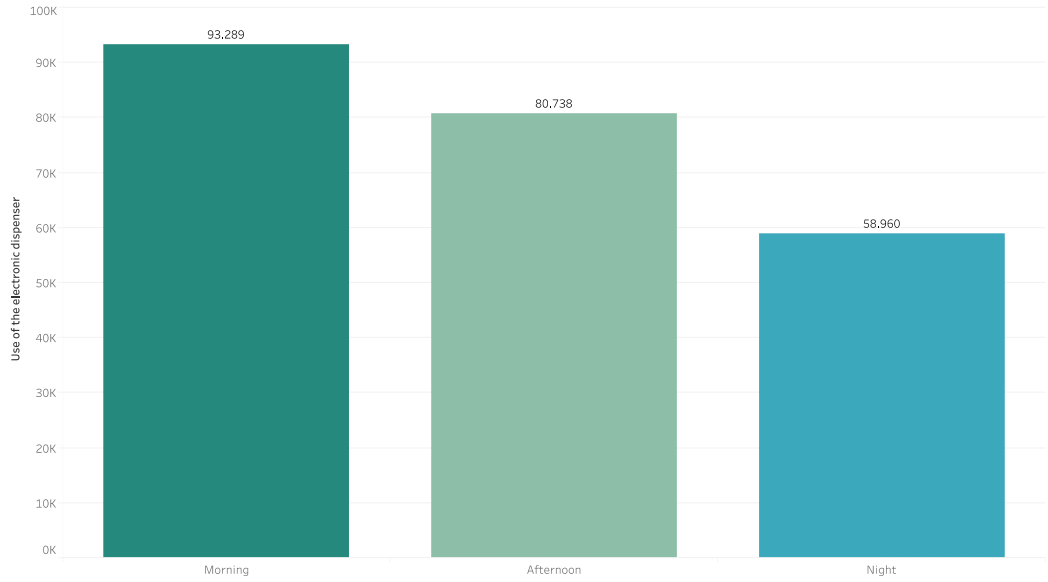


Figure 91. Use of the electronic dispensers by different shifts.

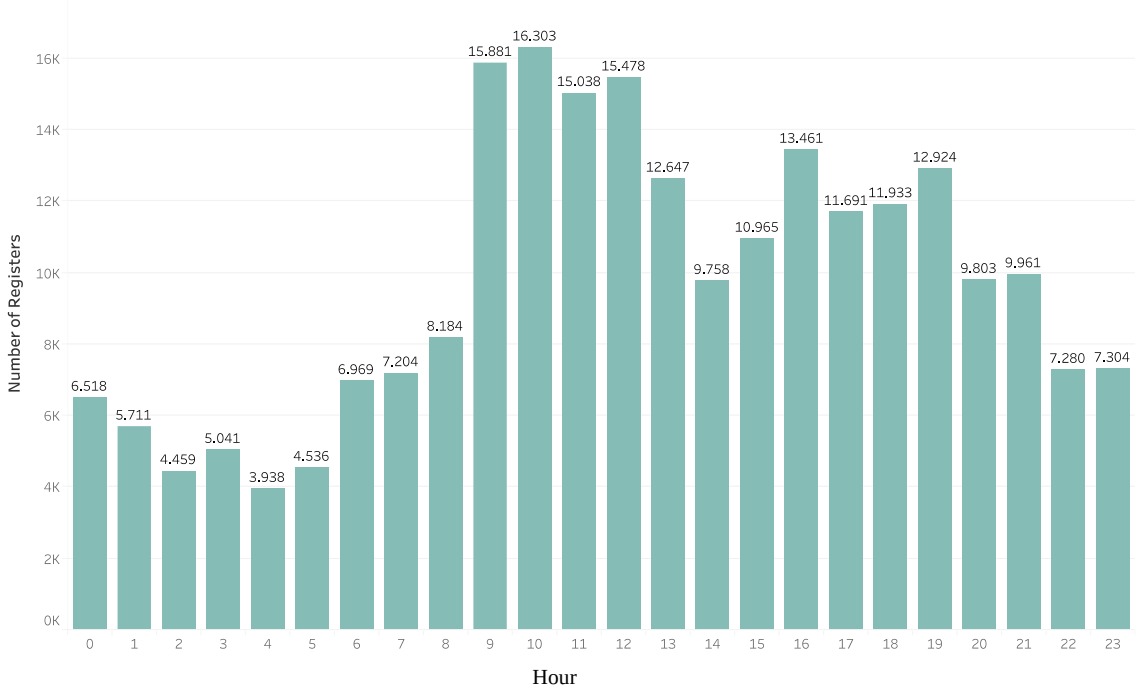


Figure 92. Total number of registers collected from the three dispensers each hour.

between 9 a.m. and 9 p.m. and the period with least use was between 10 p.m. and 8 a.m. (Figure 92). During the day, the hour after the shift changes (at 9 a.m. and 4 p.m.) presented a significant increase in the number of hand hygiene events and, consequently, indicates a higher level of patient-related activities by the clinical staff.

5.5.3. Calculation of Compliance with Hand Hygiene in the Unit Using the RTLS System

I collected the data from the whole electronic monitoring system composed of the RFID antennas of the RTLS (antennas above dispensers, antennas inside patient rooms and at the nursing station, as well as antennas above the doors of patient rooms and at the entrance to the nursing station) and three electronic dispensers for the period from April 2019 to February 2020. The hand hygiene data were collected over this period because the RTLS system was prepared to evaluate correctly the opportunities for hand hygiene (HH) at the beginning of April 2019. The type of data generated by the whole system is presented in Table 12.

Compliance with hand hygiene can be calculated using the following equation[314]:

$$HH\ Compliance = \frac{Number\ of\ actions}{Number\ of\ opportunities} x\ 100$$

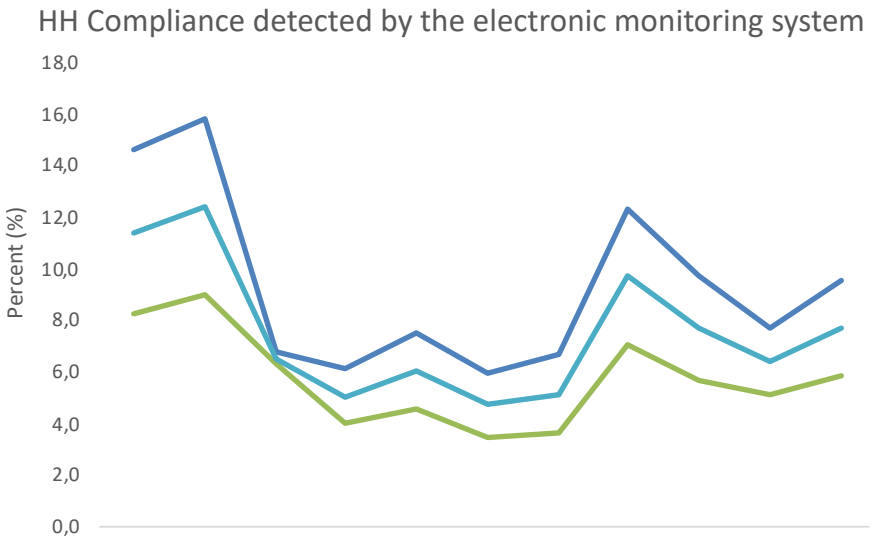
The **number of opportunities** detected by the electronic hand hygiene monitoring system is given by all the moments when people would have to wash their hands before and after leaving a specific location, and the **number of actions** is the number of times detected by the system that people effectively clean their hands. In general terms, opportunities are generated when people move from one location to another. For my evaluation of hand hygiene, I considered a period of two minutes to detect if people moved from one location to another after washing their hands to account as one effective action. I arrived at this period by considering isolated patients for whom people need more time to prepare their protective equipment.

A total of 2.394.078 opportunities and 177.656 actions of HH were detected by the whole system in the unit, considering the five patient rooms and the nursing station. I initially pre-processed the data to eliminate erroneous records captured by the system, in which the day and time of exit of a location was null. These cases occurred in 23% of all registers because the system did not have correctly detected the movement of people between different locations. The reason for this is that the tags of the cards carried by the different professionals are sensitive to the position of the antennas and it is also because if the tags are dirty or damaged, they will not work very well and they will not perform as well as a new one. For this reason, the tags of the cards carried by the professional were replaced every six months, to minimize this problem. After the data processing, I obtained a total of 550.638 opportunities and 40.861 actions of HH, which represents a total of 7.4% of global compliance with hand hygiene.

VARIABLE	FUNCTION
ENTRY DATE	Register of the day, month, year when people enter a specific location, with the format='%m/%d/%Y'.
ENTRY TIME	Register of the hour, minute and second when people enter a specific location, with the format=' %H: %M: %S'.
ENTRY HYGIENE	Register of hand hygiene at one of the dispensers (Dispenser 1, 2 or 3) before entering a specific location (Boolean variable).
EXIT DATE	Register of the day, month, year when people leave a specific location, with the format='%m/%d/%Y'.
EXIT TIME	Register of the hour, minute and second when people leave a specific location, with the format=' %H: %M: %S'.
EXIT HYGIENE	Register of hand hygiene at one of the dispensers (Dispenser 1, 2 or 3) after leaving a specific location (Boolean variable).
ID	Identification code of the people (and generic tags) registered on the system when they were detected.
CATEGORY	This variable indicates the following categories: • Doctor • Nurse • Technician • Assistant • Cleaner • Relative • Stretcher • Physiotherapist • No tag
LOCATION	Some of the locations in the unit: • Nursing station • E014001 (Patient room 0) • E014011 (Patient room 1) • E014021 (Patient room 2) • E014031 (Patient room 3) • E014041 (Patient room 4) • External corridor

Table 12.Type of data collected by the whole system.

The total compliance with hand hygiene calculated by the system during the period of study, entry compliance with hand hygiene and exit compliance are



	Apr-19	May-19	Jun-19	Jul-19	Ago-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20
Entry Compliance (%)	14,6	15,8	6,7	6,1	7,5	5,9	6,7	12,3	9,7	7,7	9,5
Exit Compliance (%)	8,3	9,0	6,3	4,0	4,6	3,4	3,6	7,0	5,7	5,1	5,9
Total Compliance (mean*) (%)	11,4	12,4	6,5	5,0	6,0	4,7	5,1	9,7	7,7	6,4	7,7

Figure 93. Compliance with hand hygiene during the period of my study.

presented in Figure 93. The total compliance is the mean between entry compliance and the exit compliance. In other words, it is the mean of all moments in which the electronic monitoring system detected actions before and after entering patient rooms. The entry compliance is significantly higher than the exit compliance and the total compliance, indicating that hand hygiene is carried out before entry to patient rooms much more frequently than after exiting in all cases, except for the month of June 2019. This is because the clinical staff can wash their hands inside patient rooms, where there are no electronic dispensers and so, these cases cannot be counted. In June 2019, the hand hygiene compliance on entrance to and exit from patient rooms were very similar. Some nurses from the Department of Preventive Medicine at HCB suggest that the most important data to consider for the system should be only the data generated at the moment of entrance to a patient room, which corresponds to moment 1 of HH (HH performed before contact with a patient). The cases of exit compliance cover a part of HH actions that can be related to moment 4 of HH (before touching a patient) or moment 5 of HH (after touching the surroundings of a patient). For my study, I considered both datasets (entry compliance data and exit compliance data) globally, considering all the limitations previously mentioned.

Treemapping of the data of hand hygiene compliance on entrance to and exit from patient rooms classified by month is presented in Figure 94. It is another way of representing the data of hand hygiene compliance and enables comparison the

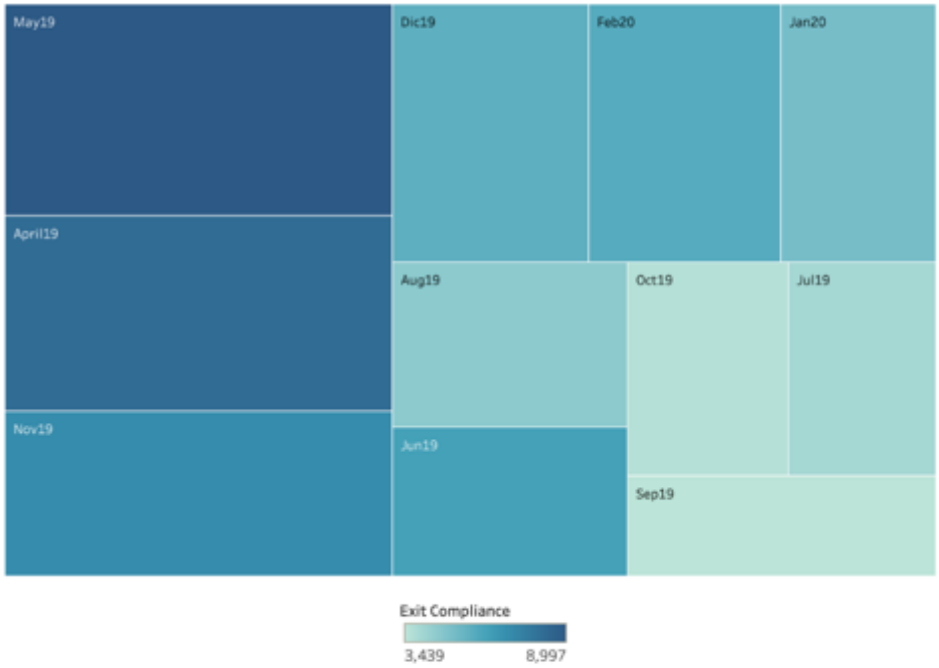


Figure 94. Treemapping of hand hygiene compliance classified by month. The colour represents exit compliance while the size represents entry compliance.

data proportions for different months by the different colours and the size of the rectangles. The months with the most hand hygiene compliance were May 2019 (12.4%), April 2019 (11.4%), and November 2019 (9.7%), as shown by the size and colour of rectangles.

The distribution of the HH opportunities I collected during the period of my study, which is the sum of all the cases detected of movements in the unit, classified according to positive cases (hand hygiene=" Yes") and negative cases (hand hygiene = "No") is presented in Table 13. The opportunities are classified according to the moment of hand hygiene (entry or exit moment) and by professional category. The positive cases correspond to the "actions" of the hand hygiene and, in this case, the data in the category "No Tag" were not collected because movements can only be collected by people who have an RFID tag on their identification card. There are some patterns of behaviour for the categories of nurses and assistants. Most of the staff in these professional categories who do not wash their hands before entering a patient room also do not wash their hands after leaving it. The strategies for promoting hand hygiene have to be designed mainly for these people because they are the people who enter rooms most frequently and have most contact with patients.

The total duration of the stay in each location of the Smart ICU calculated by the whole system during the period of my study is presented in Figure 95.

		EXIT HYGIENE																				
		No										Yes										
ENTRY HYGIENE	CATEGORY	April19	Mayo19	Jun19	Jul19	Aug19	Sep19	Oct19	Nov19	Dic19	Jan20	Feb20	April19	Mayo19	Jun19	Jul19	Aug19	Sep19	Oct19	Nov19	Dic19	Jan20	Feb20
No	Nurses	11.624	8.578	6.319	16.785	15.564	11.637	14.600	14.551	11.350	11.976	9.151	712	461	506	604	475	317	396	853	541	564	453
	Assistants	7.960	3.613	3.629	6.095	6.659	6.373	7.028	5.920	7.374	5.885	6.563	227	101	60	103	107	89	91	162	198	162	173
	Doctors	856	1.206	1.194	2.468	2.568	1.806	2.299	2.052	1.683	3.556	1.830	39	53	77	82	103	92	77	100	85	76	61
	Cleaners	796	531	485	1.075	22	460	969	1.050	939	1.260	720	21	14	7	15		2	10	16	27	41	15
	Family	327	617	883	548	681	1.058	506	1.028	880	719	566	9	31	9	13	30	8	1	14	6	7	2
	Technics	176	210	215	175	194	160	130	120	75	70	97	16	13	6	14	10	17	5	11	8	9	4
	Physiotherapist	101	112	30	180	219	62	115	55	17	76	86	9	6		2	8	1	5	2		3	6
	Stretchers							227	89	61	98	243							14	6		6	22
Yes	Nurses	1.914	1.340	541	1.079	1.125	737	1.035	2.057	1.382	1.171	1.142	876	695	178	271	437	176	296	691	444	381	414
	Assistants	587	262	102	169	170	172	218	388	365	210	280	208	107	31	36	37	25	63	155	116	67	109
	Doctors	99	157	64	168	218	176	140	212	126	117	98	38	96	17	36	96	65	39	57	34	27	29
	Cleaners	69	62	6	7		5	20	31	13	21	16	21	14	3					5	1	4	
	Family	33	55	8	13	18	12	10	19	5	9	1	30	47	11	14	8	10	8	10	5	7	
	Technics	17	21	2	12	14	7	16	3	3	13	10	2	6				4	4	1		4	1
	Physiotherapist	7	34	6	25	39	6	2	15	14	8	4	1	17		2	4						
	Stretchers							24	7		5	21							14	8		3	6

Table 13. Patterns of the hand hygiene behaviour by month considering all professional categories.

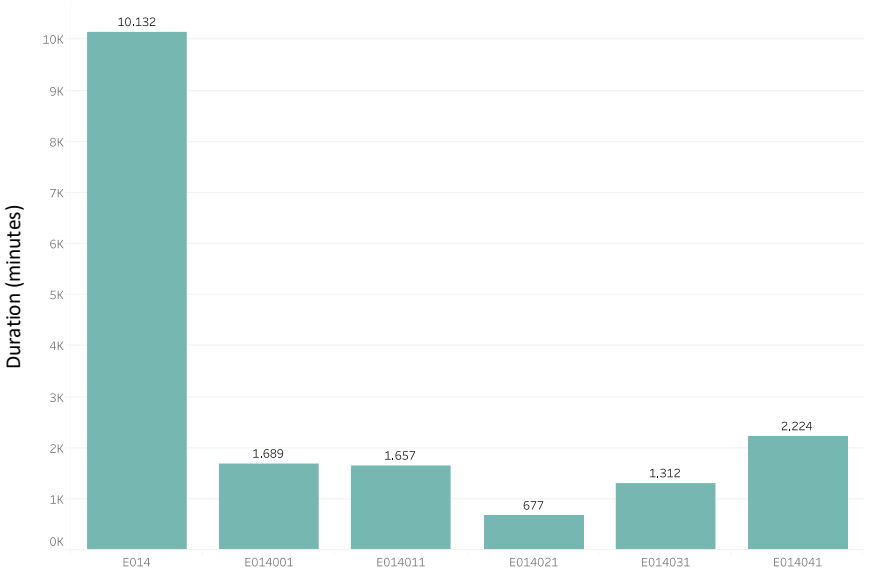


Figure 95. Count of the duration of the use of locations in the Smart ICU (in minutes) during my study.

	CATEGORY							
Location	Nurses	Assistant	Stretcher	Family	Physiotherapist	Cleaner	Doctors	Technician
E014	745,6	231,2	3,0	56,9	2,4	12,0	131,5	7,2
E014001	89,3	32,2	0,3	186,2	0,9	1,4	7,9	0,4
E014011	65,3	18,8	0,6	3,7	1,0	1,5	10,2	0,3
E014021	27,1	7,7	0,0	2,1	0,3	0,7	3,1	0,2
E014031	89,3	18,3	0,5	24,5	1,0	1,6	7,4	0,2
E014041	96,6	25,8	0,1	12,9	0,8	1,2	7,4	0,2

Duration
0,0 745,6

Table 14. Sum of the total duration of stay (in minutes) in each location classified according to professional category.

The nursing station ("E014") was the place where people remained for the longest time, followed by patient rooms 4,0 and 1, respectively. The total duration inside each patient room suggests that these patient rooms were the most used during the period of my study. In Table 13, the total duration inside each location is classified according to the professional category and the main peaks of the total time spent at the nursing station are for nurses, assistants, and doctors. For all patient rooms, the peak time is observed for nurses followed by assistants, except for the patient room number 0. In this last patient room, the system recorded a higher total duration. The distribution of the total duration (in minutes) inside the patient rooms for all workers is presented in Figure 96. HCWs, NHCWs and visitors stay inside patient rooms for 15 minutes or less in 93% of the times they enter.

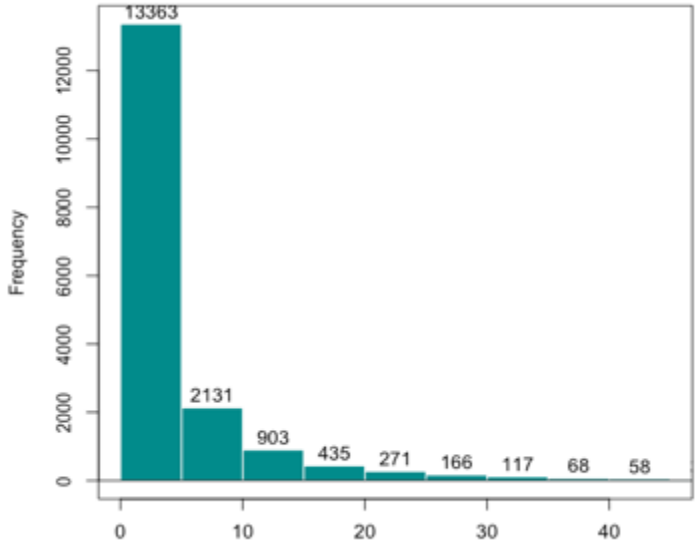


Figure 96. Distribution of the total duration (in minutes) inside patient rooms for all workers.

Generally, when HCWs enter a patient room for the first time in their daily shift they try to do all the activities planned at the start of the shift to avoid medication errors and errors in clinical procedures. In the case of the nurses and assistants, they prepare all the consumable material, medications, and therapy equipment before entering the patient rooms with the objective of optimizing their work and avoiding unnecessary entries.

The total number of hand hygiene compliance events classified hourly is presented in Figure 97; and the classification by professional category and visitors are presented in Figure 98. The hours when there was most compliance with hand hygiene in the unit were 12 noon and 7 p.m., just before the visiting times, and the hours when there was least hand hygiene activity was 4 a.m. and 2 a.m., including the hand hygiene opportunities, entry compliance and exit compliance. Moreover, there are professionals who enter patient rooms during a specific range of scheduled times, while other professional categories enter patient rooms continuously. The medical team enters patient rooms continuously, but during the interval between 9 a.m. and 1 p.m. they enter more frequently. Cleaners, porters and physiotherapists are the professional categories which entering patient rooms during specific schedules. Knowing this, hand hygiene recommendations can be personalized by ranges of hours and according to the role of the professional.

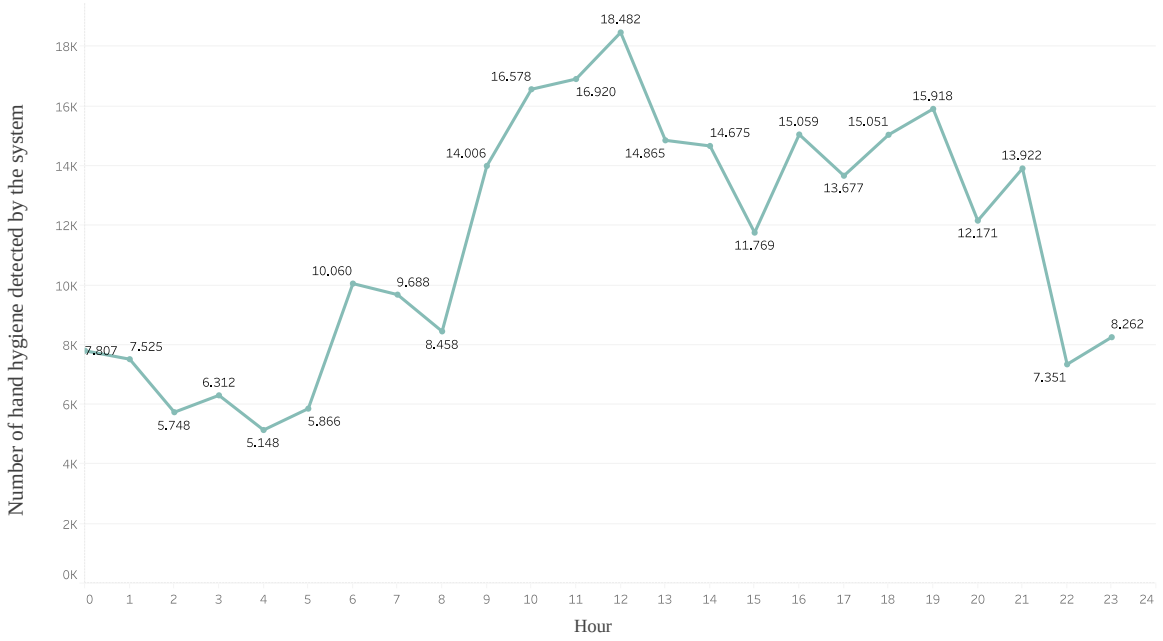


Figure 97. Total number of hand hygiene compliance events classified according to the time of occurrence.

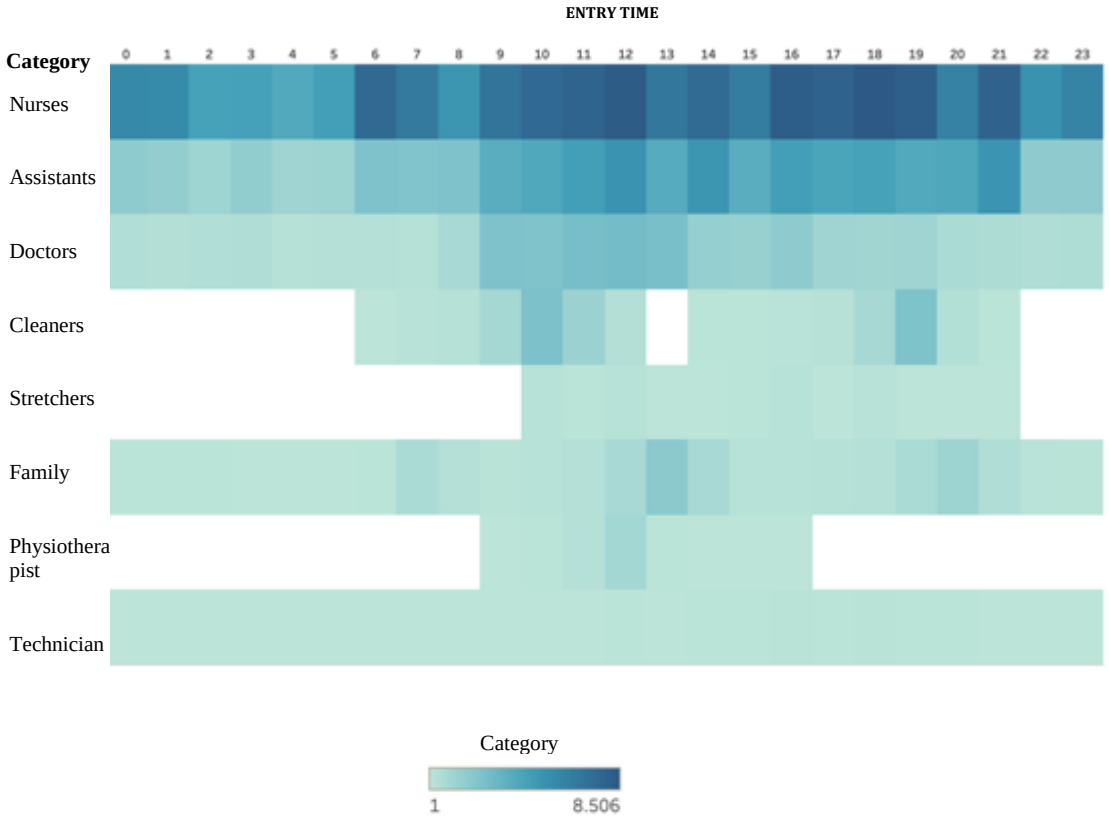


Figure 98. Treemapping of the entry time count classified according to professional category.

5.5.4. The Use of Mathematical Models to Predict Hand Hygiene Compliance Among Staff and Visitors

Mathematical models can be used to predict hand hygiene compliance and to identify at which moments it would be useful to display some recommendations for people based on the data collected, such as entry date, entry time, exit date, exit time, ID, category, and location. The main challenge consists of predicting the behaviour of people and classifying which people will wash their hands and which people will not wash their hands under some visual stimulations. I evaluated the data I collected using classification models considering the type of variables collected by the system. Classification models are an attempt to classify if people will disinfect their hands (event 1: "Yes", event 2: "No") at one of the three electronic dispensers before entering or leaving a patient room. The first step is to apply the process of data cleansing to a hand hygiene dataset with the aim of ensuring the elimination of missing data and all data with inaccuracies during the period of the study. In the data cleansing process, I performed the following steps:

i. **Eliminating rows in which the date of exit was null.**
ii. **Eliminating data for the external corridor.**
iii. **Eliminating the days in which there were less than 400 registers to ensure that the data I will analyse represent a medium or high flow of people inside patient rooms.**
iv. **Eliminating data for which the time inside a patient room is more than two hours.**
v. **Eliminating categories with less than 100 registers.**
vi. **Normalizing the months with respect to the total number of days.**
vii. **Eliminating repeated events in which the entrance in one zone is the exit from another.**
viii. **Considering only one event when more than one hand washing event is detected during a period of 30 seconds.**

The original dataset had 2,394,078 registries, which represents the opportunities detected by the system; and after applying all the 8 rules of the data cleansing, the final dataset had 70,000 registers (6,364 registers per month). I uploaded the dataset into the Weka® software to analyse it. Figure 99 shows the distribution and the general characteristics of the variables of the pre-processed dataset in Weka®. This software reads the 'csv' file and detects missing data. Moreover, the software enables visualization of the data according to each variable

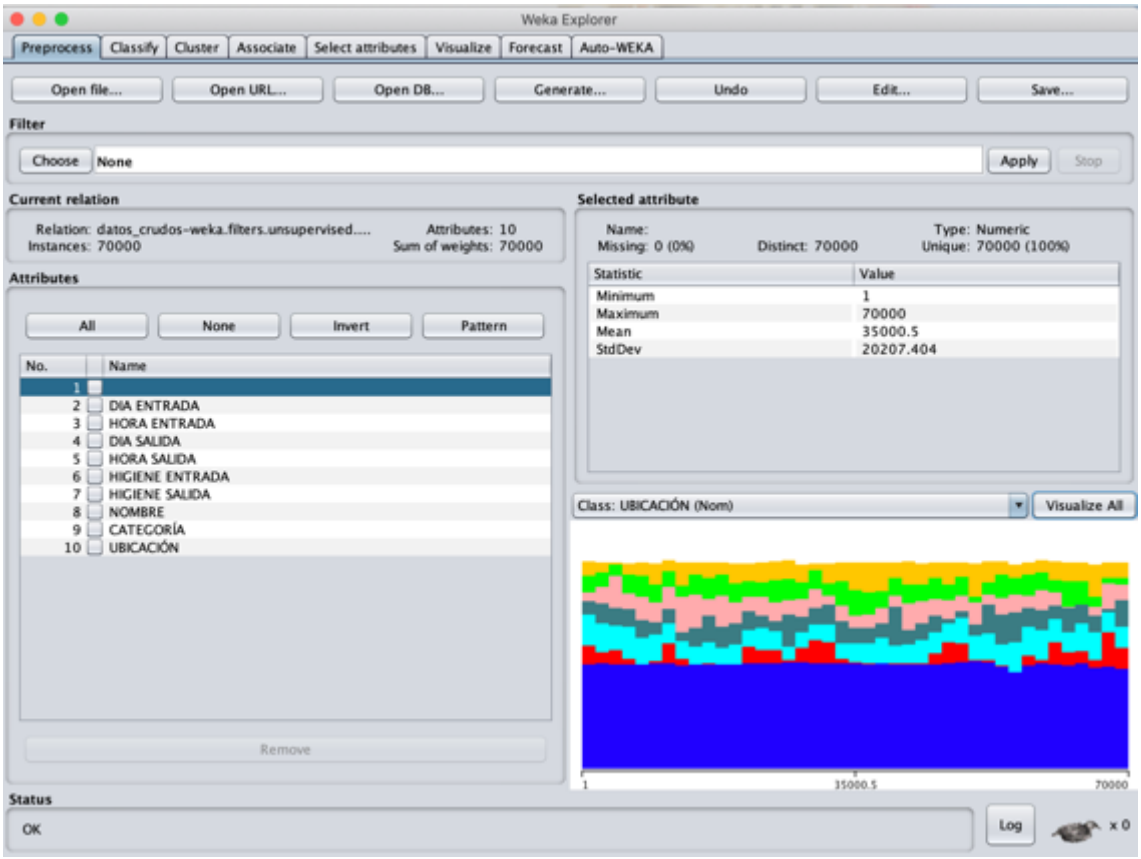


Figure 99. General distribution of the variables of the hand hygiene dataset in Weka.

variable in the dataset. In the case of the hand hygiene dataset, Weka® detected that visualization of the parameters was best as a function of location. In Figure 100 the data can be visualized as a function of the different locations in the dataset. The colour dark blue represents the nursing station, dark green represents patient room 0, light green represents patient room 1, red represents patient room 2, yellow represents patient room 3, and pink represents patient room 4. In Annex 9, the meaning of the statistical parameters in WEKA are explained in more detail.

I evaluated the variables in the dataset to predict hand hygiene on entry and exit of patient rooms, as independent events. Using the function "InfoGainAttributeEval"[25], [26] of Weka®, I obtained a list of the most important attributes classified according to their information gain in the context of their class and all the data combined. In the case of hand hygiene on entry, the most important attributes are: exit time, entry time, the ID of the people concerned and hand hygiene on exit (Figure 101). In the case of hand hygiene on exit, the most important attributes are: entry time, exit time, location and hand hygiene on entrance (Figure 102). In summary, the most important attributes to predict hand hygiene on entry and exit are the entry and exit times.

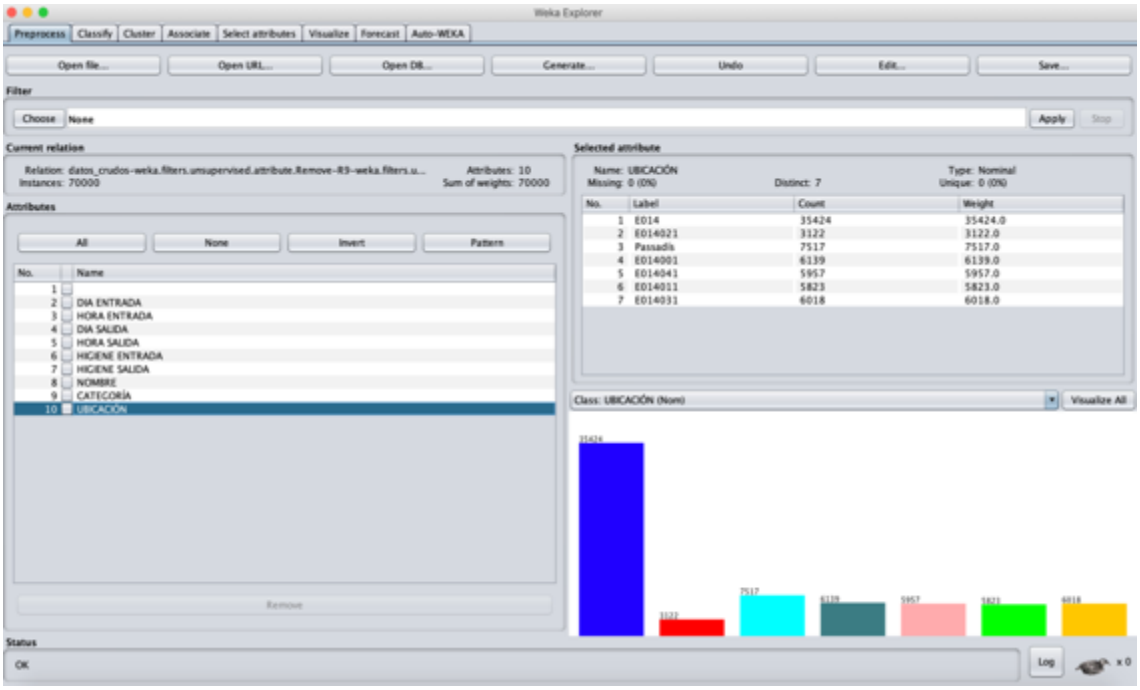


Figure 100. Use of the location detected by the electronic hand hygiene monitoring system.

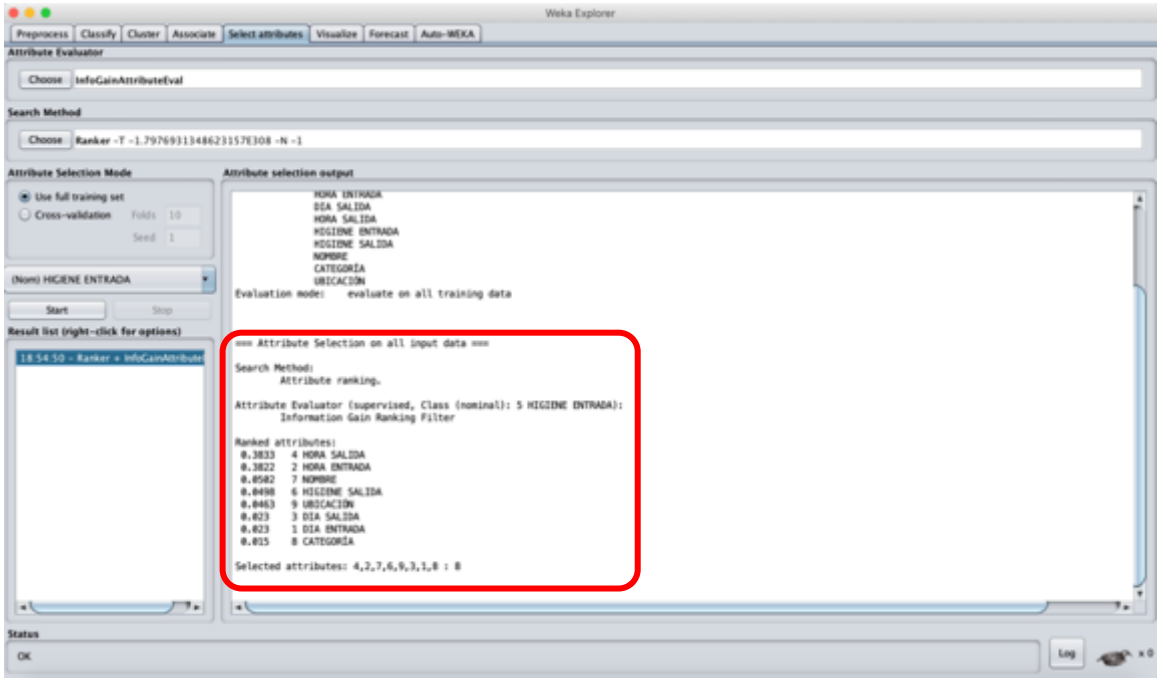


Figure 101. Ranking of the most important attributes for predicting hand hygiene on entry.

I then created a new dataset called "Transformed Dataset" containing only a subset of the variables, those which had most influence in the prediction of hand hygiene compliance. This subset was composed of six attributes (entry time, entry hand hygiene, exit time, exit hand hygiene, ID, and location) to maximize the accuracy of the prediction models. I divided the new dataset into two random groups using Weka®. The first (training data) contained 75% of the whole dataset, while the second (test data) had the remaining 25%. In both groups, the proportions of hand hygiene compliance on entry and exit were similarly stratified. The training data were used to build the prediction models using machine learning algorithms. These models can detect data patterns and generalize the behaviour of data for future observations. The machine learning applied to the "Transformed Dataset" was as Zero R [27], [28], Decision table [29], [30], Bagging [31], [32], Logit Boost [33], [34], Naive Bayes [35], [36], J48 [37]–[39], Random Tree [40], [41], Random Forest [42], [43], Lazy ibk 1 [44], [45] and Lazy ibk 20 [46].

Once the models were created with the training data, I used the test data to evaluate them and to compare their accuracy and other statistical parameters. In Figure 103 the results of the statistical evaluation of the dataset are presented using one of the ML methods. In Table 18 and 19, the results of the statistic evaluation of the models for the hand hygiene on entry and exit of patient rooms using Weka are presented, respectively. After applying all the mathematical models, I compared their performance of classification potency. In both cases, for entry to and exit from patient rooms, the best method to classify the hand hygiene compliance was Lazy ibk 20, which had better sensitivity and specificity to correctly classify the events of hand hygiene compliance in the unit. This method and the others classify better the actions when people would not disinfect their hands, because most of the dataset (90% of all data, approximately) is data on non-compliance with hand hygiene.

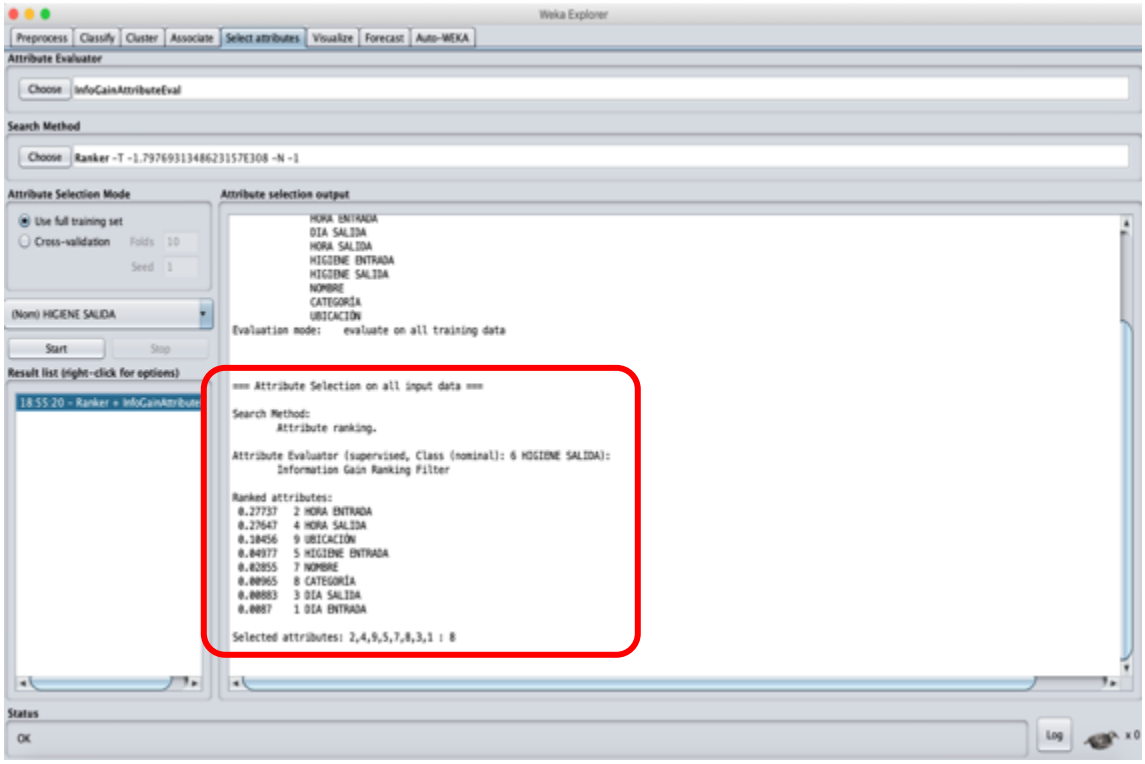


Figure 102. Ranking of the most important attributes for predicting hand hygiene on exit.

```
=== Summary ===

Correctly Classified Instances        1114               89.12    %
Incorrectly Classified Instances       136               10.88    %
Kappa statistic                          0.2487
Mean absolute error                      0.1626
Root mean squared error                  0.2868
Relative absolute error                 81.1508 %
Root relative squared error             92.9278 %
Total Number of Instances             1250

=== Detailed Accuracy By Class ===

               TP Rate   FP Rate   Precision   Recall  F-Measure  MCC      ROC Area  PRC Area  Class
               0,218     0,029     0,475       0,218   0,299      0,271    0,808     0,350     Si
               0,971     0,782     0,913       0,971   0,941      0,271    0,808     0,966     No
Weighted Avg.  0,891     0,702     0,866       0,891   0,873      0,271    0,808     0,900

=== Confusion Matrix ===

   a    b   <-- classified as
  29  104 |    a = Si
  32 1085 |    b = No
```

Figure 103. Statistical parameters generated by Weka in the evaluation of the ML methods.

	Hand Hygiene on Entry									
Classifier	Correctly classified instances	Incorrectly classified instances	TPR	FPR	ROC curve	F-score	Precision	Kappa	MAE	RMSE
1.De. Rule	82.72%	17.28%	0.83	0.011	0.78	0.80	0.80	0.35	0.12	0.24
2. Naïve B.	80.36%	19.64%	0.80	0.019	0.83	0.83	0.81	0.37	0.14	0.26
3. Lo.Boost	82.78%	17.22%	0.83	0.016	0.83	0.22	0.81	0.36	0.11	0.23
4. Zero R	89.35%	10.5%	0.81	0.017	0.78	0.81	0.89	0.58	0.19	0.25
5. Bagging	89.11%	10.89%	0.81	0.013	0.74	0.87	0.79	0.31	0.32	0.36
6. J48	88.45%	11.55%	0.80	0.016	0.64	0.86	0.81	0.34	0.14	0.25
7. R. Tree	88.15%	11.85%	0.79	0.017	0.76	0.83	0.89	0.69	0.12	0.21
8. R. Forest	89.35%	10.65%	0.79	0.010	0.51	0.84	0.87	0.77	0.14	0.26
9. Lazy 1k	88.55%	11.45%	0.79	0.014	0.72	0.86	0.89	0.74	0.13	0.14
10. Lazy 20k	90.78%	9.22%	0.88	0.018	0.86	0.87	0.91	0.74	0.21	0.28

Table 15. Evaluation of the machine learning methods for hand hygiene on entry. De. Rule means Decision Rule Algorithm. Naïve B. means Naïve Bayes Algorithm. Lo.Boost means LogitBoost Algorithm. R. Tree means a Random Tree Algorithm. R. Forest means a Random Forest Algorithm. TPR= true positive rate. FPR = false positive rate. ROC curve = receiver operating characteristic curve. MAE = mean absolute error. RMSE = root-mean-square error.

	Hand Hygiene on Exit									
Classifier	Correctly classified instances	Incorrectly classified instances	TPR	FPR	ROC curve	F-score	Precision	Kappa	MAE	RMSE
1.De. Rule	85.99 %	14.01%	0.96	0.020	0.72	0.93	0.92	0.31	0.07	0.19
2. Naïve Bayes	83.28%	16.72%	0.93	0.019	0.86	0.34	0.94	0.49	0.09	0.22
3. Lo.Boost	89.11%	10.89%	0.96	0.011	0.86	0.06	0.94	0.31	0.06	0.18
4. Zero R	81.35%	18.65%	0.78	0.019	0.78	0.49	0.79	0.44	0.18	0.10
5. Bagging	83.18%	16.82%	0.76	0.017	0.74	0.87	0.66	0.33	0.32	0.27
6. J48	79.47%	20.53%	0.77	0.011	0.54	0.88	0.77	0.58	0.08	0.19
7. R. Tree	87.42%	12.58%	0.83	0.012	0.76	0.88	0.79	0.43	0.18	0.15
8. R. Forest	89.02%	10.98%	0.85	0.011	0.84	0.94	0.87	0.53	0.33	0.17
9. Lazy 1k	89.07%	10.93%	0.86	0.018	0.82	0.88	0.88	0.50	0.12	0.23
10. Lazy 20k	89.12%	10.88%	0.86	0.014	0.85	0.85	0.88	0.51	0.20	0.21

Table 16. Evaluation of the machine learning methods for hand hygiene on exit. De. Rule means Decision Rule Algorithm. Naïve B. means Naïve Bayes Algorithm. Lo.Boost means LogitBoost Algorithm. R. Tree means a Random Tree Algorithm. R. Forest means a Random Forest Algorithm. TPR= true positive rate. FPR = false positive rate. ROC curve = receiver operating characteristic curve. MAE = mean absolute error. RMSE = root-mean-square error.

5.6. Discussions and Conclusions

In this chapter, I collect and analyse a total of four subgroups of critical care data (AmI Environment data, code blue data, code red data and hand hygiene data). In all cases the approval of the Ethics Committee was given, and I saved the data in a secure database on a hospital server.

The data obtained from the building automation system indicates that the clinical environment is a very dynamic location, as clinical staff touch the lighting configuration frequently during their patient-related activities. Starting in February 2020, when the unit received its first confirmed case of Covid-19, the use of the system decreased continuously. This can be related to the changes in the working practices of the professionals, in addition to the strain they were under during this period. The main times when most use of the system was detected were between 9 a.m. and 12 noon. This period can be an estimation of the period of the highest workload for HCWs. The functionalities most detected were Door, Supporting Lighting, Medical Examination Lighting and Ceiling Lighting. One or more of these functionalities were used at the same time in order to improve the lighting level and create privacy during the daily activities.

I used the simulated data I obtained from the vital signs manikin to test the Code Blue algorithm and to detect potentially avoidable CAs in the Smart ICU under the four conditions explained in the previous chapters, in order to evaluate the reduction of false positive alarms. The number of artefacts and true positive life-threatening alarms, as well as the number of true positive HR anomalies, were detected; while I estimated the number of false positives based on previous studies. The global reduction of false positive alarms was 37.1%. In a real scenario, the number of false positive alarms obtained using this algorithm remains very high and the activation of the code blue scenario can occur in many unnecessary situations, thereby causing extra stress for the clinical team. New ML algorithms could be used to improve the performance of the Code Blue algorithm and the use of a large volume of real data would be useful.

I used the vital signs data of nine critical patients in the Smart ICU to calculate the clinical indicator NEWS2, which is used to generate “Code Red” in the unit. I also evaluated he clinical indicator NEWS2 and the variation of NEWS2 over 24 hours to differentiate patients with a prolonged LOS. A large part of the data I collected represented a high risk NEWS2 score calculated hourly (67%) and daily (63%), evidencing the high risk of deterioration for most of the patients during their stay in the ICU and reflecting the severity of their state of health. For this reason, only the high risk NEWS2 data obtained hourly and daily should be analysed to predict a prolonged ICU stay. The cut-off points for ΔNEWS2>=7 over 24 hours was 14.5 days, with 84.2% sensitivity and 45.3% specificity. For NEWS2>=7, the cut-off point was

9.5 days, with 81.2% sensitivity and 40% specificity. The ΔNEWS2 high risk score over 24 hours proved to be a better predictor of a prolonged length of stay than the NEWS2 high risk score collected hourly. In both cases more data are needed to validate my findings.

I analysed the hand hygiene data on three different levels: use of the electronic dispensers, hand hygiene compliance detected by the whole system and the use of mathematical methods to predict hand hygiene. The three categories with the most registers of the use of the dispensers for hydroalcoholic gel were nurses, assistants and "No tag". I studied the hourly distribution of hand hygiene disinfection among the different professional categories. The range of between 9 and 21 hand hygiene events per hour was common for most of the professional categories. The period with the most use of the dispensers was between 9 a.m. and 9 p.m. During the day, the hour after the shift changes (9 a.m. and 4 p.m.) presented a significant increase in the number of hand hygiene events and consequently indicates a high level of patient-related activities by the clinical staff.

In the case of hand hygiene data collected by the whole system, the three categories with the most registers of hand hygiene compliance were nursing, assistants and doctors. I detected some patterns of behaviour in nurses and assistants. Many of the staff in these professional categories who do not wash their hands before entering a patient room do not wash their hands after leaving it either. The hourly data obtained from the electronic dispensers, the whole hand hygiene system, and data from the building automation systems present most recordings in the period between 9 a.m. and 1 p.m. So, strategies to promote the hand hygiene compliance should be designed mainly for this timeframe and for the clinical staff of this period because they are the people who enter the rooms most frequently and have most contact with patients. Moreover, it is interesting to highlight that the local peaks of use of the electronic dispensers during the months of April 2019, May 2019 and November 2019 also correspond to the local peaks of the hand hygiene compliance data. This means that the period of most use of the system also corresponds to the greatest rate of hand hygiene compliance by professionals and visitors.

I evaluated the data I collected using classification models, considering the type of variables collected by the system. I evaluated the variables in the dataset to predict hand hygiene on entry to and exit from patient rooms, as independent events. Once the classification models were created with training data, I used the test data to evaluate them and to compare their accuracy and other statistical parameters. In both cases, on entry to and exit from patient rooms, the best method for classifying hand hygiene compliance was Lazy ibk 20.

CHAPTER 6. GENERAL DISCUSSION, CONCLUSION AND FUTURE WORK

The results I have obtained in this thesis represent an advance in the implementation of new technologies for improving patient safety and quality of care at HCB. The Smart ICU with an AmI environment has become a better place to work (more human, safe and comfortable). The development and implementation of the AmI environment also represents an improvement for the multidisciplinary ICU team, given that the incorporation of a person with a profile of bioengineering and transversal skills has facilitated the management of the devices and the execution of continuous educational training of the staff.

The HCWs, NHCWs and technicians have gained experience in using digital tools in their daily activities over the last four years and have been deeply engaged in all the activities that are the subject of this thesis to improve the functionalities of the unit. The synergic collaborations between all the principal agents using this space have generated many improvements at the unit and the means of working.

Considering that a major part of the preventable errors which put a patient's safety at risk are due to human factors, I believe that the initiative this thesis represents has contributed to finding new ways to improve the cognitive abilities, skills and management of devices by HCWs. Critical medicine becomes more high-tech and complex every day and continuous learning processes are very important to improve patient safety.

This thesis is composed of three parts. Firstly, the prototype of the AmI environment was designed, built and tested in a laboratory setting considering the main patient safety issues which occur in ICUs. Six patient safety issues were considered: code blue, code red, code pink, the control of nosocomial infections, drug-related errors and finally, noise management. Secondly, the prototype was adapted for implementation in a real environment and it was implemented in a Smart ICU at HCB. Thirdly, I retrospectively analysed the clinical and ambient data generated by the AmI environment. In this thesis I present and discuss new contributions regarding ambient data and clinical data in ICUs. Specifically, I discuss data collected by the building automation system of the unit, by the electronic hand hygiene monitoring system and by the RTLS system. Regarding clinical data, I present and discuss data from HIS and from medical devices, such as vital signs monitors and mechanical ventilators.

6.1. Thesis Assessment

6.1.1. Development of AmI Environment

In the context of the epidemic caused by the SARS-Cov-19 virus and daily clinical practice, the ICU is a very dynamic hospital area in which patients are around a high concentration of devices. There is a need for continuous care by interprofessional teams. The data generated by patients and their environment can be transformed into useful information to help guarantee patient safety.

The construction of the prototype was very useful to understand how ambient variables can be controlled remotely. I was able to simulate environmental responses in patient rooms and at the nursing stations after triggering an important clinical alert, such as Code Blue, Code Red or Code Pink.

As today there is no unified protocol for data collection and for commercial reasons there is no true interoperability between IoT providers of medical and non-medical equipment, to recover ambient and clinical data I had to work with different communication architecture standards, such as SOAP (for example, I used this for the building automation system), REST (for medical device variables and HIS variables) and proprietary standards (to access the camera recordings). In the construction of the web-based application of *Infobox4Health*, I integrated all these standards to collect all the data generated by the AmI environment.

6.1.2. The Implementation of Strategies to Improve the Efficiency of Processes Related to Patient Safety

The adaptation of a renovated ICU or the creation of new Smart ICUs including elements of AmI can bring many benefits for patients and HCWs. The inclusion of lighting alerts and changes in the physical architecture could decrease the distractions caused by noise disturbances from medical devices and the number of preventable deaths, in addition to improving the detection of cases of patient deterioration.

The different screens installed around the units can display information on patient health and can be an excellent resource continuous educational training. The transformation of the contents of clinical procedures in an attractive and interactive multimedia format combined with AmI technologies can improve awareness of processes related to patient safety and quality in ICUs.

The use of RFID based technologies enabled me to detect the location of people inside the unit and account for the time spent by people inside patient rooms. Moreover, this technology allowed me to know the profile of the people who entered

the patient rooms and to personalize notifications and feedback on the screens about important events concerning patient health.

In conclusion, this thesis contributes to (1) evaluating the usability of new technologies for improving patient safety processes in critical care, (2) improving clinical and educational standards regarding patient safety processes in an ICU, and (3) gaining more clinical context awareness in which the patient is involved during their ICU stay.

6.2. Final Conclusions

PHASE I. Framework and Development

- The main characteristics of the AmI environment (sensitivity, responsibility, adaptability, transparency, ubiquity, intelligence and sociability) make it an interesting approach that can be applied in many fields, including the healthcare sector.

- The morphological evolution of the infrastructures, equipment and facilities of the ICU makes it more complex and creates the need to build a safer and more comfortable clinical environment for patients.

- The proposal to create an AmI environment for ICUs is a strategy focused on the improvement of patient safety at the unit through an adaptive and dynamic distribution of useful clinical information based on the role of each professional and the clinical health status of patients.

- The AmI environment for critical care aims to generate real-time clinical and environment monitoring variables, clinical event detection, and feedback for healthcare workers as well as reports on events detected.

- To build the AmI environment for critical care it was necessary to engage HCWs in all the activities that fall within the range of this thesis in addition to understanding the workflow of all the professionals and the architectural elements as well as the clinical needs of critical ill patients.

- The design and construction of the AmI prototype involved the work of many professionals. The framework of the AmI environment evolved with the development of the prototype and finally it constituted four layers: physical, communications, information and decision.

- All the layers were correctly secured and protected using proper network platforms and programming to avoid cyber-attacks by external agents.

- The different modules of the prototype (functional, visual and data transforming modules) were interconnected and enabled ambient and patient healthcare monitoring remotely in real time.

- The Infobox server was created to manage the ambient and clinical data. This server was responsible for storing, managing and processing all the data recovered from the different IoT devices and the other support servers.

- A hand hygiene monitoring system associated to the RTLS system was constructed and incorporated into the design of the AmI prototype. With both systems it was possible to know the location and hand hygiene compliance of people, in addition to showing real-time and monthly feedback from the unit.

- The data recovered by the building automation system, medical devices and HIS were highly heterogeneous and presented varied periodicities. (Data from medical devices have more periodicity while ambient data have less.)

- The working principle of the prototype included seven types of functionalities (baseline, code blue, code red, code pink, hand hygiene event, noise and medication procedures), all of which I describe in detail in this thesis.

PHASE II. Implementation in a Real Environment

- The implementation of the AmI environment at the Smart ICU was progressive and included three phases: implementation of the building automation system, of the clinical resources and of the hand hygiene system.

- Most of the elements and functionalities previously tested on the prototype were implemented in a real environment. The Infobox web application and the digital interfaces were improved and implemented in the ICU.

PHASE III. Data Analysis

- Before analysing the critical care data generated by the AmI environment in the Smart ICU, I reviewed relevant aspects of the data management by the Infobox server, such as: the data analytics, data visualization, data quality,

data privacy, data security, data repositories, data simulation and ethical issues.

- The implementation of the building automation system enabled me to evaluate its usability in a clinical environment. The data I obtained from this system indicates that the behaviour of the clinical staff around patients is very dynamic, because they switch lighting functionalities on an off very frequently.

- In February 2020, when the firsts cases of Covid-19 were admitted to the unit, the use of the building automation system decreased continuously. Moreover, the number of people who entered the unit and the frequency of entrance was also drastically reduced as the protocols for taking care of patients changed (use of double gloves, gowns, masks and hair protectors).

- The period from 9 a.m. to 12 noon was when there was most use of the automation system by HCWs. This could be an indicator of a period of higher workload for the staff. Moreover, the system detected that the use of the functions was more intensive during the week (from Monday to Thursday) and during the morning shift (8 a.m. to 3 p.m.).

- The Door, Supporting Lighting, Medical Examination Lighting and Ceiling Lighting were the most commonly used functionalities of the system. The most common characteristic they share is that all these activities are used in the direct care of patients, such as for patient hygiene, medical visits, preparation and administration of medication, wound dressing, intubation and weaning.

- The use of these functionalities has undergone weekly variations that can be attributed to the frequency of use of patient rooms, the severity of patients, and period of overuse can be associated with periods when HCWs had most activities to perform inside patient rooms.

- I tested the Code Blue algorithm with the aim of studying new strategies to detect potential avoidable CAs in the Smart ICU and to decrease the false positive alarms from vital signs monitor. I collected data using a vital signs manikin and performed tests under four types of conditions (at rest, under bed vibration and percussion therapy, under upper and lower limb movements, and under continuous bed therapy).

- Globally, the reduction of false positive alarms using Rules 1, 2 and 3 of the Code Blue algorithm was 30%, 42% and 39%, respectively. The global reduction of the false positive alarms was 37.1%. In a real scenario, the number of false positive alarms resulting from using this algorithm remains

very high and the activation of the Code Blue scenario can occur in many unnecessary situations placing extra stress on the clinical team.

- I collected clinical data on nine patients to study their NEWS2 scores, associated with Code Red in the Smart ICU. I evaluated the NEWS2 clinical indicator and the variation of NEWS2 scores over 24 hours to identify patients likely to require a prolonged ICU LOS (equal to or more than 14 days).

- I obtained a total of 2,210 complete verified records. Most of these represented a high risk NEWS2 score calculated hourly (67%) and daily (63%), evidencing the high risk of deterioration of most patients during their stay in the ICU and reflecting the serious state of their health. For this reason, only the high risk NEWS2 data obtained hourly and daily will be analysed to predict prolonged ICU stay.

- The odds ratio I obtained indicates that a prolonged ICU stay is 3.3 times more probable when there is a high risk NEWS2 score. The high risk NEWS2 score has low values of sensitivity and specificity, and so this parameter is not a good estimator of a longer ICU stay. The PPV I obtained indicates that out of every 100 patients who had NEWS2>=7, 67 patients will eventually have a prolonged stay and their NPV indicates that out of every 100 patients who had NEWS2>=7, 64 patients are still likely to have a prolonged stay.

- When the variation of NEWS2 over 24 hours is equal to or more than 7, a prolonged ICU stay is 9.1 times more probable, based on the odds ratio. ΔNEWS2 is not specific for prolonged stays (19.7%); however, it has a high sensitivity (92.1%) at detecting such cases. The PPV I obtained indicates that out of every 100 patients who had ΔNEWS2>=7, 58 patients will eventually have a prolonged ICU stay and their NPV indicates that out of every 100 patients who had ΔNEWS2>=7, 88 patients are still likely to have a prolonged stay. The specificity of NEWS2 is greater than that of ΔNEWS2 (59.7%), but it has a lower sensitivity (52.2%) and is counterproductive as it does not cover all patients who will have a prolonged stay. The PPV for NEWS2 >=7 is higher than for ΔNEWS2 (66.9%) but the NPV is lower (63.7%), and a considerable number of patients could still have a prolonged stay with NEWS2 >=7.

- The cut-off point for ΔNEWS2 over 24 hours was 14.5 days, with 84.2% sensitivity and 45.3% specificity. For NEWS2, the cut-off point was 9.5 days, with 81.2% sensitivity and 40% specificity. Thus, I have shown that the ΔNEWS2 high risk score over 24 hours is a better predictor of a prolonged ICU stay than the NEWS2 high risk score collected hourly.

- I analysed the hand hygiene data on three different levels: use of the electronic dispensers, hand hygiene compliance detected by the whole system and the use of mathematical methods to predict hand hygiene. The three categories with the most registers of the use of the alcoholic solution dispensers were nurses, assistants and “No tag”.

- I further studied the hourly distribution of the hand hygiene disinfection among the different professional categories. A range of between 9 and 21 hand hygiene events per hour was the most common for the majority of the professional categories. The period with the most use of the dispensers was from 9 a.m. to 9 p.m. During the day, the hour after shift changes (9 a.m. and 4 p.m.) presented a significant increase in the number of hand hygiene events and consequently indicates a high level of patient-related activities by the clinical staff.

- In the case of hand hygiene data collected by the whole system, the three categories with the highest hand hygiene compliance were nurses, assistants and doctors. I detected some patterns of behaviour for the categories of nurses and assistants. Most of the members of these professional categories who do not wash their hands before entering a patient room do not wash their hands after leaving it either.

- The hourly data obtained from the electronic dispensers, the whole hand hygiene system and the building automation systems all presented a higher number of recordings in the period between 9 a.m. and 1 p.m. So, strategies to promote hand hygiene compliance should be designed mainly for this timeframe and for clinical staff in this period, because they are the people who enter patient rooms most frequently and have most patient contact.

- It is interesting to highlight that the local peaks of use of the electronic dispensers during the months of April 2019, May 2019 and November 2019 also corresponds to the local peaks of the hand hygiene compliance data. This means that the period of most use of the system corresponds to the highest rate of hand hygiene compliance by professionals and visitors.

- I evaluated the variables in the dataset to predict hand hygiene on entry to and exit from patient rooms, as independent events. Once I had created the classification models with training data, I used test data to evaluate them and compare their accuracy and other statistical parameters. In both cases, entry to and exit from patient rooms, the best method to classify hand hygiene compliance was the Lazy ibk 20.

6.3. Future Work

With the Covid-19 epidemics, institutions from different sectors are accelerating the process of creating AmI environment in which workers and users can be connected virtually. This trend will increase the number of IoT devices and web platforms in our daily lives, especially in healthcare, due to the increased potential for the prevention of highly infectious disease contagion. Specifically in ICUs, the use of telemedicine is increasing exponentially, using intelligent screens for communication between patients and doctors and between patients and their families.

The implementation of new physical and virtual infrastructures to support the creation of the AmI Environment I propose in this thesis has prepared this ICU for precision medicine. Data analysis using advanced statistical methods combined with the use of adaptive interfaces will allow for improvements in the response time of HCWs when detecting risk clinical situations. This will contribute to saving more lives and decreasing the number of preventable adverse events for ICU patients.

The quantity of heterogeneous data generated by the environment and healthcare of one patient that I collected and analysed was around 8 TB per day. Currently the extraction of the useful information from such a quantity of data is extremely difficult. I am currently working on programming the *InfoboxforHealth* web application to improve the management of such a large quantity of data. Finally, powerful data storage and processing are necessary to generate effective real-time feedback for HCWs. HCWs should receive continuous education about the systems involved in the AmI environment so as to be able use them properly and generate increasing benefits for themselves and, consequently, for patients.

ANNEX 1. TABLE OF TECHNIQUES USED TO ENSURE DATA PRIVACY

Technique	Definition	Method
De-identification	The process used to eliminate obvious identifiers and, consequently, to make it difficult to identify individuals.	Methods to hide sensitive data: -K-anonymity: this method consists of applying rules to hide the number of k attributes of a database. It can use data suppression techniques (for example, substituting the rows of a data column for "*") and generalization techniques (for example, substituting the age column by an age range column). In this type of approach, some rows can be identical after applying this method and hackers can re-identify individuals if they have knowledge of people due to data similarities. In addition, if data is not correctly distributed in a heterogeneous way, attackers can deduce some confidential information. -L-diversity: it is an extension of k-anonymity including the application of data suppression and generalization techniques. The difference is that this technique differentiates all data for each individual and consequently creates data diversity. The result is that there are no two rows with the same values. The disadvantage of this technique is that it is still unsafe because it uses redundant techniques and is insufficient to prevent attribute disclosure. -T-closeness: it is the extension of l-diversity and decreases the information that attackers can obtain about any specific subject assuming that he or she knows the data distribution. The difference is that this technique makes a similar distribution of the confidential data within each data class and in the entire dataset. The principle of t-closeness is fulfilled if and only if the distance between an attribute of a given class and the whole table is equal to or less than a threshold, t. This distance is called the Earth Mover Distance (EMD) and measures semantic similarities in the attribute values.
Differential privacy	The process used to obtain useful personal information without revealing individual identities.	This technique is mainly applied to a public database (provided for example by Google, Apple, Uber, or government agencies) that can be accessed by companies or researchers. A determined quantity of random noise is introduced in the database in order to protect personal data from individuals and the quantity of distortion added is proportional to the privacy risk.
Identity based anonymization	The process used to protect personal data in a private cloud used by companies.	The main method used to protect data in private clouds is the GDS (Group Digital Signature). This method consists of making the traceability of users anonymous by applying the concept of generalization. If one team member access and edits a database, in the cloud the team appears to have made the database modifications. Only the manager can check access by team members. Access to projects in the cloud is via a single group key.

ANNEX 2. TABLE OF TECHNIQUES USED TO ENSURE DATA SECURITY

Technique	Definition	Applications	Main Technologies	Comments
Authentication	The process used to identify individuals. It only guarantees that the individual is who he or she claims to be.	-Login access: identification by username and password with programmed expiry. -Ensure solidity of password. -Physical authentication tokens.	Cryptographic protocols for securing communications over networks: Transport Layer Security (TLS) and Secure Sockets Layer (SSL). The Bull's Eye algorithm is used to monitor access to and edition of sensitive information.	New ways of authentication are being developed based on biometrics: fingerprint, retina and voice identification.
Encryption	The process used to encode data. It guarantees that only authorized people can access the data using a correct encryption key.	- End-to-end protection of data transmitted across networks. - Encryption makes the data unreadable even if unauthorized people have access to them. - Encryption key should be protected with passwords and should be confidential to each user.	Encryption algorithms: -RSA (Rivest, Shamir y Adleman). -IDEA (International Data Encryption Algorithm). - Advanced Encryption Standard (AES). - Triple Data Encryption Standard (3DES). - Blowfish and Twofish.	In healthcare applications, data are encrypted from the server to end user devices, including mobile devices used by physicians, clinicians, and patients.
Data Masking	The process used to hide data. It guarantees the confidentiality of sensitive data.	- Create a similar structure similar to that of real data but it is filled with simulated data. - Allow providers to test databases' environments without having access to sensitive data. - Used in software development and user training.	- Real data can be replaced by random data, null data or encoded data.	The cost of the implementation of data masking techniques is reduced when securing a big data infrastructure, compared to other techniques.
Access Control	The process used to manage user rights and privileges in a software application. It enables different levels of access or permission.	-Report of connection time and type of activity per user. -Registry of failed access. -Block of access of the application after repeated unsuccessful attempts.	- Local Directory Access Protocol (LDAP) - Role-Based Access Control (RBAC) - Attribute-Based Access Control (ABAC) - Mandatory access control (MAC)	A secure method for access control includes two-factor authentication: one authentication to check the credentials and the second to corroborate user identity.

ANNEX 3. TABLE OF CLINICAL DATA

Clinical data			
Parameter	**Data Typology**	**Origin**	**Frequency**
Demographic and Administrative Data	-Text (result status, date and time) -Code for HIS identificatory - Date of hospital admission - Date of ICU admission - Date of birth - Type of admission: elective doctor, urgent doctor, urgent surgery, scheduled surgery. - Country of birth - Place of birth - List of episodes - Risk factors -Allergies - Known health issues - Diagnostics - Procedures -Record of all the rooms/ICUs which patients have passed during the episode (place, date of entry, date of departure).	• HIS	Variable
Medication Management Medication prescription Medication dispenser Medication notes of nursing Medication incidences Medication pumps	-Text (result status, date and time) - drug name - Status - infusion mode - doses -alarms -volume to be administrated -volume administrated -units - infusion flow	• HIS • Drug dispenser • Medication pumps	Variable. Each 5 seconds for medication pumps. Each hour for drug dispenser and each eight hours for HIS.
Patient vital sign monitor, mechanical ventilator and haemodialysis machine	-Text (result status, date and time) - Binary 0/1 - Oxygen saturation - Breathing frequency - Heart rate - Blood pressure (systolic, diastolic and mean) - temperature - Glasgow Coma Scale - FiO2 - arterial PaO2 - arterial PaCO2 - Arterial bicarbonate - Alarms - Type of ventilation - Type of renal support - External heater temperature -Transmembrane pressure -Inlet pressure -Return pressure -Effluent pressure -Blood flow	• Medical Devices	Each millisecond or each second
Microbiology	-Text (result status, date and time) - Binary 0/1 - Blood cultures - Urine culture - CSF culture -Respiratory sample cultures - Catheter tip culture	• HIS	Variable in days

(continuation of this table in the next page)

Clinical data			
Parameter	**Data Typology**	**Origin**	**Frequency**
Microbiology (continued)	-Ag. Legionella urine -Ag. Urine pneumococcus -Clostridium difficile toxin in stool -Text (result status, date and time) - Binary 0/1	• HIS	Variable in days
Laboratory	- Total leukocytes - Neutrophils - Percentage of bands - Haemoglobin - Prothrombin rate - Activated partial thromboplastin time - Platelets - Blood glucose - Creatinine - Sodium - Potassium -Estimated glomerular filtering - Creatinine clearance - C-reactive protein - Lactate - Bilirubin -Text (result status, date and time) - Binary 0/1	• HIS	Variable in days
Medical and nursing notes	- Free text - Structured text - Text (result status, date and time) - current health problems - health problems in the past - daily treatment -Text (result status, date and time) - Binary 0/1	• HIS	Variable in days
Hydric balance	- Inputs and outputs - Time input - Daily entry - Hourly urine output - Daily urine output - Drains outlet - Daily departure -Depositions (number and / or volume)	• HIS	Each hour
Radiology	- Text (result status, date and time) - Binary 0/1 - Images with DICOM format	• HIS	Variable in days
NEWS, SOFA, Code Blue, Code Red, Code Pink calculated with data from HIS	-Text (result status, date and time) - Binary 0/1	• HIS	Each hour

ANNEX 4. TABLE OF ENVIRONMENT DATA

Data from clinical environment			
Parameter	**Data Typology**	**Origin**	**Frequency**
Number of times and moments when a certain light functionality is used inside patient room and nursing station: work lights, exploration, circadian, floor, ceiling, hallways, polarization of the door glass and the window of the boxes.	- Binary 0/1 to save the moments when there is activation/deactivation of the function; - Numeric to save number of times; of activation/deactivation per day; - Date time format for activation/deactivation moments;	• Manually: Tablets from patient rooms and from nursing station • Automatically: Smart Application of the Information Layer	The status of each function (active / inactive) can change an average of 50 times a day.
Number of times and moments when the clinical event detections are activated automatically and manually.	- Binary 0/1 to save the moments when there is activation/deactivation of the function; - String format to save activation type: manual or automatic; - Numeric to save number of times of activation/deactivation per day; - Date time format for activation/deactivation moments;	• Manually: Tablets from patient rooms and from nursing station • Automatically: Smart Application of the Information Layer	Clinical event detections are activated only in emergency situations. They will be activated at most three times a day.
Number of times and the moments when the camera is disabled or enabled.	- Binary 0/1 to save the moments when there is activation/deactivation of the function; - String format to save activation type: manual or automatic; - Numeric to save number of times of activation/deactivation per day; - Date time format for activation/deactivation moments;	• Manually: Tablets from patient rooms and from nursing station • Automatically: Smart Application of the Information Layer	The status of each function (active / inactive) can change an average of 50 times a day.
If patient rooms are under positive and negative pressure or without pressure.	- Binary 0/1 to save the moments when there is positive and negative pressure inside the box every day; - Date time format for pressure moments every day;	• Manually: Tablets from patient rooms and from nursing station • Automatically: Smart Application of the Information Layer	The status of each function (active / inactive) can change an average of once a day.
Date and time when professionals of different categories and family members of each box enter and leave the boxes and the unit.	- Binary 0/1 to save the moments when there is entry / exit of the boxes and the unit; - Numeric to save number of times when there is entry / exit of the boxes and the unit; Date / time format for times when there is entry / exit of the boxes and the unit;	RTLS	The change of state (entry/exit) can change an average of 300 times a day for the boxes and 1000 times a day for nursing station;

(continuation of this table in the next page)

Data from clinical environment			
Parameter	**Data Typology**	**Origin**	**Frequency**
Continued.	String format: to save the different categories: doctor, nurse, assistant, family, technician, and cleaning;	continued	continued
Date and time when professionals and family members disinfect their hands before entering and after leaving each patient room.	- Binary 0/1 to save the moments when there is entry / exit of the pits; Numeric to save number of times when there is entry / exit of the boxes and the unit; - Date / time format for times when there is entry / exit of the boxes and the unit; - String format: to save the different categories: doctor, nurse, assistant, family, technician and cleaning;	RTLS	The change of state (disinfected/non disinfected) can change an average of 300 times a day for the boxes and 1000 times a day for nursing station;
Number of times and the moment when the nursing workload is detected.	- Binary 0/1 to save the moments when there is activation/deactivation of the function; - Numeric to save number of times of activation/ deactivation per day; - Date and time format for activation/deactivation moments;	Camera	The status of each function (active / inactive) can change an average of 8 times a day.
Number of times and the moment in which isolation protocol is activated and deactivated within each patient room.	- Binary 0/1 to save the moments when there is activation/deactivation of the function; - Numeric to save number of times of activation/ deactivation per day; - Date and time format for activation/deactivation moments;	• Manually: Tablets from patient rooms and from nursing station • Automatically: Smart Application of the Information Layer	The status of each function (active / inactive) can change an average of once a day.
Number of times and the moment in which different data visualization is activated and deactivated in the screen of each patient room and nursing station	- Binary 0/1 to save the moments when there is activation/deactivation of the function; - Numeric to save number of times of activation/ deactivation per day; - Date and time format for activation/deactivation moments;	• Manually: Tablets from patient rooms and from nursing station • Automatically: Smart Application of the Information Layer	The status of each function (active / inactive) can change an average of 8 times a day.
State of HVAC system of the ICU	- Binary 0/1 to save the moments when there is activation/deactivation of the function; - Numeric to save number of times of activation/ deactivation per day; - Date and time format for activation/deactivation moments;	• Manually: Tablets from patient rooms and from nursing station	The status of each function (active / inactive) can change an average of once a day.

ANNEX 5. ETHICS COMMITTEE APPROVAL OF ARTIFICIAL INTELLIGENCE STUDY

CLÍNIC
BARCELONA
Hospital Universitari

DICTAMEN DEL COMITÉ DE ÉTICA DE LA INVESTIGACIÓN CON MEDICAMENTOS

NEUS RIBA GARCIA, Secretario del **Comité de Ética de la Investigación con medicamentos del Hospital Clínic de Barcelona**

Certifica:

Que este Comité ha evaluado la propuesta del promotor, para que se realice el estudio:

CÓDIGO:
DOCUMENTOS CON VERSIONES:

CIF – G-08431173

Tipo	Subtipo	Versión
Protocolo		V 1.0 3.4.2018

TÍTULO: Desarrollo de un sistema de monitorización inteligente para Unidades de Cuidados Intensivos
PROMOTOR: UNIVERSIDAD DE BARCELONA
INVESTIGADOR PRINCIPAL: JOSE MARIA NICOLAS ARFELIS; BRUNA CORREA VOLPINI

y considera que, teniendo en cuenta la respuesta a las aclaraciones solicitadas (si las hubiera), y que:

- Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles.
- La capacidad del investigador y los medios disponibles son apropiados para llevar a cabo el estudio.
- Que se han evaluado la compensaciones económicas previstas (cuando las haya) y su posible interferencia con el respeto a los postulados éticos y se consideran adecuadas.
- Que dicho estudio se ajusta a las normas éticas esenciales y criterios deontológicos que rigen en este centro.
- Que dicho estudio cumple con las obligaciones establecidas por la normativa de investigación y confidencialidad que le son aplicables.
- Que dicho estudio se incluye en una de las líneas de investigación biomédica acreditadas en este centro, cumpliendo los requisitos necesarios, y que es viable en todos sus términos.

Este CEIm acepta que dicho estudio sea realizado, debiendo ser comunicado a dicho Comité Ético todo cambio en el protocolo o acontecimiento adverso grave.

y hace constar que:
1º En la reunión celebrada el día 26/04/2018, acta 8/2018 se decidió emitir el informe correspondiente al estudio de referencia.

Reg. HCB/2018/0450

HOSPITAL CLÍNIC DE BARCELONA
Villarroel, 170 - 08036 Barcelona (España)
Tel. 93 227 54 00 Fax 93 227 54 54
www.hospitalclinic.org

Generalitat de Catalunya
Departament de Salut

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3º Listado de miembros:

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- BEGOÑA GÓMEZ PÉREZ (Farmacéutica Hospitalaria, HCB)

Vicepresidente:
- JOAQUIM FORÉS I VIÑETA (Médico Traumatólogo, HCB)

Secretario:
- NEUS RIBA GARCIA (Médico Farmacólogo Clínico, HCB)

Vocales:
- ITZIAR DE LECUONA (Jurista, Observatorio de Bioética y Derecho, UB)
- MONTSERRAT GONZALEZ CREUS (Trabajadora Social, Servicio de Atención al Usuario, HCB)
- JOSE RIOS GUILLERMO (Estadístico. Plataforma de Estadística Médica. IDIBAPS)
- OCTAVI SANCHEZ LOPEZ (Representante de los pacientes)
- MARIA JESÚS BERTRAN LUENGO (Médico Epidemiólogo, HCB)
- JOAQUÍN SÁEZ PEÑATARO (Médico Farmacólogo Clínico, HCB)
- SERGIO AMARO DELGADO (Médico Neurólogo, HCB)
- JULIO DELGADO GONZÁLEZ (Médico Hematólogo, HCB)
- EDUARD GUASCH I CASANY (Médico Cardiólogo, HCB)
- VIRGINIA HERNANDEZ GEA (Médico Hepatólogo, HCB)
- NURIA SOLER BLANCO (Farmacéutica Hospitalaria, HCB)
- MARINA ROVIRA ILLAMOLA (Farmacéutico Atención Primaria, CAP Eixample)
- JOSE LUIS BLANCO ARÉVALO (Médico Medicina Interna, HCB)
- MIRIAM MÉNDEZ GARCÍA (Abogada, HCB)
- MERCÈ VIDAL FLOR (Enfermera, HCB)

En el caso de que se evalúe algún proyecto del que un miembro sea investigador/colaborador, este se ausentará de la reunión durante la discusión del proyecto.

Para que conste donde proceda, y a petición del promotor,

RIBA GARCIA NEUS - 46540984R

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Fecha: 2018.06.29 16:15:49 +02'00'

Barcelona, a 28 de junio de 2018

HOSPITAL CLÍNIC DE BARCELONA
Villarroel, 170 - 08036 Barcelona (España)
Tel. 93 227 54 00 Fax 93 227 54 54
www.hospitalclinic.org

ANNEX 6. ETHICS COMMITTEE APPROVAL OF HAND HYGIENE STUDY

CLÍNIC
BARCELONA
Hospital Universitari

DICTAMEN DEL COMITÉ DE ÉTICA DE LA INVESTIGACIÓN CON MEDICAMENTOS

ANDREA SCALISE, Secretario del **Comité de Ética de la Investigación con medicamentos del Hospital Clínic de Barcelona**

Certifica:

Que este Comité ha evaluado la propuesta del promotor, para que se realice el estudio:

CÓDIGO:
DOCUMENTOS CON VERSIONES:

Tipo	Subtipo	Versión
Protocolo		Versión 1.2 – 10 de julio de 2019

TÍTULO: Efectividad de un sistema electrónico de incentivación de higiene de manos en Cuidados Intensivos
PROMOTOR:
INVESTIGADOR PRINCIPAL: JOSE MARIA NICOLAS ARFELIS; INMACULADA CARMONA DELGADO

y considera que, teniendo en cuenta la respuesta a las aclaraciones solicitadas (si las hubiera), y que:

- Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles.
- La capacidad del investigador y los medios disponibles son apropiados para llevar a cabo el estudio.
- Que se han evaluado la compensaciones económicas previstas (cuando las haya) y su posible interferencia con el respeto a los postulados éticos y se consideran adecuadas.
- Que dicho estudio se ajusta a las normas éticas esenciales y criterios deontológicos que rigen en este centro.
- Que dicho estudio cumple con las obligaciones establecidas por la normativa de investigación y confidencialidad que le son aplicables.
- Que dicho estudio se incluye en una de las líneas de investigación biomédica acreditadas en este centro, cumpliendo los requisitos necesarios, y que es viable en todos sus términos.

Este CEIm acepta que dicho estudio sea realizado, debiendo ser comunicado a dicho Comité Ético todo cambio en el protocolo o acontecimiento adverso grave.

y hace constar que:
1º En la reunión celebrada el día 14/03/2019, acta 5/2019 se decidió emitir el informe correspondiente al estudio de referencia.

Reg. HCB/2019/0172

CIF – G-08431173
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3º Listado de miembros:

Presidente:
- BEGOÑA GOMEZ PEREZ (Farmacéutica Hospitalaria, HCB)

Vicepresidente:
- JOAQUIM FORÉS I VIÑETA (Médico Traumatólogo, HCB)

Secretario:
- ANDREA SCALISE (Médico Farmacólogo Clínico, HCB)

Vocales:
- ITZIAR DE LECUONA (Jurista, Observatorio de Bioética y Derecho, UB)
- MONTSERRAT GONZALEZ CREUS (Trabajadora Social, Servicio de Atención al Usuario, HCB)
- JOSE RIOS GUILLERMO (Estadístico. Plataforma de Estadística Médica. IDIBAPS)
- OCTAVI SANCHEZ LOPEZ (Representante de los pacientes)
- MARIA JESÚS BERTRAN LUENGO (Médico Epidemiólogo, HCB)
- JOAQUÍN SÁEZ PEÑATARO (Médico Farmacólogo Clínico, HCB)
- SERGI AMARO DELGADO (Médico Neurólogo, HCB)
- JULIO DELGADO GONZÁLEZ (Médico Hematólogo, HCB)
- EDUARD GUASCH CASANY (Médico Cardiólogo, HCB)
- VIRGINIA HERNANDEZ GEA (Médico Hepatólogo, HCB)
- MARINA ROVIRA ILLAMOLA (Farmacéutico Atención Primaria, CAP Eixample)
- MIRIAM MENDEZ GARCÍA (Abogada, HCB)
- MERCÈ VIDAL FLOR (Enfermera, HCB)

En el caso de que se evalúe algún proyecto del que un miembro sea investigador/colaborador, este se ausentará de la reunión durante la discusión del proyecto.

Para que conste donde proceda, y a petición del promotor,

P.O.

GOMEZ PEREZ PILAR BEGOÑA - 22691104V

Firmado digitalmente por GOMEZ PEREZ PILAR BEGOÑA - 22691104V
Fecha: 2019.07.19 14:52:38 +02'00'

Dra. Begoña Gómez

Barcelona, a 19 de julio de 2019

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ANNEX 7. CONSENT INFORM OF HAND HYGIENE STUDY

EFECTIVIDAD DE UN SISTEMA ELECTRÓNICO DE INCENTIVACIÓN DE HIGIENE DE MANOS EN CUIDADOS INTENSIVOS

Anexo 4: **CONSENTIMIENTO INFORMADO**

D/Dña…….....

MANIFIESTO:
Que he sido informado por
……..……..……..
del estudio que se realiza en el Hospital Clínic de Barcelona sobre la efectividad de un sistema electrónico de incentivación de higiene de manos en las Unidades de Cuidados Intensivos del HCB, así como de la importancia de mi colaboración, no suponiendo riesgo alguno para mi salud.

ACEPTO:
Participar en el estudio colaborando en cada uno de los puntos expuestos a continuación:

1. Hacer la formación educacional sobre los 5 Momentos de Lavado de Manos propuestos por la Organización Mundial de la Salud.
2. Permitir la observación directa de los momentos de contacto con el paciente para estudiar el cumplimiento de los 5 Momentos de Lavado de Manos.
3. Permitir contabilizar el uso de los dispensadores de solución alcohólica ya sea de forma automatizada o por observación directa.
4. Permitir registrar los movimientos diarios dentro de la unidad, entre las habitaciones, la estación de enfermería y las áreas de soporte.
5. Datos del participante cedidos para la estadística:

    a. Género…… b.Edad…… años

    c. Categoría Profesional…….…… d. Posee especialización: …… Sí ……..No

    e. Tiempo de experiencia en UCI…….. años

☐ Marque esta casilla si desea recibir un reporte mensual sobre el cumplimiento de la higiene de manos personal y de la unidad por email.
E-mail:……..……..……..

Las personas que realizan el estudio garantizan, que, en todo momento, la información recogida de los participantes del estudio será confidencial y sus datos serán tratados de forma anónima y sólo serán usados con propósitos profesionales, codificando la información y manteniéndola en archivos seguros. Sólo los investigadores tendrán acceso a esta información. El profesional puede retirarse del estudio en cualquier momento y esto no implicará pérdida de ninguno de sus derechos.

Después de ser debidamente informado, deseo libremente participar y me comprometo a colaborar en todo lo anteriormente expuesto, pudiendo interrumpir mi colaboración en cualquier momento.

Los responsables de la conducción de las actividades de investigación son Inmaculada Carmona y José M. Nicolás, Coordinadora del Área de Vigilancia Intensiva y Director del ICMID del HCB, respectivamente. Teléfonos de contacto: 380635 (IC) y 381329 (JMN). Emails: icarmona@clinic.cat y nicolas@clinic.cat.

En Barcelona, a……de…….. de……

Firma del Profesional Sanitario Firma del profesional

ANNEX 8. ETHICS COMMITTEE APPROVAL OF OPTICAL SYSTEM'S STUDY

CLÍNIC
BARCELONA
Hospital Universitari

DICTAMEN DEL COMITÉ DE ÉTICA DE LA INVESTIGACIÓN CON MEDICAMENTOS

ANDREA SCALISE, Secretario del **Comité de Ética de la Investigación con medicamentos del Hospital Clínic de Barcelona**

Certifica:

Que este Comité ha evaluado la propuesta del promotor, para que se realice el estudio:

CÓDIGO:
DOCUMENTOS CON VERSIONES:

CIF – G-08431173

Tipo	Subtipo	Versión
Protocolo		Versión 2.0, 1 de octubre 2019
Hoja Información de Paciente		Versión 2.0, 1 de octubre 2019

TÍTULO: Estudio piloto de un sistema óptico para analizar el entorno de trabajo de la Unidad de Cuidados Intensivos en el Hospital Clínic de Barcelona
PROMOTOR: FUNDACIO CLINIC
INVESTIGADOR PRINCIPAL: JOSE MARIA NICOLAS ARFELIS; BRUNA CORREA VOLPINI

y considera que, teniendo en cuenta la respuesta a las aclaraciones solicitadas (si las hubiera), y que:

- Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles.
- La capacidad del investigador y los medios disponibles son apropiados para llevar a cabo el estudio.
- Que se han evaluado la compensaciones económicas previstas (cuando las haya) y su posible interferencia con el respeto a los postulados éticos y se consideran adecuadas.
- Que dicho estudio se ajusta a las normas éticas esenciales y criterios deontológicos que rigen en este centro.
- Que dicho estudio cumple con las obligaciones establecidas por la normativa de investigación y confidencialidad que le son aplicables.
- Que dicho estudio se incluye en una de las líneas de investigación biomédica acreditadas en este centro, cumpliendo los requisitos necesarios, y que es viable en todos sus términos.

Este CEIm acepta que dicho estudio sea realizado, debiendo ser comunicado a dicho Comité Ético todo cambio en el protocolo o acontecimiento adverso grave.

y hace constar que:
1º En la reunión celebrada el día 26/09/2019, acta 16/2019 se decidió emitir el informe correspondiente al estudio de referencia.

Reg. HCB/2019/0841

Mod_04 (V4 de 18/06/2018) PR

Página 1/2

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Secretario:
- ANDREA SCALISE (Médico Farmacólogo Clínico, HCB)

Vocales:
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- MERCÈ VIDAL FLOR (Enfermera, HCB)
- JOSE TOMAS ORTIZ PEREZ (Médico Cardiólogo, HCB)

En el caso de que se evalúe algún proyecto del que un miembro sea investigador/colaborador, este se ausentará de la reunión durante la discusión del proyecto.

Para que conste donde proceda, y a petición del promotor,

SCALISE ANDREA VIVIANA - X4915014Y

Firmado digitalmente por SCALISE ANDREA VIVIANA - X4915014Y
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Barcelona, a 03 de octubre de 2019

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ANNEX 9. MEANING OF STATISTICAL PARAMETERS OF WEKA® SOFTWARE

- **Correctly classified instances**: also called accuracy, is a sum of all samples predicted as positive or negative that really are positive or negative between all the instances that we have, that would be the sum of TP and TN as a percentage of all the number of instances.

- **Incorrectly classified instances**: in this case we find a percentage that indicates the rest of the sample, that is, the not correctly classified instances or sum of FP and FN in relation of all the sample.

- **Kappa statistic**: This statistical measure allows to have a relationship between the selected method and chance. A value greater than 0 indicates that the chose classifier works better than chance.

- **Mean absolute error**: This measure allows us to know the average error of the obtained results from the real ones by averaging over the test sample the differences between predictions and observations.

- **Root mean squared error:** With this parameter we can know the dispersion of the results obtained with the model in contrast to the true results or instances. It can be defined as a standard deviation that only considers the prediction errors.

- **Relative absolute error:** This measure allows us to know how far the results obtained are from the real ones, that is, the deviation from a bad classified parameter to its real value.

- **Root relative squared error:** This measure takes all the square errors and normalizes it dividing by the total squared error of the simple predictor, so as a relative, measures in percent compared to the real value.

- **Total number of instances:** total number of observations or of rows in the dataset.

- **TP rate:** rate of instances correctly classified or rate of true positives of each class.

$$TP\ rate = \frac{TP}{TP + FP}$$

- **FP rate:** rate of instances incorrectly classified or rate of false positive of each class.

$$FP\ rate = \frac{FN}{FN + TN}$$

- **Precision:** the same as TP rate, a proportion obtained dividing the number of correctly classified instances of a class by the total number of instances classified in that class.

$$Precision = \frac{TP}{TP + FP}$$

- **Recall:** the result of the correctly classified instances in a class divided by the total number of instances in that class or TP rate.

$$Recall = \frac{TP}{TP + FN}$$

- **F-measure** combines both precision and recall doing a harmonic mean of them. This parameter reaches its best value at 1 as precision and recall.

$$F - measure = \frac{2 \cdot Precision \cdot Recall}{Precision + Recall}$$

- **MCC:** This parameter presents a correlation coefficient between the real class of the instances and the classified ones, returning a value between -1 and +1. A perfect prediction is expected with value of 1, a value of 0 represents that the classification does not better than chance and a value of -1 indicates total incorrectly classified instances.

- **ROC area:** The ROC curve presents the sensitivity as a function of false positives for different cut points. We expect better results in classification in the area under de curve (AUC) approaches 1. If the value is 0.5 it can be comparable to a Kappa statistic of 0 or random guessing.

- **PRC area:** This parameter gives the result of the area under the precision-recall curve (PRC). In this case we will obtain different values for each classifier, so this let us know how the classifier is behaving on one class.

- **Class:** name of the classification.

- **Confusion matrix:** it allows us to see how data has been classified, that is, the number of variables classified in each category. Diagonal indicates correct classifications. Next, we find a table that summarizes a confusion matrix in the case data is classified into positive or negative.

ANNEX 10. ACRONYMS

AAL – Ambient Assisted Living

AHRQ – Agency for Healthcare Research and Quality

AI – Artificial Intelligence

AmI – Ambient Intelligence

ANN - Artificial Neural Network

APACHE – Acute Physiology and Chronic Health Evaluation

AR – Augmented Reality

ARDS - Acute Respiratory Distress Syndrome

ASY – Asystole

BAN – Body Area Networks

BPM – Beats per minute

CA – Cardiac Arrest

CART – Cardiac Arrest Risk Triage

CCHIC – Critical Care Health Informatics Collaborative

CPR – Cardiorespiratory Resuscitation

COPD - Chronic Obstructive Pulmonary Disease

CPU - Central Processing Unit

DAC – Digital-Analog Converter

DB – Database

DICOM - Digital Imaging and Communications in Medicine

DMX – Digital MultipleX

DNS - Domain Name System

ECG – Electrocardiogram

EHR – Electronic Healthcare Record

EMD – Electromechanical Dissociation

ESICM – European Society of Intensive Care Medicine

EWS – Early Warning Systems

FHIR – Fast Healthcare Interoperability Resources

FN – False Negative

FP – False Positive

FTP – Foil screened Twisted Pair

GDPR – General Data Protection Regulation

GPS – Global Positioning System

GUI – Graphical User Interface

HAI – Health care-associated infection

HCB – Hospital Clínic of Barcelona

HCW – Healthcare Workers

HH – Hand Hygiene

HIPAA – Health Insurance Portability and Accountability Act

HIS – Hospital Information System

HL7 – Health Level Seven

HR – Heart Rate

HG - Hydroalcoholic Gel

HTTPS - HyperText Transfer Protocol Secure

HVAC – Heating, Ventilation and Air Conditioning

ICD-10 – International Classification of Diseases version 10

ICT – Information and Communication Technology

ICU – Intensive Care Unit

IEEE – Institute of Electrical and Electronics Engineers

IHCA – In-Hospital Cardiac Arrest

IoT – Internet of Things

IP – Internet Protocol

iSS – i.Lon Smart Server

ISSC – Intrinsic Self-Sensing Concrete

ISTAG – Information Society and Technology Advisory Group

ITS – Intelligent Transport System

JSON – JavaScript Object Notation

LAN – Local Area Network

LOCs – Levels of Care

LOS – Length of Stay

LPS – Light and presence sensor

LR – Logistic Regression

LTE – Limitation of Therapeutic Effort

MAS – Multi-Agent Systems

ME – Medication Errors

MET – Medical Emergency Team

MIMIC-IV – Medical Information Mart for Intensive Care Unit VI

ML – Machine Learning

MPM – Mortality Prediction Model

NHCW – Non-healthcare workers

NHS – National Health Service

OECD – Organization for Economic Co-operation and Development

PS – Patient Safety

PSLL – Patient Safety Learning Laboratory

REST – Representational State Transfer

RFID – Radio Frequency Identification

RR – Respiratory Rate

RTLS – Real Time Location System

SAPS – Simplified Acute Severity Score

SDC – Service-oriented Device Connectivity

SNOMED – CT – Systematized Nomenclature of Medicine-Clinical Terminology

SOA – Service Oriented Architecture

SOFA – Sequential Organ Failure Assessment Score

SPB – Systolic Blood Pressure

SNMP - Simple Network Management Protocol

TEMP – Temperature

TN- True Negative

TP – True Positive

UAV – Unmanned Aerial Vehicles

UK – United Kingdom

URL - Uniform Resource Locator

VF – Ventricular Fibrillation

VT – Ventricular Tachycardia

Weka – Waikato Environment for Knowledge Analysis

WHO – World Health Organization

WSN – Wireless Sensor Network

XML – Mark-up Language

ANNEX 11. CURRICULUM VITAE OF THE AUTHOR

BRUNA CORREA VOLPINI

Biomedical Engineer, Hospital Clínic of Barcelona, Spain
PhD candidate in Biomedicine at the University of Barcelona
www.linkedin.com/in/bruna-corrêa

Professional Profile

I am a biomedical engineer with a profile aimed at developing technologies to improve patient safety and quality of care in hospital environments. I love working with nurses, doctors, bioengineers, and technicians who are motivated to transform the clinical reality and generate benefits for society. I work with smart tools that can be adapted to clinical use and can optimize workflow for medical and nursing staff. I believe that these tools can help healthcare staff feel better supported and be more confident about their tasks, and consequently patients can receive better care.

Education

Big Data & Data Science Master's Degree
University of Barcelona – Institute for Lifelong Learning Foundation (IL3-UB)
2020 – in course

EIT Health Impact Program - Health innovation and creativity in interdisciplinary teams
Scholarship of 6.000 euros granted to cover the costs of the course and trips from EIT Health - Department of Health in Spain, France and Sweden
2019

Biomedical Engineering Master's Degree
University of Barcelona

2014-2015

Biomedical Engineering Bachelor's Degree
University of Barcelona
2010-2014

Publications & Projects

Presentation and Poster: ***Development of hand hygiene monitoring system using electronic devices in an ICU***
I. Carmona, Cecilia Cuzco, Bruna Corrêa, Sara Fernández, Pedro Castro, J.M. Nicolás
XLV Annual Conference of the Spanish Society of Intensive Nursing and Coronary Units
June 09-12, 2019. Palma de Mallorca Convention Centre. Palma de Mallorca, Spain.

Presentation and Poster*: Experimental prototype for improving the detection of Code Blue Events in an Intensive Care Unit*
Bruna Corrêa, J.M. Nicolás, Neus Vidal
XXXVI Annual Conference of the Spanish Society of Biomedical Engineering
November 21-23, 2018. University of Castilla - La Mancha. Ciudad Real, Spain.

Presentation*: Design of an Interface between Critical Care Monitoring and an Ambient Intelligent System in an ICU*
Bruna Corrêa, J.M. Nicolás, Neus Vidal, Pedro Castro, Sara Fernández
XXXV Annual Conference of the Spanish Society of Biomedical Engineering
November 29 to December 1, 2017. University of Bilbao. Bilbao, Spain.

Teaching of theoretical and practical seminaries in Clinical Engineering, Health Systems and Ethics
Topic: The Role of the Clinical Engineer in Hospital Environments
Third-year seminar in the Biomedical Engineering Bachelor's Degree. Duration: 3 hours. March 25, April 2 and 3, 2019. Faculty of Medicine of the University of Barcelona. Barcelona, Spain.

Co-direction of bachelor's degree final projects and departmental stays of students studying Biomedical Engineering, Computer Engineering, and Industrial Design

Final project*: Data analysis of electronic hand hygiene monitoring system*
Student: María Guerrero López
Co-direction with Dr. J.M. Nicolás /February 2020 – June 2020
Degree in Biomedical Engineering – University of Barcelona, Spain
Qualification: Excellent

Departmental Stay*: Development and implementation of IoT devices in a patient room of an ICU*
Student: Julia Soler Porcà
Co-direction with Dr. J.M. Nicolás /July 2019 – August 2019

Degree in Biomedical Engineering – University of Barcelona, Spain
Qualification: Excellent

***Final project and departmental stay**: Design of an intelligent audio and video surveillance system applied to an intensive care unit*
Student: Pablo López Morón
Co-direction with Dr. J.M. Nicolás /February 2018 – January 2019
Degree in Biomedical Engineering – University of Barcelona, Spain
Qualification: Excellent

***Departmental stay**: Design of a hands hygiene monitoring system applied to an intensive care unit*
Student: Seiji Gerard Anthony Bernabela
Co-direction with Dr. J.M. Nicolás /July 2018 – August 2018
Degree in Industrial Design – University of Eindhoven, Netherlands
Qualification: Excellent

***Final project**: Design of an interactive platform to families of an intensive care unit*
Student: Elia Gil Peña
Co-direction with Dr. J.M. Nicolás /February 2018 – June 2018
Degree in Design – University of Barcelona, Spain
Qualification: Excellent

***Final project**: Experimental study of a patient motion surveillance system applied to an intensive care unit*
Student: Gabriel Crespí Serra
Co-direction with Dr. J.M. Nicolás /February 2017 – June 2017
Degree in Biomedical Engineering – University of Barcelona, Spain
Qualification: Excellent

***Final project**: Development of an RTLS web system for a hospital environment*
Student: Marc Casillas Sunyer
Co-direction with Aleix Garcia /February 2017 – June 2017
Degree in Informatics Engineering – University of Barcelona, Spain
Qualification: Excellent

Computer Skills

Seven years of experience in programming using .NET Framework, SQL, Javascript, C#, Python, R Studio, Matlab, XML, HTML, Weka, Power BI, Qlik, Dash and Tableau. Several courses on app development using C# and Visual Studio at the Microsoft Virtual Academy. Advanced user of Microsoft Office.

Languages

Portuguese: Native Spanish, English & Catalan: Professional Proficiency

REFERENCES

[1] "The economics of patient safety in primary and ambulatory care | READ online." https://read.oecd-ilibrary.org/social-issues-migration-health/the-economics-of-patient-safety-in-primary-and-ambulatory-care_baf425ad-en#page1 (accessed Sep. 27, 2019).

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