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The safe administration of medication within the electromagnetic scenarios of the Internet of Things (IoT): looking towards the future

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Presentation

Within society today, ubiquitous wireless communications are fully integrated into most daily activities, not only domestically, but also in the workplace, in leisure and sports activities, in the areas of travel and transportation, and even with regards to human relationships. Greater access to information, transformations and a better adaptation to the environment are at the core of the new technological services on offer.

And digital healthcare is no exception, since it benefits can be seen in various aspects of health care: in the monitoring of physical and physiological parameters, assistance in dangerous situations and accidents, in health emergencies and for the automatic identification of people, as well as devices and products, etc., all of these based on the automatic connectivity of medical devices to hospital networks in order to facilitate the exchange of clinical data between health centers, laboratories and pharmacies.

In addition, the digital health sector, due to its integrative nature and its ability to incorporate social innovation models in its developments, is perceived as an area where the intensive use of Internet of Things (IoT) applications can be found. This allows for communication between objects themselves and between objects and people and is a clear example of the interaction that exists between the fields of medicine and Information and Communication Technologies - ICTs.

Healthcare environments are especially sensitive spaces when it comes to exposure to electromagnetic fields- EMFs, without forgetting that they are sources of non-ionizing radiation. Work on new innovative developments, such as the growing use of sensor networks for monitoring patients and biological parameters at any time or location, leads to the control and minimization of the short- and medium-term effects that come from exposure to all forms of radiant devices. The special relationship that exists between these devices and health and safety requirements suggests the need for the monitorization of their operating conditions, compliance with all recommended standards, as well as promoting correct user practices.

This monograph originally published in December 2018, with the aim of analyzing the contribution of ICTs in the analysis and prevention of errors that occur in the administration of drugs, as well as the health risks that may exist in environments with concurrent EMFs, has become especially relevant following the global pandemic caused by SARS-COV-2, since mobility restrictions and population lockdowns have led to an unprecedented use of wireless communications.

The authors of this work have a long research career in evaluating the ever-increasing use of wireless technologies, and the consequent increase in concurrent radiation sources which, given the nature of IoT, operate at different frequencies.

This fact, alongside the warm reception of the first edition in Spanish, the opportunity to incorporate recent technological advances such as 5G, and changes in legislation and in some bibliographic references, has led to the publication of this revised version, now in English in order to reach a wider audience.

Adolfo Muñoz Carrero

Head of the Telemedicine and e-Health Area

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Abstract

This paper has focused on analyzing the impact of Information and Communication Technologies (ICTs) to prevent or reduce errors during therapeutic drug administration. The methodology used has included scientific literature and marketed appliances reviews and laboratory tests on radiant devices.

The role of the patient has been analyzed, both in terms of compliance with the prescribed treatments and user of technical solutions designed for administering medication. In addition, it has taken into account, how a future characterized by multiple technologies designed to support our daily routines, including health care, might affect the current model of relationship between health professionals and patients.

Particular attention has been given to safety risks of ICTs in environments characterized by concurrent electromagnetic emissions operating at different frequencies. Implications and new scenarios from Internet of Things or IoT, have been considered, in light of the approach taken jointly by the European Commission and the European Technology Platform on Intelligent Systems Integration – EPoSS, in their 2008 report *Internet of Things in 2020: a roadmap for the future,* and how the concept has evolved since then.

Introduction

In the 1990s, when the magnitude and severity of adverse drug reactions began to spread within hospitals, it was suggested that many of these came from preventable errors, and that the Information and Communication Technologies (ICTs) could eliminate, them, or at least, reduce these reactions.

This use of the ICTs has been the subject of studies that have highlighted the interest in wireless devices in the prevention of errors within healthcare facilities, but also as a support for outpatients or clinics in the therapeutic administration of drugs. However, the use of these technologies has raised other questions regarding efficacy and safety that should be analysed.

On the one hand, it is necessary to determine whether the Information and Communication Technologies, despite the expectations and interest that they are arousing, effectively contribute to avoiding, or minimizing, the errors that cause adverse events in drug therapy treatments.

Additionally, it is essential to go into more depth regarding the personal safety aspects, with regard to electromagnetic emissions (EME), of these technical solutions. This aspect takes on a special relevance when considering the rise of the Internet of Things or IoT, and especially its medical application or Internet of Medical Things (IoMT). This proposes converting everyday objects into smart objects, with the ability to exchange information, without geographical or temporal limitations, with other objects and people, thanks to wireless communication systems, leading to the creation of environments that are characterized by multiple and concurrent EMEs. In this regard, it is relevant to address both the possible absence of safety guidelines, as well as non-adherence with the existing ones.

The starting point for the IoT study was the September 2008 report, jointly prepared by the European Commission and the European Technology Platform on Smart Systems Integration (EPoSS), *Internet of Things in 2020: a roadmap for the future*, and that now, in the year 2021, and mainly since the emergence of 5G, shows us that IoT is here to stay. The magnitude of the technological revolution that the Internet of Things supposes, and its effect on personal safety, justifies all contributions, whilst it is also desirable that any reflection adopts the precautionary principle in order to safeguard health.

CHAPTER 1. ADVERSE DRUG EVENTS

According to the report *Pharmaceutical expenditure in Spain 2015. International evolution and situation from a national point of view*, published by the School of Business Administration - EAE Business School, in July 2015 [1]: "medications are one of the most important expenditure items for the health system of any country that wishes to maintain the Welfare State" are products that are increasingly manufactured and distributed on a global level, but for all the expected benefits that they bring, there could be an unwanted drawback with a rise in Adverse Drug Events–ADE, with the consequent impact on the health of citizens and on the financial resources of the health system.

In the 1990s, an awareness arose that medicines, in addition to the risk they carry of producing adverse reactions when used under appropriate conditions, could also produce numerous harmful effects due to errors made during their clinical use. Consequently, the lines of work aimed at improving patient safety include, as one of their priorities, medication safety.

All drugs are known to have inherent risks, which are generically called adverse drug reactions. In 1991 the national health centers that participated in the WHO Program for International Drug Monitoring defined an adverse drug reaction (ADR), as "any response to a drug which is noxious, unintended and occurs at doses normally used for prophylaxis, diagnosis, or therapy..."[2]. ADRs are, therefore, the unwanted or idiosyncratic harmful effects of drugs, even if their use and administration procedures have been appropriate. Their unavoidable nature distinguishes them from preventable adverse drug events (PADEs), which can occur at any stage of the drug use process: medical prescription, transcription - to computer applications, medical notes, or paper prescriptions-, dispensing and, finally, administration. They are also called harmful medication errors, to distinguish them from medication errors with little or no impact on the health of the patient or near misses (Table 1.1.).

Table 1.1. Summary of risks associated with drug therapy.

Adverse Drug Reaction - ADR: any response to a drug which is noxious, unintended and occurs at doses normally used for prophylaxis, diagnosis, or therapy. ADRs are therefore unwanted or unintended effects of a medicine, including idiosyncratic effects, which occur during its proper use.
Preventable adverse drug event - PADE: result from a medication error that reaches the patient and causes any degree of harm, and which can happen in the course of prescribing, transcribing, dispensing, administration and monitoring practices.
Medication safety: actions aimed at improving patient safety by avoiding medication errors.

Spanish legislation, initially set out by Royal Decree 1344/2007, of October 11, now repealed, defined medication error in practically the same terms: “failure due to an action or omission in the treatment process with medications that causes, or may cause harm to the patient“, differentiating it from adverse reactions that were described as “the response to a drug that is harmful and unintentional“.

Changes in European legislation, specifically those derived from the Directive 2010/84 / EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83 / EC on the Community code relating to medicinal products for human use, and the Directive 2012/26 / EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83 / EC as regards pharmacovigilance, gave rise to the Royal Decree 577/2013, of July 26, which regulates pharmacovigilance of medicines for human use and which replaced the Royal Decree of 2007. Among the new features that it introduces, the broadening of the definition of adverse reaction stands out, considering as such "any harmful and unintended response to a medication", including among its possible causes are marketing authorization, substance abuse and medication errors.

But beyond these definitions, what is a proven fact is that patients can be harmed during drug therapies, and that the result is often fatal. In these circumstances, preventing their occurrence, or at least minimizing them as much as possible, should be a priority, especially if we consider that, in many cases, adverse events stem from preventable errors. The fundamental thing is therefore to determine the causes in order to establish the most appropriate prevention strategies. Taxonomies of errors are created for this purpose. An example is the one elaborated by the Ruiz-Jarabo Working Group in 2000 [3] from the classification proposed by the National Coordinating Council for Medication Error Reporting and Prevention - NCC MERP [4], and later updated by the aforementioned Working Group in 2008 [5] (Table 1.2.).

Table 1.2. Medication errors Classification by Ruiz-Jarabo work group.

MAIN TYPES OF MEDICATION ERRORS ACCORDING TO THE SPANISH TAXONOMY OF MEDICATION ERRORS	
Types of medication errors	**Description**
1. Wrong medication • Inappropriate drug selection. ◦ Medication not indicated/ appropriate for the diagnosis to be treated. ◦ Previous history of allergies or similar adverse effect with the same or similar medications. ◦ Contraindicated medication. ◦ Inappropriate medication for the patient due to age, clinical situation or underlying pathology. ◦ Therapeutic duplication. • Unnecessary medication. • Transcription / dispensing / administration of a drug other than the one prescribed.	Within the category of wrong medication the inappropriate selection of a drug based on its recognized indications, contraindications, known allergies, existing drug treatment and other factors are included, as well as the prescription of a drug for which there is no indication (unnecessary medication). Also within this category are the transcription/ dispensing and administration of a non-prescribed medication.

MAIN TYPES OF MEDICATION ERRORS ACCORDING TO THE SPANISH TAXONOMY OF MEDICATION ERRORS	
Types of medication errors	**Description**
2. Missed dose or medication • Missed prescription of a necessary medicine. • Omission in the transcription. • Omission in dispensing. • Omission in the administration.	A medication omission is considered a failure to prescribe a necessary medication, such as a lack of prophylaxis or forgetting a medication when writing the prescription. Failure to transcribe / dispense / administer a prescribed medication is also included. Dose omission is considered to be the non-transcription / dispensing / administration of a prescribed dose to a patient prior to the next scheduled dose, if appropriate. Cases in which the patient willingly refuses to take the medication, the decision not to administer the medication when recognizing that contraindications exist, or when there is an obvious explanation for the omission are excluded (for example, the patient was outside the nursing unit to carry out some tests).
3. Incorrect dose • Higher dose than the correct one. • Lower dose than the correct one. • Extra dose.	Prescription / transcription / dispensing / administration to the patient of a higher or lower dose than necessary. It excludes accepted deviations according to each institution based on criteria established for the professionals in charge of administration (for example, not administering a dose based on the patient's temperature or glucose level) and the administration of doses of topical pharmaceuticals when the quantity is not indicated in the prescription. Extra dose includes re-administering a dose that has already been administered previously.
4. Incorrect frequency of administration	Prescription / transcription / dispensing / administration of a medicine at different time intervals than that required by the patient.
5. Wrong pharmaceutical form	Prescribing a drug in a different pharmaceutical form than the one required by the patient, or transcription / dispensing / administration of a pharmaceutical form other than the one prescribed, for example, administering a delayed release formulation when a conventional formulation is prescribed. Excluding accepted protocols (established by the Pharmacy and Therapeutics Commission or its equivalent) that authorize the pharmacist to dispense alternative pharmaceutical forms to patients with special needs (for example, liquid pharmaceutical forms for patients with a nasogastric tube or who have difficulty swallowing).
6. Preparation, handling and / or packaging error	Incorrectly formulating or handling medicine before administration. It includes, for example, improper dilution or reconstitution, mixing of drugs that are physically or chemically incompatible, and improper packaging of the product.
7. Incorrect administration technique	Inappropriate procedure or technique in the administration of a drug. It includes, for example, incorrect activation of a dosing pump or inappropriate crushing of tablets or pills.
8. Wrong route of administration	Administration of a drug by a route other than the one administered, or by a route other than the one prescribed, for example, use of an exclusively intramuscular formulation by an intravenous route.

MAIN TYPES OF MEDICATION ERRORS ACCORDING TO THE SPANISH TAXONOMY OF MEDICATION ERRORS	
Types of medication errors	**Description**
9. Incorrect administration rate	Administration of intravenous medication at an incorrect rate.
10. Incorrect time of administration	Administration of the medication outside the time interval programmed in each institution for the hourly administration of the medication.
11. Wrong patient	Prescription / transcription / dispensing / administration of the medication to a different patient than the one who should receive the treatment
12. Incorrect treatment duration • Longer duration than the correct one. • Shorter duration shorter than the correct one.	Duration of treatment longer or shorter than necessary. It also includes the early withdrawal of a drug or its administration after the prescription has been suspended.
13. Insufficient treatment monitoring	Failure to review the prescribed treatment to verify its suitability and detect possible problems, or failure to use relevant clinical or analytical data to adequately assess the patient's response to the prescribed therapy.
14. Spoilt or damaged medication	Dispensing / administration of a medicine that has expired or whose physical or chemical integrity is altered, for example, due to improper storage
15. Lack of patient compliance	Inappropriate patient compliance with prescribed treatment.
16. Others	Other medication errors not included in the categories described above.

The need to establish effective safety practices in relation to the therapeutic use of drugs has been made evident in numerous studies. The *ADE Prevention Study* [6] stands out, for being the first to consider medication errors as a system, rather than a human failure. Equally relevant is the report drawn up by the Institute of Medicine (IOM) [7], an organization that raised the alarm in 1999 by publishing that, annually, there were tens of thousands of deaths and injuries in hospitalized patients in the United States due to treatment errors.

Although the origins of the concerns regarding adverse drug events come from hospital settings, this same reality can be extrapolated to outpatients or clinics. Although errors can occur at any stage of the drug use process, it is those that occur during administration that are most likely to cause damage. In outpatients, the responsibility of administration usually falls directly on patients themselves, or on informal caregivers - family, friends, non-professional contracted workers, etc. - a group that is therefore even more vulnerable to errors during the administration of treatment.

Returning to the taxonomy of the Ruiz-Jarabo Working Group (2008), the most common errors outside health facilities and that are attributable to the patient, or their informal caregivers are:

- the administration of a medicine other than the one prescribed,
- the omission of doses or even of the medicine itself,
- incorrect doses,
- incorrect frequency of administration,
- incorrect time of administration,
- administration of a spoilt or damaged medicine and
- incorrect treatment duration.

Others, such as the prescription of a drug that doesn't correspond to the pathology, the lack of a drug prescription when required, or incorrect dispensing, for example, administering a delayed release formulation when a conventional formulation is prescribed, all correspond to specific professionals: doctors, pharmacists ..., and, therefore, prevention measures should be directed at these collectives.

In the search for the most effective strategies to preserve the five rights of patients in the therapeutic use of drugs - the correct medication, administered to the correct patient, with the appropriate dose, at the correct time and with the appropriate frequency, and in the right route and also to avoid harmful medication errors, the US Food and Drug Administration (FDA) concluded that "at least half of the errors that occur in hospital settings could be prevented with the use of adequate Information and Communication Technologies (ICTs)" [8], and in accordance with the studied literature [9], ICTs seemed to be able to contribute positively to the monitoring and control of patients, medications and doses, giving a faster incident response, and a better record, documentation and analysis.

Already in 2010, according to the review carried out by Schmidt M. et al. [10], most health systems, both in the United States and in Europe and Asia, already had ICTs that could contribute to the prevention of adverse drug-related events:

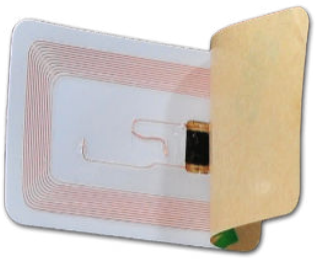
- Electronic Medical Record.
- Computerized Physician Order Entry.
- Pharmacy Information System.
- Smart Infusion Pumps.
- Barcodes.

In addition, as a potential successor to the barcodes, the authors mentioned Radiofrequency IDentification (RFID), a technology that already bore a close resemblance to the Internet of Things or IoT, a concept that suggests that everyday objects in our immediate environment could collaborate in sustaining the environment and people in all areas of their lives, and with an unprecedented degree of automation.

At that time, the barcodes were fully integrated into healthcare operations and their usefulness in avoiding the incorrect interpretation of handwritten texts was unquestionable, both when labeling devices, products, and biological samples, as well as when filling out medical records. Like barcodes, RFID enabled digital marking, but also included certain unique characteristics that anticipated promising new features for telemedicine and telecare. Thus, while barcodes contain fixed

information and can only communicate data when being read, requiring visual alignment with the receiver, RFID allows objects to identify themselves without requiring such alignment. Also, the information is not static, but is stored in a rewritable memory contained in tags, which can be attached or incorporated to products, animals, and people. (Figure 1.1.).

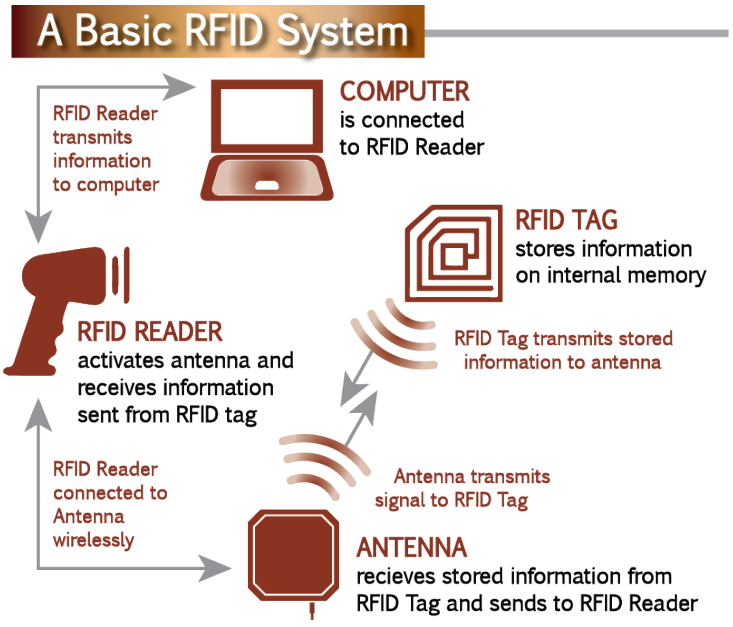
Figure 1.1. Adhesive RFID tag. Source: http://www.enzocard.eu/.



These tags also have antennas, which allow them to receive and respond to information requests by radio frequency. The exchanged data will, in turn, be processed in a remote computer system for a specific use, for example, for warehouse stock management, for the monitoring of the drugs themselves as they go from the laboratory to the point of sale in order to avoid theft or being tampered with, or, within the health facilities to trace clinical or surgical material.

In short, RFID technology allows objects to have their own identity, similar to a unique serial number, and to be able to transmit it autonomously by radio frequency, without having to wait for a reader or interrogator to interpret the information. (Figure 1.2.).

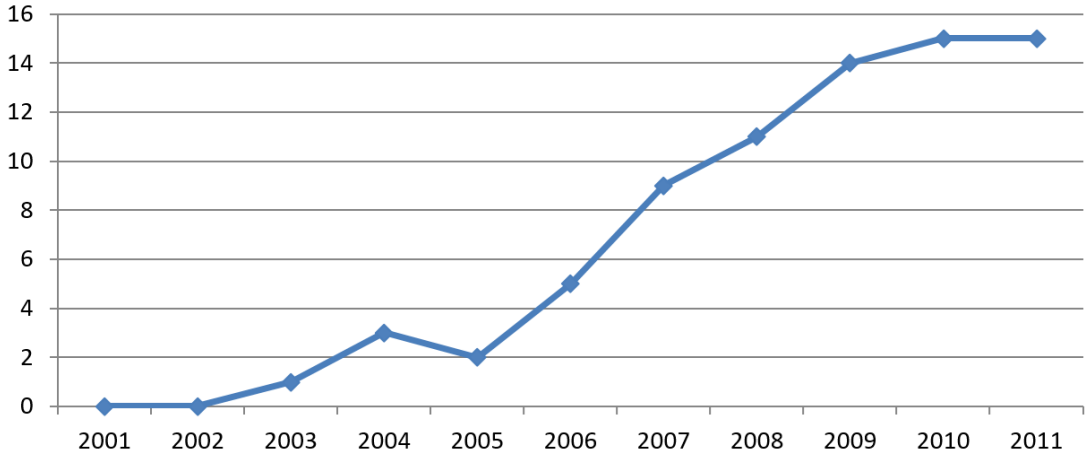
Figure 1.2. Smartt-tags, April 2021. Source: http://smartt-tags.com/#what-is-rfid?.



The review carried out by the authors on the works published in the IEEE Xplore document base [11], revealed the growing interest within the health sector with regard to RFID technology during the first decade of the 2000's, being one of the most frequently used applications within health centers to monitor clinical material and other hospital goods. Furthermore, its usefulness for monitoring and locating patients seemed to be gaining prominence, especially concerning those most vulnerable because of age (the elderly and children) or by the type of ailment (dementia, Alzheimer's…). The attention that all sectors involved in blood collection and processing were giving this technology, either for diagnostic or therapeutic purposes, was also evident. As was the case with the barcodes, the area of hemotherapy and transfusion medicine once again proved to be a pioneer in the incorporation of technological innovations that positively impact patient safety.

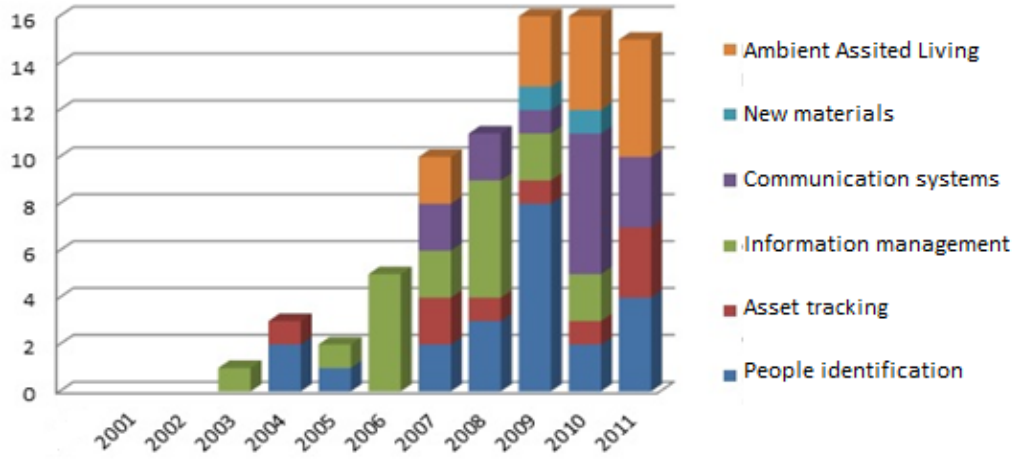
Regarding the prevention of adverse drug events, the number of studies mentioning the possible effectiveness of Radio Frequency Identification for this purpose had increased substantially (Figure 1.3.).

Figure 1.3. Variation in the number of publications about RFID for preventing ADE from 2001 to 2011. Source: IEEE Xplore.



The review also revealed other RFID applications that were being studied and that could be essential to successfully addressing the problem of medication errors inside and outside hospital settings. They are based on the integration of Radio Frequency Identification with other ubiquitous computing technologies, such as communication protocols and wireless sensor networks, to support our daily lives and take care of our health in so-called Ambient Assisted Living (Figure 1.4.). Here, ICTs can play a proactive role, with a minimum of human intervention, in the provision of medical care, or simply to provide us with greater comfort, being able to satisfy our requests and even anticipate our needs.

Figure 1.4. RFID applications areas in terms of functionality.



From the reviewed research, it was clear, however, that until 2011 most of the research concerning the contribution of RFID, and in general of ubiquitous computing technologies, to medical or health care, had been done in restricted, controlled, and remote environments away from real life situations. But considering that public health systems must provide assistance to increasingly ageing societies with a growing number of chronically ill or dependent patients, ICTs as a support to daily life and health, could become a complement, or even an alternative in the provision of quality health care. Therefore, they deserve special attention, and the next chapter analyzes how this experimental line has evolved up to the present day.

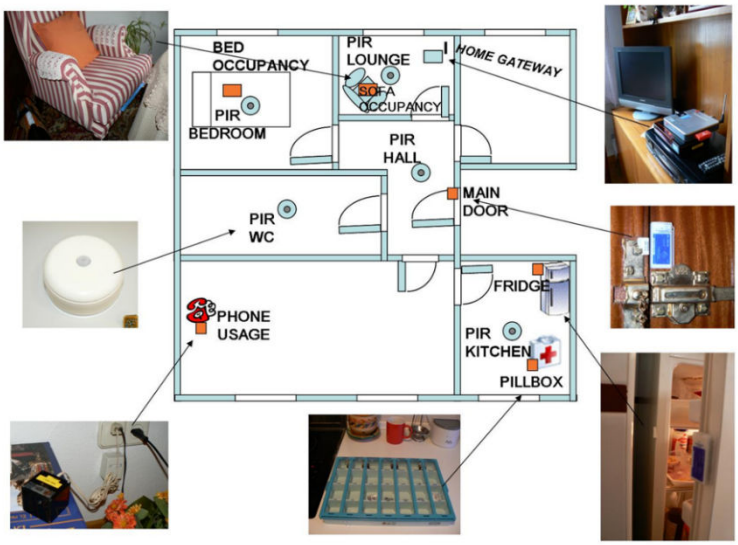
CHAPTER 2. ICTs IN EVERYDAY LIFE AND HEALTHCARE

AMBIENT ASSISTED LIVING

Using ICTs to facilitate our daily habits, avoid isolation and improve social skills, is the goal of Ambient Assisted Living (AAL).

Using sensors and other wireless communication technologies installed in the home, or ubiquitously through mobile devices, the daily activities of patients could be monitored and, where appropriate, recorded, in order to detect and correct abnormal or inadequate behaviour (Figure 2.1.).

Figure 2.1. Ambient assisted living. Source: "New wireless Solutions for Health and welfare" Wireless Vitae 09. I International Conference on Wireless Communication, Aalborg, Dinamarca 17-20 mayo 2009. Procedings IEEE Catalog Number: CFP0969G-CDR. ISBN: 978-1-4244-4067-2. Library of Congress: 2009901216.



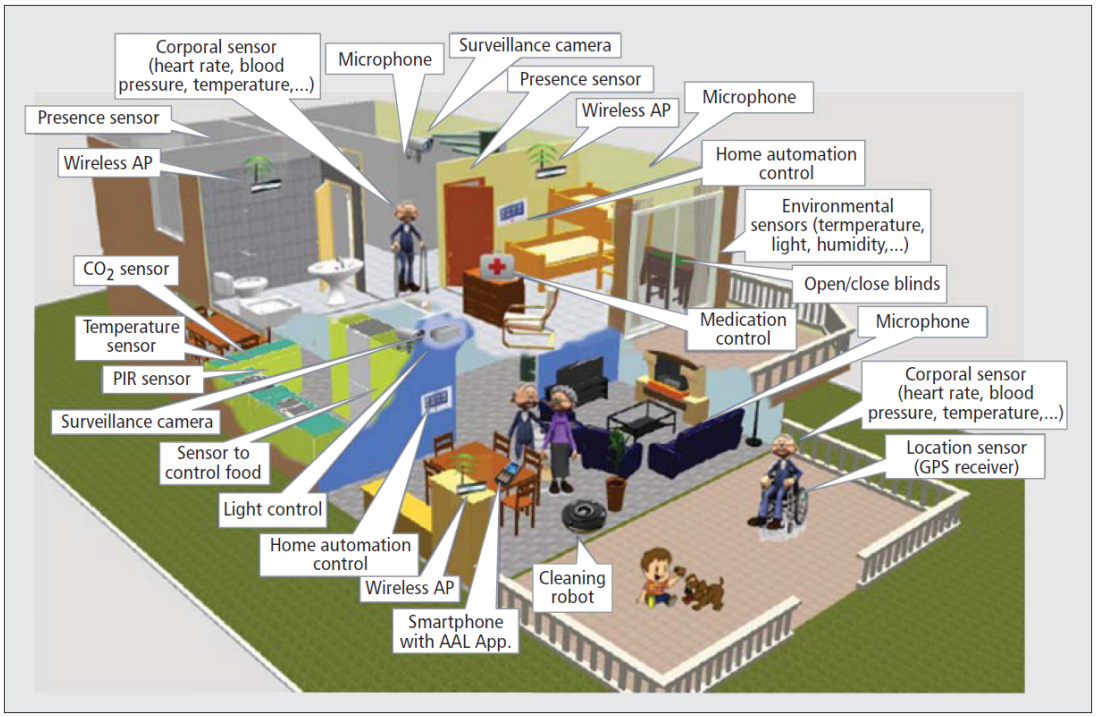
One of the undeniable advantages of ambient assisted living is the possibility of providing personalized care, but remotely and outside health facilities [12], [13]. This, not only facilitates continuity in the daily routines of health professionals and patients, but also the personal autonomy of the latter [14], [15].

Furthermore, ambient assisted living allows for the evaluation and medical monitoring of a higher percentage of the population, in cases where direct contact with healthcare professionals is not essential. Consequently, the most efficient use of resources in this sector would be achieved, at a time when, together with the significant increase in life expectancy, we are seeing a notable rise in chronically ill patients. In 2012, in Spain alone, there were already more than nineteen million cases according to the National Health Survey [16a], and in 2017 there was an increase equal to, or greater than, one percentage point [16b], a number that was reached without including many pathologies, for example, data concerning

Parkinson's or Alzheimer's diseases. For its part, the National Survey of Chronic Patients, stated in 2014 that 71.8% of the population aged 65 or over suffers from a chronic disease, with figures ranging between 66.7% in people between 65 and 74 years old, and 77.6% in people aged 85 or over [17] [1].

Since 2014, the European Union AAL Program has become known as the *Active and Assisted Living Program*. The program proposes the total integration of ICTs in our immediate environment (Figures 2.2a and 2.2b), and its scope is expanded to address the management of chronic diseases, social inclusion, access to the self-service society, mobility of the elderly, support from non-professional caregivers - family, friends… -, support in daily and work life.

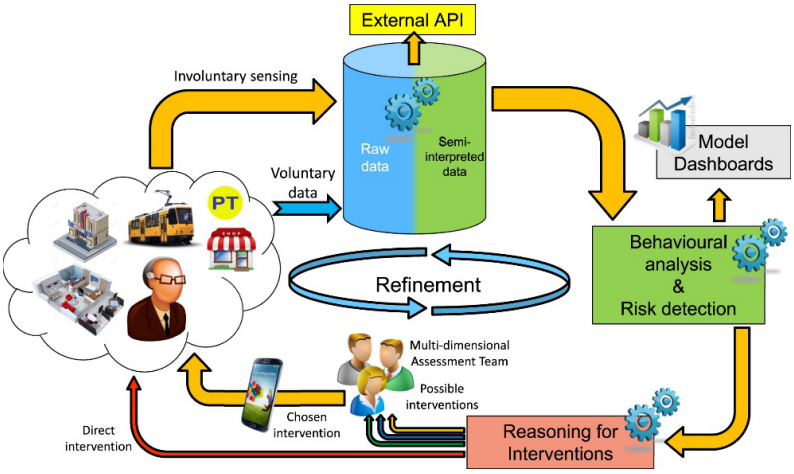
Figure 2.2a. Regular AAL elderly people residency or house. Source: J. Lloret et al., "A smart communication architecture for Ambient Assisted Living", *IEEE Communications Magazine*, Volume: 53, Issue 1, January 2015.



But in fact, this line of work has been promoted by the European authorities for years. In 2008, the European Parliament and the Council of the European Union began to finance public-private collaboration projects in the field of information and communication technologies, with the aim of achieving active and healthy aging. However, it is now, a decade later, when this objective seems more tangible, thanks to the enormous expansion of communication networks, mainly the Internet, and the advances that have occurred in the field of sensors and other Short Range Devices (SRD).

[1] In 2020, the pilot phase of the PaRIS project promoted by the Organization for Economic Co-operation and Development OECD was launched, which aims to measure the results reported by Primary Care patients with chronic diseases. The results of the project, which has the participation of 15 countries, including Spain, were not yet available at the time of publishing this monograph Available on: https://www.oecd.org/health/paris/.

Figure 2.2b. System architecture of the City4Age project. Source: A. Almeida et al., "A critical analysis of an IoT-aware AAL system for elderly monitoring", *Future Generation Computer Systems*, Volume: 97, August 2019, pages 598-619.



SRD are technologies capable of transmitting information at a distance using electromagnetic waves, and they work with differing standards that determine some of their characteristics, such as the data transfer rate, the range, or the type of modulation used (Table 2.1.). These particular characteristics are very relevant, since they allow us to know their current uses and their potential, and it is therefore worthwhile giving a more detailed description here:

Table 2.1. Comparative of Wireless Protocols. Source: Prepared by the authors.

Item	Bluetooth	UWB	Zigbee	Wi-Fi	5G
Standard(s)	IEEE 802.15.1 (No longer maintained)	IEEE 802.15.3a (No longer maintained)	IEEE 802.15.4	IEEE 802.11/b/a/g/n/ ac/ad/ah/af/ax	3GPP Releases 15/16/17 Several components standarized by ETSI
Frequency band	2.402-2.480 GHz	3.1-10.6 GHz	315/433/784/868/ 915/953 MHz; 2.4 GHz	2.4/5/6 GHz	700 MHz; 3.4-3.8 GHz; 28-42 GHz
Max signal rate	1/2/3/8/24/ 32/50 Mbps	110/480 Mb/s; 1.6 Gbps	20/40/100/250 kbps	11/54/600/6933/9608 Mbps	> 1 Gbps
Nominal range	10-400 m	0.1-10 m	10-100 m	100-250 m	200-300 m
Nominal Tx power	(-20)-20 dBm	(-)41.3 dBm/MHz	(-25)-20dBm	15-30 dBm	75 dBm/100 MHz
Number of RF channels	40/79	16	1/16/30	11/13/14/45	16
Channel bandwidth	1-2 MHz	500MHz-7.5GHz	0.3/0.6 MHz;2 MHz	20/22/40/80/160 MHz	50/100/200/400 MHz
Modulation type	GFSK, pi/4-DQPSK, 8DPSK	BPSK, QPSK, OFDM, PPM, ASK…	BPSK(+ ASK), O-QPSK	BPSK, QPSK, COFDM, CCK, M-QAM	pi/2-BPSK, BPSK, QPSK, 16QAM, 64QAM, 256QAM
Spreading	FHSS	DS-UWB, MB-OFDM	DSSS	DSSS, CCK, OFDM	CP-OFDM, DFT-s-OFDM
Coexistence mechanism	Adaptive frequency hopping	Frecuency hopping (FH-UWB), impulse radio (IR-UWB)	Dynamic freq. Selection	Dynamic freq. Selection (DFS), Transmit power control (TCP)	Dynamic Spectrum Sharing
Basic cell	Piconet	Piconet	Star, peer-peer	BSS	MANETs
Extension of the basic cell	Scatternet	Peer-peer	Cluster tree, mesh	ESS, IBSS	OSPF-MDR
Max number of cell nodes	8	8	> 65000	2007	>100000
Data protection	16-bit CRC	32-bit CRC	16-bit CRC	16/32-bit CRC	24-bit CRC

- **Bluetooth** is a specification that defines the Wireless Personal Area Network (WPAN), a low-power, short-range communications standard that operates at the 2.4 GHz frequency. Like all technologies, Bluetooth has evolved over the years, gaining in speed and capacities depending on its transmission power and its effective coverage. Bluetooth LE Audio is a standard released in early 2020, and it improves sound quality and energy efficiency in all devices that connect for audio functions. Bluetooth incorporates a system designed to avoid interference, the Adaptive Frequency Hopping - AFH. Regarding the transmission range that this technology allows, it can operate between 0.5 and 100 meters.
- **Wireless Fidelity, Wi - Fi or Wi-Fi** is one of the most widely used wireless communication technologies today. A trademark of Wi - Fi Alliance, it is also known as a Wireless Local Area Network or WLAN, or as the IEEE 802.11 standard. It was designed to replace the equivalent of the 802.3 standard Medium Access Control or MAC physical layers, making it fully compatible with all local Ethernet cable services. There are several standards whose main differences are both the frequency band in which they operate, and the speed of information transfer.
- **ZigBee** is a wireless communication technology created specifically for its application in fields related to domotics[2], inmotics[3] and the automatic control of industrial plants. This is mainly due to its low consumption, since the nodes under this standard have a special energy saving capacity, and to its mesh network topology, which provides great robustness in communications and ease of integration, since each node has a low electronic requirement and therefore a very low cost.
- **Ultra - Wide Band or UWB.** This technology, which began to be developed in 1950, achieves transmission speeds of up to 1.6 Gbps, and up to a maximum distance of 10 meters, much higher than other wireless technologies. It simultaneously carries audio, video, and data, making it very useful for digital camcorder systems or mp3 players. The high transmission speeds of the UWB are due to the fact that it makes use of a large bandwidth of channels within the 500MHz-7.5GHz range, and therefore, transmits with a very low power output, giving it low levels of energy consumption. In the field of medicine, UWB communication systems are very interesting, particularly for implanted devices, due to their low power consumption, low cost, small size and high data transmission speeds.
- **Near Field Communication or NFC,** which allows devices to communicate with each other at a low frequency. NFC works through RFID tags and uses a special chip, usually located on the battery, or the back cover in the case of mobile phones.

[2] Domotics or home automation involves the integration of various products, systems and services which allow the automation of domestic functions, even with equipment (home appliances, boilers, lamps, audio/video devices...) which already has a traditional place in the home.

[3] Inmotics offers the possibility of monitoring the general operation or workings of buildings, that is, elevators, energy balance, irrigation, air conditioning and lighting of common areas, capturing analog variables such as temperature and humidity, controls and alerts depending on a set of determined parameters, fire detection systems, etc. In the same way, it allows greater access control and continuous monitoring of who has entered the premises. It has been successfully applied in residential and office buildings, hotels, hospitals, museums, shopping malls, data processing centers, housing estates, and industrial facilities.

- Finally, we must consider smartphones, since they are currently the most widely used medium for exchanging information between devices that are located a long way from each other due to their ability to connect to the Internet. For the generation of 5G devices, the Radio Spectrum Policy Group (RSPG), high-level advisory group that assists the European Commission in the development of radio spectrum policy, approved the frequency bands between 3.4 and 3.8 GHz, part of the 26 GHz band, and some bands below 1 GHz, in particular the 700 MHz band as it is necessary for rural areas and inside buildings. In Spain, according to the 2018-2020 National 5G Plan of the Ministry of Energy, Tourism and Digital Agenda (currently the Ministry of Economic Affairs and Digital Transformation), the definitive bands are 700 MHz, 1.5 GHz, 3.6 GHz and 26 GHz, which allow speeds in mobility of greater than 100 Mbit / s and peaks of up to 1 Gbit / s, as well as very reliable communications and a very low latency, around 1 millisecond (ms) compared to the 20-30 ms typical of 4G networks.

The new Digital Agenda called *Spain Digital 2025* , was presented on Thursday, July 23, 2020 and it consists of about 50 measures that are articulated around ten strategic axes, one of them is to continue with the deployment of 5G technology in Europe and encourage its contribution to increasing economic productivity, social progress and territorial structuring. A goal is set for 100% of the radio spectrum to be ready for 5G by 2025.

It is important to underline that both SRD and 5G are crucial elements for the Internet of Things or IoT, a technological approach in which everyday objects would be able to not only participate actively and proactively with regards to environmental sustainability, but also in our health and well-being. It is therefore necessary to go into more depth regarding the whole concept of IoT to try to determine to what extent, and at what time these ends could be achieved, and, above all, if the safe administration of medicines is among them.

INTERCONNECTED OBJECTS: INTERNET OF THINGS - IOT

Internet of Things or IoT began as just the title of a business presentation by Kevin Ashton, co-founder and CEO of the Auto-ID Center of the Massachusetts Institute of Technology (MIT) for the American multinational consumer goods company Procter & Gamble. In that 1999 presentation, Ashton linked, for the first time, the Internet to Radio Frequency IDentification (RFID) within supply chains. Since then, the concept of the Internet of Things has appeared in the titles of books, articles, conferences, reports and debates, although according to the creator of the term, the interpretation given to it is not always correct, as argued in an article published more than ten years later [18].

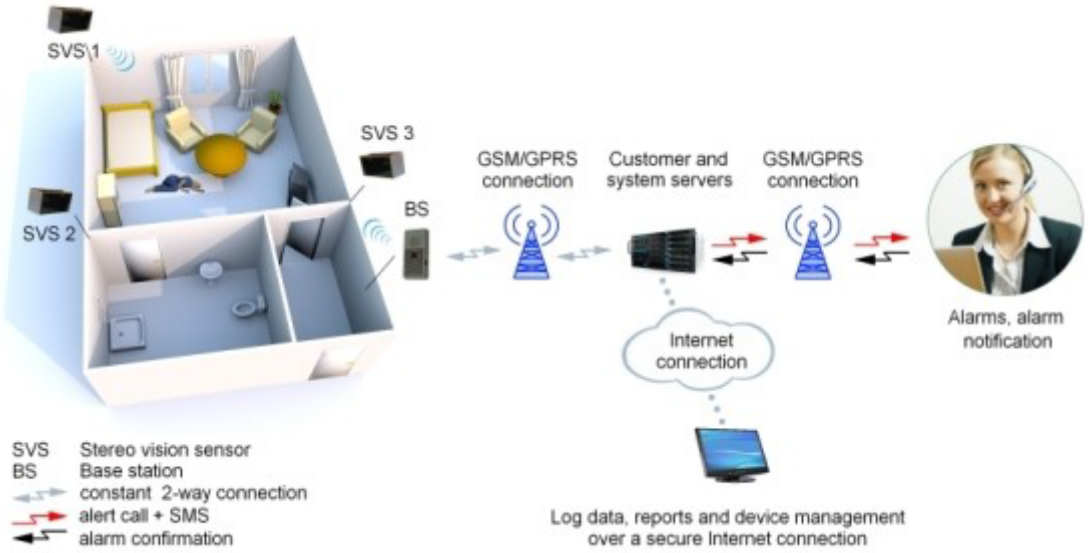
Internet of Things comes from the composition of two words: Internet and thing. Therefore, from a semantic point of view, the Internet can be defined as "the global network of interconnected computer networks, based on a standard communication protocol, the Internet suite TCP / IP", as it is the way to refer to objects in general. From this perspective, the Internet of Things could be defined as "a global network of things interconnected by standard communication protocols."

But the real interest in the Internet of Things, and in which all its potential lies, is that, within this concept, all objects, and not just computers, could have their own IP address. In addition, they would have the ability to detect or perceive, identify and understand the world autonomously, and without the need for people to enter in data.

These capacities would be common to all objects, even the most simple and everyday ones, allowing them to connect between themselves, exchange information and even make decisions, in the total absence, or with a minimun level, of human intervention, therefore turning them into smart objects.

The reality is that the Internet of Things has not only attracted great interest, but it has also been the subject of multiple specific funding lines (Figure 2.3.). For example, the European Union's Horizon 2020 program, for the period 2014-2020, will have invested almost € 500 million in research, innovation and deployment related to IoT [19].

Figure 2.3. CARE System. Project running under the Ambient Assisted Living Joint Programme (http://care-aal.emt.bme.hu/).



But interest in IoT came much earlier. Already in 2007, the European Commission's Directorate General (DG) Information Society and Media (DGINFSO[4])) and the European Technology Platform on Smart Systems Integration (EPoSS), had begun to raise, independently, the need for a common regulatory framework, both for Radio Frequency Identification, as well as for intelligent systems capable of assuming complex human cognitive and perceptual functions.

Both organizations agreed on the use of Radio Frequency Identification (RFID) so that everyday objects could be turned into smart objects with multiple applications. These would include the provision of support to the elderly or people with disabilities, allowing for a close monitorization of goods which would lead to an improvement in food or pharmaceutical safety, having smart products that store information about their components, and managing waste recycling more efficiently in line with individual characteristics.

At that time, when the notion of the Internet of Things was still very vague and still the subject of debate in many academic circles, the DG INFSO and EPoSS shared the same vision, which was based on the following technological evolutions: i)moving from passive RFID tags to active RFID tags working in conjunction with wireless sensors, ii) shifting from simple object identification to real-time awareness and responsiveness, iii) moving from open data exposure to privacy, and finally, iv) a shift from the security of devices or appliances to trust.

The rise of ubiquitous services and the integration of everyday objects into the world of the Internet would constitute the next step in the development of IoT.

Aware that the Internet of Things created great opportunities for European industry, but also posed new challenges for privacy, trust, security and governance, the DG INFSO and EPoSS organized a symposium in February 2008 entitled *Beyond RFID Internet of Things*, the results of which were specified in the report published in September of that same year under the title *Internet of Things in 2020: a roadmap for the future* [20]. The foundations on which IoT should be based, according to the criteria of both organizations, are set out below:

- As a starting point, RFID technology, which as already mentioned, seemed destined to replace the bar code, became much more than a simple digital marker thanks to it having active components.
  In combination with new communication protocols, any object could have an identification, which is commonly known in the field of computer networks as a unique IP address, creating an addressable set of computers, sensors[5], actuators[6] and smartphones. In this group of related objects, they will be able to interrogate with each other, verify their identities, exchange information and, if necessary, actively process it according to predefined, although not necessarily deterministic, schemes.

[4] DG INFSO was renamed DG CONNECT (European Commission Directorate General for Communications Networks, Content & Technology) the first of July 2012.

[5] Sensors collect information from the physical world and deliver it to the control system, for interpretation and decision-making. They can be used, for example, to measure temperature, humidity, air speed, CO2 level, etc. Also to measure the state of objects or furniture (door open / closed, bed occupied / empty ...), which allows for the monitoring of people's lifestyle and behavior.

[6] Actuator is a component of a machine that is responsible for moving and controlling a mechanism or system. It is a part of a device or machine that helps it to achieve physical movements by converting energy, often electrical, air, or hydraulic, into mechanical force.

- The next step would be to integrate the communication capabilities of RFID tags, sensors and actuators to configure hybrid wireless networks, characterized by modularity, reliability, flexibility, robustness and scalability. By integrating these technologies in objects, which have now become intelligent, there would no longer be a limit to the actions that they would be able to perform as long as they had their own identity and that they were capable of recognizing the identity of others. That the object is aware of itself and possesses features such as creation, recycling, transformation, change of ownership, and also characteristics for different purposes, will allow the most common things to interact with the surrounding environment actively and decisively. However, to reach such a level of ambient intelligence, important innovations will be necessary, such as the progressive miniaturization of devices, their packaging and integration in different substrates and their ability to create a continuous self supply of energy, conditions that would constitute the third pillar of IoT.
- Another key element would be communication and contextual awareness. For this, the objects must have non-volatile memory, antennas and more efficient and unlimited energy sources. In addition, they will have to be able to integrate different communication standards and protocols operating at different frequencies, and when well-defined global standards are established, also manage to significantly increase the transmission speed. Advances in standardization, interoperability, fully global communication protocols and energy sustainability will be the great Governance challenges in a world of global services.
- The final pillar of IoT, and also the one that was considered the most critical at that time, would be to gain the trust of citizens to prevent them from having the feeling of being watched instead of being cared for. For decision-making purposes citizens must give authorization for their personal information to be treated automatically and indistinctly by people and objects, thus affecting our immediate environment and even our behavior.

According to the DG INFSO and EPoSS, these objectives would be achieved at specific time intervals, starting from the publication date of the report and going on until until beyond 2020, as shown in Table 2.2.

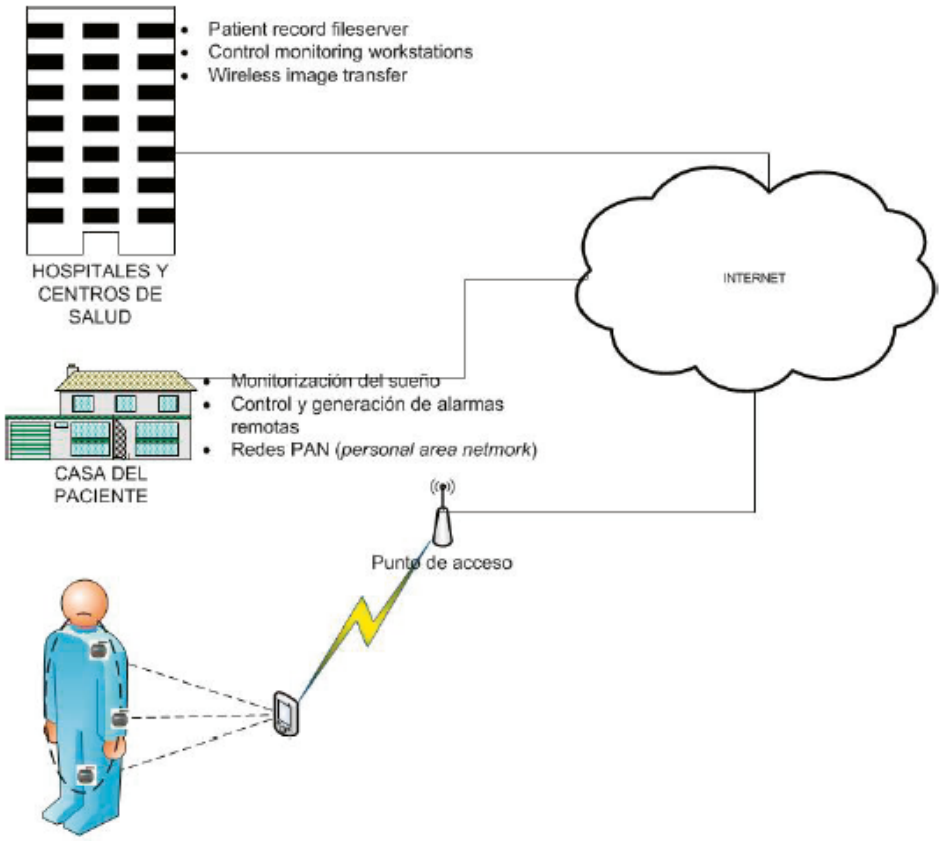
Table 2.2. Extrapolation of technology trends and ongoing research. *DG INFSO & EPoSS. Internet of Things in 2020: a roadmap for the future.* European Commission. Information Society and Media. 2008.

Vision society	• Socially acceptable RFID	• Pervasive RFID	• Interacting objects	• Personalised objects
People	• Realising benefits (food safety, anti counterfeiting, health care) • Consumer concerns (privacy) • Changing ways to work	• Changing business (processes, models, ways to work) • Smart appliances • Ubiquitous readers • Access rights • New retail and Logistics	• Integrated appliances • Smart transportation • Energy & Resource conservation	• Mastered ambient intelligence • Interaction of physical and virtual worlds • Search the physical world (google of things) • Virtual Worlds
Politics & Governance	• De-facto governance • Privacy legislation • Address cultural barriers • Future Internet governance	• EU governance • Frequency spectrum Governance • Sustainable Energy Consumption guidelines	• Authentication, trust and verification • Security, social well-being	• Authentication, trust and verification • Security, social well-being
Standards	• RFID security and Privacy • Radio frequency use	• Sector specific standards	• Interaction Standards	• Behavioural Standards
	Before 2010	**2010-2015**	**2015-2020**	**Beyond 2020**
				
	Before 2010	**2010-2015**	**2015-2020**	**Beyond 2020**
Vision technology Use	• Connecting objects	• Networked objects	• Executable objects /semi-intelligent objects	• Intelligent objects
Use	• RFID adoption in logistics, retail and pharmaceutics.	• Increased interoperability	• Decentralised code execution • Global applications	• Unified network that connects people, things and services • Integrated industries
Devices	• Smaller and cheaper tags, sensors and active systems	• Increasing memory and sensing capacities	• Ultra high speed	• Cheaper materials • New physical effects
Energy	• Low power chipsets • Reduced energy consumption	• Improved energy management • Better batteries	• Renewable energy • Multiple sources	• Elements of energy harvesting

FROM IOT TO IOHEALTHT

For almost a decade, the healthcare sector has considered that the introduction of wireless communication systems would, in general, allow for greater efficiency in personal health (IoHealthT), or, more specifically, in outpatient care (IoMedicalT), irrespective of whether they are inside or outside of their place of residence [21] (Figure 2.4.).

Figure 2.4. Outpatient monitoring scheme (at home and using ubiquitous devices). Source: Innovación tecnológica para la salud y la seguridad electromagnética personal. Ramos, V. Ed. Madrid, Unidad de Investigación en Telemedicina y e-Salud. Instituto de Salud Carlos III 2013, dic.: pg. 23.

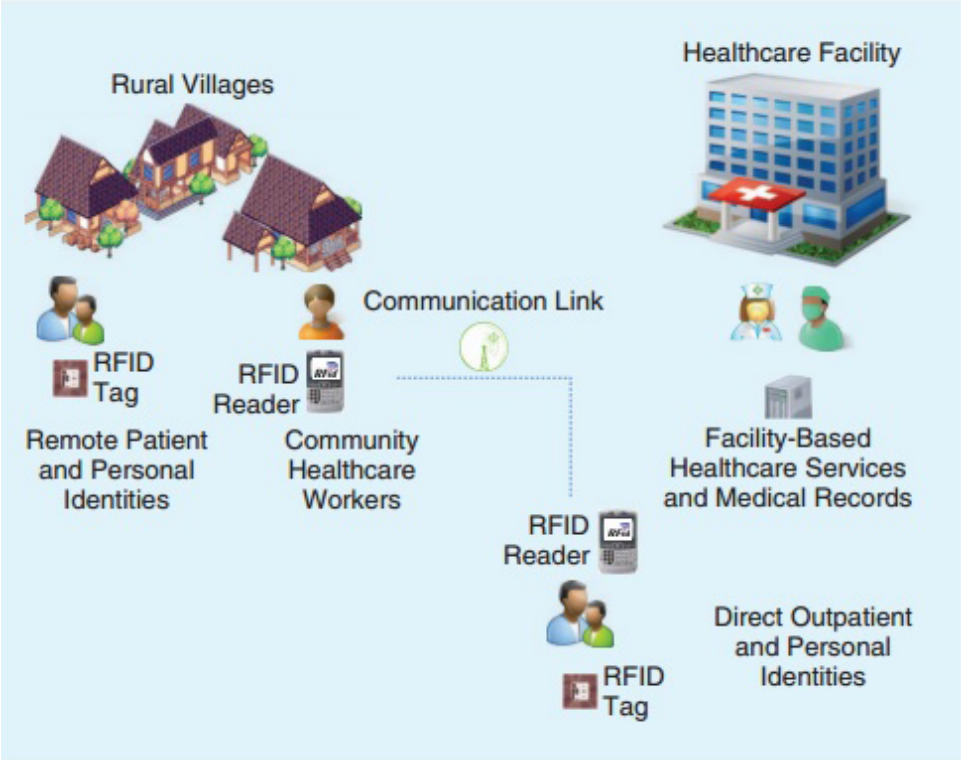


The transition from a more theoretical approach to a truly applied or practical one has been made possible to a large extent, at least in the European Union (EU), thanks to the joint efforts of public administrations and industry, through actions such as the aforementioned Internet of Things in 2020: a roadmap for the future. It is important to mention in this regard other initiatives that member states have carried out individually, such as those carried out and run in our country by the Spanish Technological Platform for Convergence towards the Internet of the Future - es.Internet. Through reports, prepared by members of this platform within the European Future Internet Public and Private Partnership initiative [22], which began in 2010 [23], Internet-based research and development lines are set up for all sectors, including healthcare, and are financed by the European Commission.

Other factors, such as the 2020 global pandemic caused by SARS-COV-2, have consolidated the Internet as a means of supporting medical services or other services intended for health care in general, having devices that permit an Internet connection is essential in this aspect. Among them would be the Radio Frequency Identification, a technology that, as has just been explained, has been central to approaches concerning the Internet of Things.

The goal of having an RFID solution is not only focused on enabling easy and reliable identification and location of individual patients, but also on maintaining more accurate medical records, facilitating better healthcare, and even improving the quality of life of patients who are a long way from a medical facility [24] (Figures 2.5a. and 2.5b.).

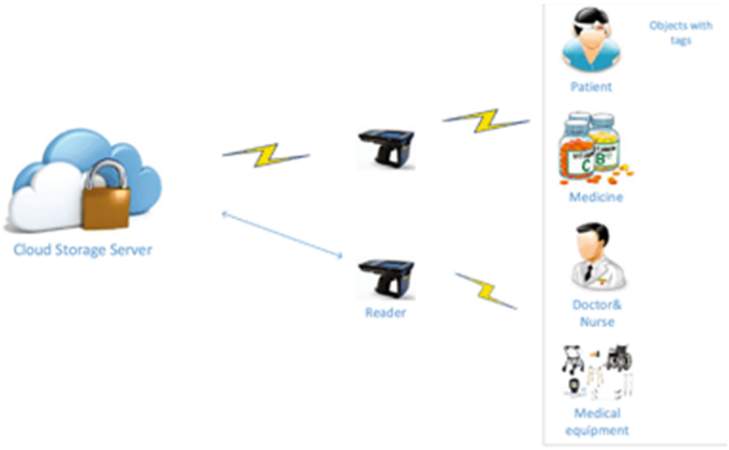
Figure 2.5a. RFID e-health System. Source: Chia S et al., «Intelligent Technologies for Self-Sustaining, RFID-Based, Rural E-Health Systems», IEEE Technology and Society Magazine, pp. 36-43, spring 2013.



Within healthcare environments, RFID systems would be useful for the following functionalities:

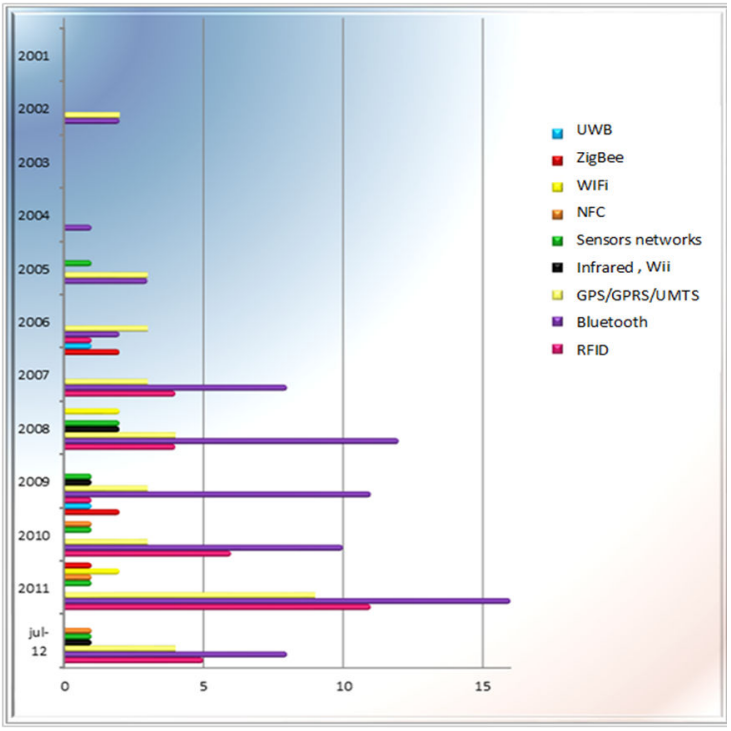
- Identification of patients and material that are necessary for the carrying out of health activities.
- Transfer of collected data from the RFID units to the central server.
- Detection, telemetry and diagnosis.
- Integration with other information infrastructures.

Figure 2.5b. Structure of RFID-based e-healthcare systems.
Source: Wu, F., Xu, L., Kumari, S. et al. «A lightweight and anonymous RFID tag authentication protocol with cloud assistance for e-healthcare applications», J Ambient Intell Human Comput 9, 919-930 (2018).



The purpose of Radio Frequency Identification is to put an emphasis on safety and quality in patient care, pharmaceutical applications and the management of material, supplies and equipment. But as has already been explained, evolution and advancement in the field of wireless communications has led to the development of other types of Short Range Devices - SRDs that could be valid for the same purposes. RFID technology has been coexisting with other SRDs (Figure 2.6.), such as Bluetooth, whose capabilities have attracted even greater interest from researchers [25].

Figure 2.6. Useful technologies for patients, informal caregivers and healthcare professionals in emerging healthcare settings. Source: Marcos, MD., Bardasano, JL. "Los dispositivos de corto alcance para ambientes asistidos de cuidados de la salud" en *Monografía: Innovación tecnológica para la salud y la seguridad electromagnética personal*. Ramos, V. Editor. Unidad de Investigación en Telemedicina y Salud Digital del Instituto de Salud Carlos III, Ministerio de Economía y Competitividad. Madrid. Diciembre 2013, pp. 51-60.



The reality is that RFID has not turned out to be ubiquitous, which seemed an essential condition for the Internet of Things (Table 2.2.), and yet the lines of work focusing on IoT continue.

Other forecasts in the report *Internet of Things in 2020: a roadmap for the future* do seem to have materialized at the predicted rate, such as the ultra-high speed of 5G, considered to be the substrate of IoT in the strictest sense, that in addition to allowing a lot more devices to be connected simultaneously, manages to reduce the latency response to limits below 4 milliseconds, whilst not exceeding 1 or 2 in many cases.

Progress is also being made as planned in terms of standardization, authentication, trust and verification. In this regard, it is worth highlighting the strong commitment that, mainly since 2016, large companies have made to promote electronic payment methods with NFC technology, an extension of RFID, and the massive use that is being made of this technology.

However, it is not possible to ignore the fact that the immediate consequence of creating environments with a technological deployment of such magnitude is the notable increase in electromagnetic emissions - EME around people, which makes it essential to analyze their risks and determine, if necessary, what the most appropriate security measures should be.

The expected benefits of technological advances for health could depend on the acceptable thresholds of human exposure to simultaneous, and in many cases, continuous electromagnetic fields. It is also essential to establish unequivocally the technical conditions that would avoid interference with other devices or systems, mainly electromedical ones. How these critical factors are addressed may depend not only on the degree of SRD penetration in healthcare applications, but also on its acceptance or rejection on the part of healthcare providers, industry professionals and patients.

However, it is worth noting that neither in the ever-increasing news about IoT, nor in the reports from official institutions dedicated to this matter, is there any allusion to the possible direct, or indirect effects, of electromagnetic emissions on personal safety. An exception here are cases where data privacy is compromised, by the malicious use of the data, or by harmful effects deriving from the failure of the devices or the communications.

Electromagnetic emissions have on other occasions raised heated debate, both among researchers and the general public, due to their possible negative effects on health. Given that, it is expedient to ask whether enough evidence already exists on the safety of these emissions to justify the lack of attention by those involved in the development and deployment of IoT.

CHAPTER 3. THE CHALLENGE OF ELECTROMAGNETIC SAFETY

Electromagnetic fields - EMF, static electric fields, static magnetic fields, and time variable electric, magnetic and electromagnetic fields, are those with frequencies up to 300 GHz.

Frequency is one of the main magnitudes that characterize EMFs. It describes the number of oscillations or cycles per second, and the expression wavelength refers to the distance travelled between two successive maxima of the wave. Consequently, wavelength and frequency are inseparably linked: the higher the frequency, the shorter the wavelength.

Electric fields are more intense the shorter the distance to the generator, and their intensity, measured in volts per meter (V/m), decreases rapidly with increasing distance. Electromagnetic fields originate from the movement of electric charges. The intensity of electromagnetic fields is expressed in amperes per meter (A/m), although in research on electromagnetic fields scientists more frequently use another magnitude, the magnetic flux density measured in Tesla (T) or micro Tesla (μT), both of these linked through magnetic permeability. The greater the intensity of the current, the greater the intensity of the magnetic field.

Like electric fields, magnetic fields are most intense at points close to their source and their intensity decreases rapidly as the distance from the source increases. At radio and microwave frequencies, the two components of an electromagnetic wave reflect the power density, measured in watts per square meter (W/m^2).

Time variable magnetic fields produced by electrical appliances are an example of Extremely Low Frequency fields - ELF, with frequencies generally up to 300 Hz. Other technologies produce Intermediate Frequency fields - IF, with frequencies ranging from 300 Hz to 10 MHz, and Radiofrecuency fields - RF, with frequencies going from 10 MHz to 300 GHz.

Non-ionizing electromagnetic radiation has various biological effects on living beings. In an initial classification, two types can be distinguished: thermal and non-thermal, depending on the amount of energy absorbed by the organisms. In this regard, the text by José Luis Bardasano and José Ignacio Elorrieta Biomagnetismo is especially clear. *Biomagnetismo. Ciencia y Salud* [26].

The effects of EMFs will depend on the frequency band. Thus, ELF fields induce electric fields that can cause biological effects such as cell stimulation, modulating or initiating nervous or muscular system activity. In the RF range, when the maximum cellular stimulation is exceeded, the energy absorption of EMFs takes place with the subsequent heating of the tissues. This does not imply that at extremely low frequencies energy absorption and heating are not occurring, but rather that it is negligible compared to the stimulating effects of induced electric fields.

In addition to the biological effects, EMFs can impair the proper functioning of electrical or electronic devices, which could also have repercussions on people's health, some of them harmful. Therefore, it is necessary to consider what would happen in Ambient Assisted Living scenarios or IoT in general, since they involve multiple, simultaneous, and constant electromagnetic emissions coming from all the radiating devices that are required for their configuration.

Given that objects, especially electronic ones, may see their functionality altered when in the proximity of an EMF, the concept of Electromagnetic Compatibility - EMC, becomes especially relevant. EMC occurs when a piece of equipment, or an installation, is capable of satisfactorily operating in an electromagnetic environment without producing interference or electromagnetic disturbances that affect the normal operation of any other apparatus or device that is nearby.

Electromagnetic compatibility can only be achieved in two ways: by restricting or controlling electromagnetic emissions, or by ensuring that electronic systems have sufficient immunity against Electromagnetic Interferences - EMI.

Different institutions work on harmonizing developments in electronic devices, trying to reduce the indirect effects of electromagnetic emissions, for example, the European standardization organizations[7]: the European Telecommunications Standards Institute - ETSI, the European Committee for Standardization - CEN, the European Committee for Electrotechnical Standardization - CENELEC, the International Telecommunication Union - ITU, the International Organization for Standardization - ISO, the International Electrotechnical Commission - ICE and the Spanish Association for Standardization and Certification - AENOR.

Their role is especially relevant when it comes to avoiding or minimizing the personal risks that are derived from radiant technologies, such as those outlined below:

- The degradation in the performance of electronic devices due to electromagnetic interferences - EMI.
- The use of medical devices in the vicinity of radiant technologies whose electromagnetic emissions can cause the devices to malfunction.
- The loss of data stored in microprocessors and the need for intervention by the system operator.
- The increase in the number of homes and health centres located in the vicinity of broadcasting stations and vice versa.
- The lack of knowledge that users have regarding their electromagnetic environment.
- The attribution of the degradation in performance of electronic devices, including those for medical use, to causes other than electromagnetic interferences.
- Isolated interference incidents that may be impossible to record or repeat without an ad hoc study.
- Failure to take responsibility, both by users and manufacturers, in EMI based problems.

[7] Recognized in Regulation (EU) No. 1025/2012 of the European Parliament and Council, of October 25, 2012.

- Failure to apply appropriate design techniques, or lack of compliance with existing legislation and relevant test methods to control emissions and ensure the protection of people and equipment.

Even though there is unanimity in recognizing that it is necessary to avoid or minimize the risks of EME as much as possible, neither in Spain or Europe do the aforementioned organizations have the power to oblige manufacturers to comply with their standardization mandates except in cases where they voluntarily adhere to them, or they are integrated into royal decrees, directives or other legislation. In the United States, however, medical device manufacturers are required to report to the FDA any incident involving their devices that has led to, or contributed to, the death or serious injury of the user.

Currently in Europe electronic equipment is regulated by Directive 2014/53/UE of the European Parliament and of the Council of 16 April 2014, on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment - RED (Radio Equipment Directive) and repealing Directive 1999/5/EC [27]. For its part, the Directive 2014/30/UE, or the European Parliament and of the Council of 26 February 2014 [28] establishes the harmonization of the Member State legislation on electromagnetic compatibility (recast), repealing Directive 2004/108/EC.

Medical devices, in turn, were regulated by specific legislation, initially the Council Directive 93/42/CEE of 14 June 1993, modified by the Directive 2001/104/CE of the European Parliament and of the Council of 7 December 2001. The Council Directive 90/385/CEE of 20 June 1990 deals with active implantable medical devices, however, both were subsequently modified by Directive 2007/47/CE of the European Parliament and of the Council, which also included specific legislation for in vitro diagnostic medical devices and for those incorporating derivatives of human blood or plasma.

As for legislation aimed at avoiding indirect biophysical effects caused, by among other factors, incompatibilities or electromagnetic interference, the focus is on avoiding the direct effect of electromagnetic emissions on people's health.

The direct biophysical effects on the human body that have been recognized so far are:

- Thermal effects, such as the heating of tissues due to the absorption of energy coming from electromagnetic fields.
- Non-thermal effects, such as the stimulation of muscles, nerves or sensory organs that could be detrimental to the physical and mental health of exposed persons. In addition, stimulation of the sensory organs could give rise to transient symptoms, temporary discomfort or affect cognizance or other brain or muscle functions. Therefore, people whose work exposes them to these emissions could see their ability to carry out their activities safely being hampered.
- Currents in the extremities of the body

To avoid all the aforementioned biophysical effects, the need to establish exposure thresholds for electromagnetic emissions is required. At an international level, the International Commission on Non-Ionizing Radiation Protection - ICNIRP, has established the most widespread legislation regarding exposure levels. For its part, the European Parliament in its Resolution on the fight against harmful effects caused by non-ionizing radiation of 5 May 1994, invited the Commission to propose legislative measures to limit the exposure of workers and the general public to electromagnetic radiation in the range between 0 Hz and 300 GHz. These measures were included in the Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz) (1999/519/CE) [29]. Subsequently, Spanish legislation approved the Royal Decree 1066/2001, of September 28 [30], which establishes the conditions for protection in the radio-electric public domain, restrictions on radio emissions and health protection measures against radio emissions.

Basic restrictions have been established considering the variations that individual sensitivities and environmental conditions can produce, as well as the fact that the age and health status of members of the public vary. The Annex II, L 199/64, in the Council Recommendation of 12 July 1999 on the limitation of exposure of the public to electromagnetic fields (0 Hz to 300 GHz) [29], lists the following:

- Between 0 and 1 Hz basic restrictions are provided for magnetic flux density[8] for static magnetic fields (0 Hz) and current density[9] for time-varying fields up to 1 Hz, in order to prevent effects on the cardiovascular and central nervous system.
- Between 1 Hz and 10 MHz basic restrictions are provided for current density to prevent effects on nervous system functions.
- Between 100 kHz and 10 GHz basic restrictions on Specific energy absorption rate - SAR[10], are provided to prevent whole-body heat stress and excessive localised heating of tissues. In the range 100 kHz to 10 MHz, restrictions on both current density and SAR are provided.
- Between 10 GHz and 300 GHz basic restrictions on power density[11] are provided to prevent heating in tissue at or near the body surface.

[8] Magnetic flux density is a vector quantity (B), resulting in a force that acts on moving charges, it is expressed in teslas (T). In free space and in biological materials, magnetic flux density and magnetic field strength can be interchanged using the equivalence 1 A m-1 = 4π 10-7 T.

[9] Current density (J) is defined as the current flowing through a unit cross section perpendicular to its direction in a volume conductor such as the human body or part of it, expressed in amperes per square metre (A/m^2).

[10] Specific energy absorption rate (SAR) averaged over the whole body or over parts of the body, is defined as the rate at which energy is absorbed per unit mass of body tissue and is expressed in watts per kilogram (W/kg). Whole body SAR is a widely accepted measure for relating adverse thermal effects to RF exposure. Besides the whole body average SAR, local SAR values are necessary to evaluate and limit excessive energy deposition in small parts of the body resulting from special exposure conditions. Examples of such conditions are: a grounded individual exposed to RF in the low MHz range and individuals exposed in the near field of an antenna.

[11] Power density (S) is the appropriate quantity used for very high frequencies, where the depth of penetration in the body is low. It is the radiant power incident perpendicular to a surface, divided by the area of the surface and is expressed in watts per square metre (W/m^2).

The Council Recommendation also clarified the objective of the basic restriction on the current density (Annex II, L 199/64, Note 2), as shown in Table 3.1.:

> The basic restriction on the current density is intended to protect against acute exposure effects on central nervous system tissues in the head and trunk of the body and includes a safety factor. The basic restrictions for ELF fields are based on established adverse effects on the central nervous system. Such acute effects are essentially instantaneous and there is no scientific justification to modify the basic restrictions for exposure of short duration. However, since the basic restriction refers to adverse effects on the central nervous system, this basic restriction may permit higher current densities in body tissues other than the central nervous system under the same exposure conditions.

Table 3.1. Basic restrictions. Source: Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz) (1999/519/EC). Annex II, L 199/64.

Frequency Range	Magnetic flux density	Current density (mA/m^2)	Whole body average SAR	Localised SAR (head and trunk)	Localised SAR (limbs)	Power density, S
	(mT)	(rms)	(W/kg)	(W/kg)	(W/kg)	(W/m^2)
0 Hz	40	-	-	-	-	-
> 0-1 Hz	-	8	-	-	-	-
1-4 Hz	-	8/f	-	-	-	-
4-1.000Hz	-	2	-	-	-	-
1.000 Hz-100 kHz	-	f/500	-	-	-	-
100 kHz-10 MHz	-	f/500	0,08	2	4	-
10 MHz-10 GHz	-	-	0,08	2	4	-
10-300 GHz	-	-	-	-	-	10

f: frequency in Hz

and set out how to proceed in cases of localised exposure (Annex III, L199/66):

> In certain situations where the exposure is highly localized, such as with mobile phones and with an individual's head […] there must be a direct assessment as to whether the basic restrictions for localised exposure have been respected.

Subsequently, the Directive 2013/35/UE or the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) [31] was added to legislation relating to the exposure of the general public. This was intended exclusively for the exposure of workers and empowered member states to adopt even more favourable provisions for the protection of this collective. Among its most relevant incorporations it is worth mentioning that it introduces more adequate and proportionate measures to protect workers from all direct and indirect biophysical risks linked to electromagnetic fields, although it maintains in its wording that "this Directive does not address suggested long-term effects of exposure to electromagnetic fields, since there is currently no well-established scientific evidence of a causal relationship".

Three years later, the Directive was transposed into Spanish law by the Royal Decree 299/2016, of July 22, on the protection of the health and safety of workers against the risks related to exposure to electromagnetic fields.

Table 3.2. Summary of legislation with implications for personal safety by EME.

	Current regulations
Harmonisation of the laws of the Member States relating to the making available on the market of radio equipment	Directive 2014/53/UE of the European Parliament and of the Council of 16 April 2014, on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment- RED and Royal Decree 188/2016, of May 6, which approves the Regulation that establishes the requirements for the commercialization, commissioning and use of radio-electric equipment, and regulates the procedures for the evaluation of conformity assessment, market surveillance and the penalty system for telecommunication equipment.
Harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)	Directive 2014/30/UE or the European Parliament and of the Council of 26 February 2014 and Royal Decree 186/2016, of May 6, which regulates the electromagnetic compatibility of electrical and electronic equipment.
Medical devices and approximation of the laws of the Member States relating to active implantable medical devices	Directive 2007/47/CE of the European Parliament and of the Council of 5 September 2007 and Royal Decree 1591/2009, of October 16, which regulates medical devices
Limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)	Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz) (1999/519/CE) and Royal Decree 1066/2001, of September 28, approving the Regulation that establishes conditions for the protection of the radio-electric public domain, restrictions on radio-electric emissions and health protection measures against radio-electric emissions. ICNIRP 1998 VALUES (0 Hz to 300 GHz)
Safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)	Directive 2013/35/UE or the European Parliament and of the Council of 26 June 2013 and Royal Decree 299/2016, of July 22, on the protection of the health and safety of workers against the risks related to exposure to electromagnetic fields ICNIRP 2010 VALUES (1 Hz to 100 kHz)

Despite the existing legislation, there are still doubts that it can sufficiently ensure the correct functioning of equipment, and, above all, the health of people. Currently, intense work is being carried out in order to adapt the ETSI, CEN and CENELEC standards, as well as to regularize processes, so that electrical equipment for residential and industrial applications is covered by the aforementioned RED Directive. It must be taken into account that most of them already incorporate wireless communication modules, which allows them to be considered as radio equipment [12], as referred to in the aforementioned Directive.

[12] Electrical or electronic product that intentionally emits or receives radio waves for radiocommunication or radiodetermination purposes, or the electrical or electronic product that must be completed with an accessory, such as an antenna, to intentionally emit or receive radio waves for radiocommunication or radiodetermination purposes.

ELECTROMAGNETIC RISKS OF ICTS ON HEALTH CARE IN AMBIENT ASSISTED LIVING

The reality in many current households is that, although they cannot even remotely be considered assisted environments, they already have innumerable radiating devices.

The electromagnetic fields - EMFs that we are subjected to come from many different sources. When analysing their potential risks, a distinction is made between the different frequency bands in which the electromagnetic radiation they emit is located: Radiofrequency - RF (100 kHz <f ≤300 GHz), Intermediate Frequency - IF (300 Hz <f ≤ 100 kHz), Extremely Low Frequency - ELF (0 <f ≤ 300 Hz), and finally, Static (0 Hz). Emissions in extremely low frequency ranges are typical of domestic installations, electrical appliances, and power lines. In addition, homes increasingly have appliances that work within the intermediate frequency range, such as the induction hot plates that have become popular in kitchens. But without doubt, most of the emissions to which we are exposed to come from devices that work in the radio frequency range, such as mobile phones, Wi - Fi access points and the Digital Enhanced Cordless Telecommunications - DECT. For their part, smartphones, and other ubiquitous wireless technologies, such as tablets and laptops, have increased the complexity of the exposure to which users are subjected to, and have led to changes in the areas of the body that receive this radiation.

Mention should also be made of environmental emissions, which come mainly from TV and radio antennas, from antennas of private and government telecommunications services, and from mobile communication base stations. But despite the undoubted expansion of these, the greatest increase in electromagnetic fields has occurred indoors, and it can be concluded that, with respect to telecommunications applications, the technological trend, as pointed out by the Scientific Committee on Emerging and Newly Identified Health Risks - SCENIHR, is moving towards the use of low-power radiant devices, which are placed closer to, or even on the human body, and which operate at higher frequencies [32].

Other devices with a specific medical or healthcare use are gradually being added to the aforementioned radiant sources. The concurrent use of these technologies, in addition to causing direct effects on users through EEM, can also influence their functioning and performance due to interference between devices, which in turn, can also lead to risks for people.

Home teleassistance devices such as remote alarms or social alarms, are probably most frequently installed within the homes of the elderly. It should be considered that teleassistance has grown exponentially in all current societies. In just Spain, as of December 31, 2018, 942,446 people had been attended to, which implies a coverage rate[13] of 10,41 of the total number of elderly people [33], [34].

Social alarms consist of two operating units: the buttons, which users wear around the neck or attached to the wrist, and the fixed unit that connects to the home's landline. When the user is in a dangerous situation, he can press the button

[13] Coverage rate: (Users/population ≥ 65 years) × 100

and a radio frequency signal is transmitted to the fixed unit, which then makes an emergency call. The buttons transmit a signal that normally consists of three pulses (depending on the model) at the frequency of 869.21 MHz.

Furthermore, according to the guidelines of the Commission Implementing Decision of 8 December 2011 amending Decision 2006/771 / EC on harmonization of the radio spectrum for use by short-range devices [35], these remote alarm systems could be combined with other technologies that operate on frequencies from 869.2 to 869.25 MHz, such as those designed to detect falls, control wandering, monitor biological parameters, or control environmental risks: smoke detectors, flood alarms, gas leaks, etc.

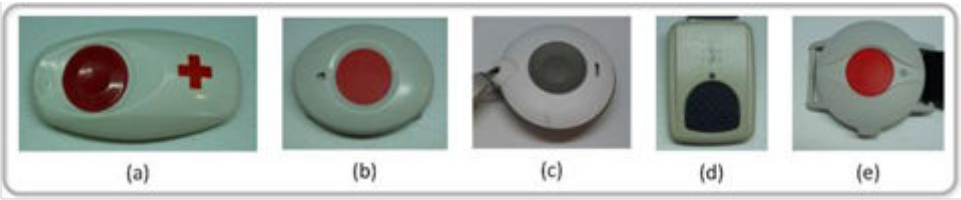
It is important to remember that to control the risks due to direct EMF exposure, the legislation defines the so-called basic restrictions, which, as has already been mentioned, determine restrictions on exposure to electric, magnetic, and electromagnetic fields that vary over time, and which have been established on the basis of known health effects and other biological considerations. Magnetic flux density (B) and Power density (S) can be easily measured in exposed individuals, although in the 2010 ICNIRP guidelines for limiting exposure in the 1 Hz - 100 kHz frequency range, Power density was replaced by a new concept, the intensity of the internal electric field or electric field inside the tissues, which depends on the physical properties of the exposure itself - such as the frequency, the polarization, and the direction of the incidence wave - and also on the anatomy of the exposed person, including height, posture and the Body Mass Index - BMI. In addition, if we consider that the dielectric properties of tissues change according to the water content, age is another influencing factor.

Reference levels are provided for practical exposure assessment purposes in order to determine the likelihood that basic restrictions will be exceeded. Some reference levels are derived from relevant basic restrictions using measurements or computational techniques, and some refer to the perception and indirect adverse effects of EMF exposure. In any given situation where exposure occurs, the measured or calculated values can be compared to the appropriate reference level. Consequently, compliance with the reference level will ensure that the relevant basic restriction is respected.

The progressive advance towards technologically assisted environments, desirable within a commitment to Ambient Assisted Living, entails a greater electromagnetic exposure. As a result, it seems appropriate to verify that these devices will not negatively affect the health and physical safety of users, precisely the same aspects that they intend to safeguard.

Consequently, the authors have carried out laboratory measurements on different social alarm devices (Figure 3.1.), with the aim of obtaining the corresponding radiation pattern that helps to quantify whether exposure levels in the assisted person remain below the recommended reference levels. Likewise, the aim was to analyse the electromagnetic compatibility of these devices with the networks and equipment that operate in the surrounding area, including those used by people with special needs (hearing aid systems, medication dosing pumps and the like) [36].

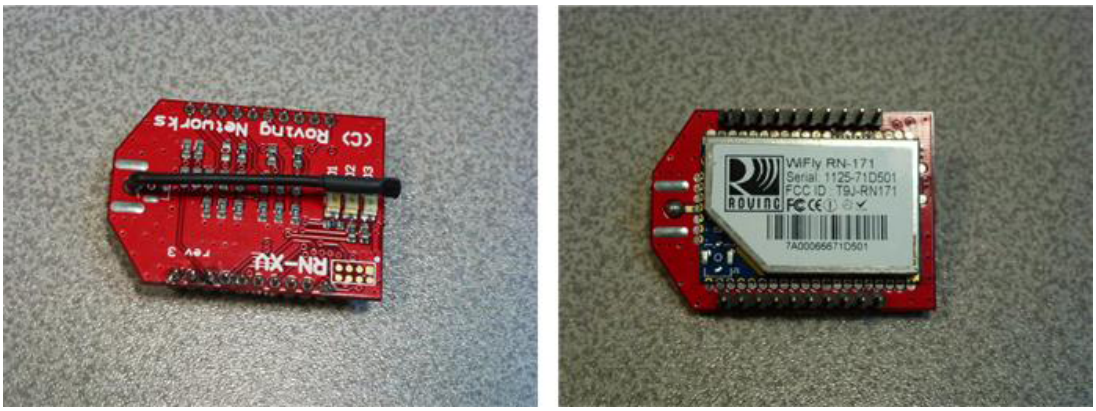
Figure 3.1. Emergency buttons tested: AMIE + Tunstall (a), Neat Atom (b), TX4 Bosch (c), S37 device (d) and Smart Call 5000 system (e).



The results, obtained in the worst operating conditions, showed that social alarm devices are apparently safe, both for users, and for the functioning and performance of other devices. An evaluation of the maximum Equivalent of Effective Isotopically Radiated Power - EIRP was carried out taking the power emitted by the antenna, the antenna gain and the attenuation due to the radiation pattern. From the EIRP, the Electric field strength (E)[14] was obtained, which remained below the ICNIRP-98 reference levels that are established to limit the exposure of the general public to variable electric fields, magnetic fields, and electromagnetic fields up to 300 GHz [37a]. EIRP levels also remained substantially lower than the thresholds that the International Electrotechnical Commission - IEC has set out in its IEC 60601-1-2 correct functioning of electromedical equipment that are not life supporting [38].

Also, it was considered pertinent to evaluate other radiant technologies that could coexist with telecare devices in the configuration of authentic ambient assisted living environments. Given that household appliances with Wi-Fi interfaces are becoming frequently more common, the need to carry out a specific study was raised with the aim of quantifying exposure levels in the vicinity of a Wi-Fi module operating in the 2.4 GHz band, whilst also analysing the compatibility between equipment and networks in different environments. For the study, the Wi - Fi WiFly GSX 802.11 b / g Wireless LAN module was chosen, which works with the 802.11g protocol and whose maximum power is 10 dBm (10 mW) (Figure 3.2.).

Figure 3.2. Wi-Fi WiFly GSX 802.11 b/g Wireless LAN Module used on laboratory tests.



The emissions of the Wi-Fi module were measured within near field conditions to analyse the influence on other electromedical equipment and the possible

[14] Electric field strength is a vector quantity (E) that corresponds to the force exerted on a charged particle regardless of its motion in space. It is expressed in volts per metre (V/m).

overexposure of people in the vicinity, without, at any time, reaching the lower limit of probe sensitivity of 0.05 V/m. It is important to note that the device being tested was continuously transmitting the information.

The Electric field strength values obtained were compared with the thresholds for exposure levels recommended by the ICNIRP - 98, as well as with the thresholds for safety and for the basic operation of electromedical equipment recommended by the IEC 60601-1-2 standard.

However, in near field conditions an Electric field strength (E) of 27.1 V/m was obtained, significantly exceeding the 3 V/m established by the IEC - EN 60601-1-2 standard to ensure the correct operation and performance of electromedical devices.

Finally, all the electric field strengths recorded in this study were well below the ICNIRP reference level of 61 V/m for the general public at 2.4 GHz working frequencies. This means that the technology evaluated is apparently safe for people, whether it is used at home, or in working environments including healthcare, but the electromagnetic immunity of electromedical devices could be compromised on certain occasions [39]

THE INTERNET OF THINGS PERSPECTIVE

As already mentioned, the 2008 report by DG INFSO and EPoSS, *Internet of Things in 2020: a roadmap for the future*, did not at any time mention electromagnetic emissions and their possible direct or indirect effects on the safety of people. But no reference to the risks or concerns that EMEs may raise has been found in subsequent official IoT-focused reports, either. This is the case of *Internet of Things - From Research and Innovation to Market Deployment*, published in 2014, which describes the commercial exploitation of many of the IoT research and innovation lines that had been developed up to that moment, as well as its proposals for future [40]. Another was the first joint text on the Internet of Things approved by the European authorities on September 16, 2014, specifically the *Opinion 8/2014 on Recent Developments on the Internet of Things* [41], which raises scenarios with a maximum exposure of users to electromagnetic emissions - wearables, biometrics and domotics - although few refer to these electromagnetic scenarios [42] and the majority focus exclusively on how the devices or users themselves can lead to vulnerabilities , such as the loss of the device , malware, unauthorized access to personal data, intrusive use of portable devices or illegal surveillance. Since then, the European Commission has continued to promote and finance lines of research on IoT, mainly for the development of the so-called *Digital Single Market*, with new documents and standards [43] that focus on this technological challenge, but, again, without referring to electromagnetic emissions.

However, all of these reports already included definitions of IoT that showed what the magnitude and scope of electromagnetic radiation would be in the very near future. For example, the one provided by the International Telecommunication Union - ITU [44], a specialized United Nations agency in Information and Communication Technologies, and which illustrates the evolution of the Internet of Things towards the Internet of Everything: "global infrastructure for the information society, which allows advanced services through the interconnection of physical and virtual things on the basis of already existing ones, with the participation of interoperable information and communication technologies" [40].

For its part, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), continues to work on providing the European Commission with any scientific evidence that may contribute to an evaluation of the risks that electromagnetic fields may pose to human health. The purpose is to keep its Opinions updated, the last one in January 2015 [32], with new available information, paying special attention to any knowledge gaps in previous Opinions.

It is important to note that the Committee recognizes that only a few studies exist that have evaluated the combined effect of electromagnetic fields, an aspect that, as has been argued, is a characteristic of ambient assisted environments, and above all, of the Internet of Things.

There are implicit drawbacks in this type of study, the SCENIHR itself has recognized that there are limitations and practical difficulties common to all lines of scientific research related to the possible effects of EMFs on biological activity and health. These limitations often result in inadequate data, or data that cannot be used to carry out a correct risk evaluation, as a result of this, the SCENIHR insists on recommending that research be strengthened in various areas, albeit categorizing them under different priority levels (Table 3.3.).

Table 3.3. Summary of recommendations organised by EMF, starting with static fields and rising through the spectrum to THz fields. Source: *Potential health effects of exposure to electromagnetic fields (EMF)*. SCENIHR 2015.

		Research recommendations	Priority
Static fields including MRI exposure	R1	Collecting data from representative population based samples on thresholds for perception, annoyance, and other effects, especially in the presence of varying ion concentrations in the air.	High
	R2	Long-term prospective or retrospective cohort studies on workers that are exposed to high stray fields from the construction or operation of MRI devices.	High
	R3	A cohort study into the effects of MRI exposure on children.	High
	R4	Genotoxic effects following MRI investigations in either patients or volunteers.	Medium
	R5	Cognitive effects of exposure to magnetic gradient fields in humans and animals.	Medium
	R6	Mechanistic studies with static magnetic fields that address basic neurophysiological effects on neurons.	Low
	R7	Exploring effects of exposure at 3 T and above on the cardiovascular system in animals.	Low
	R8	Exploring effects of exposure at 3 T and above on the cardiovascular system in humans (volunteers).	Low
	R9	Studies on gene expression and epigenetic studies.	Medium

		Research recommendations	Priority
Extremely low frequency - ELF	R10	Epidemiological studies using recently-developed mouse models of acute lymphoblastic leukaemia.	High
	R11	Possibility of strain-specific increases in sensitivity to magnetic fields.	Medium
	R12	A cohort or register-based case control study on magnetic field exposure Alzheimer's disease incidence or mortality.	High
	R13	Laboratory studies to gain insight into possible mechanisms, and studies using validated models of Alzheimer's disease.	High
	R14	Association between maternal magnetic field exposure during pregnancy and asthma and childhood obesity in offspring.	Medium
	R15	Reactions to ELF fields using best practice methods, including the prior registration of a protocol.	High
Intermediate frecuency - IF	R16	Risks on pregnancy outcome from antitheft devices in shops provided reasonably-sized occupational groups.	High
	R17	Biomarkers of exposure, provided appropriate control groups and using a wider range of exposures.	Medium
Radiofrecuency - RF	R18	A prospective cohort study in adults investigating long-term effects of RF fields associated with use of mobile phones.	High
	R19	Effects of RF fields associated with mobile phone use and brain tumours in children.	High
	R20	DNA migration, spindle disturbance and foci formation following RF exposure.	Medium
	R21	Effects of mobile use on development, cognitive function and behaviour in children.	Medium
	R22	Effects of RF exposure on sleep and sleep EEG power in elderly and children and adolescent subjects.	Medium-High
	R23	Effects of RF exposure on on waking EEG in elderly and children and adolescent subjects.	Medium-High
	R24	Effects of RF exposure on cognition in elderly and children and adolescent subjects.	Medium
	R25	Neurophysiological studies (preferably multicentre) in volunteers with pre-defined effect sizes, based on a priori considerations of power and sample size and covering a wide range of ages, look at data for females and males separately and, if possible, include patient populations, e.g. insomniacs in sleep studies or patients with neurological disorders including neurodegenerative diseases.	High
	R26	Research on symptoms attributed to RF fields.	Low
	R27	Cohort studies to evaluate RF fields impact on male fertility only if the study design can overcome potential confounding and recall bias regarding phone use and the study has appropriate exposure assessment, and an animal study investigating effects on reactive oxygen species activity in field-exposed sperm provided the study has sufficient power to	Low
THz technologies	R28	Experimental research related to possible adverse effects on the skin and the cornea.	High
	R29	Monitoring of occupationally-exposed groups for skin and eye changes and disorders.	Medium
Combined exposures to EMF	R30	Laboratory studies investigating effects of combined exposures on genotoxicity, cancer, development and neurobehaviour.	Medium

		Research recommendations	Priority
Co-exposure with other agents	R31	Animal studies to clarify the role of coexposure to magnetic fields as a co-carcinogen.	Medium
	R32	Animal studies to apparent protective effects of RF fields against the ionizing radiation.	Medium
	R33	In vitro research to clarify the relevance of combined exposures to human carcinogenicity under real life conditions and to explore the potentially beneficial (protective) effects of such exposures on humans.	Medium
Exposure assessment	R34	Quantitative investigation of the interaction of electromagnetic fields at the microscopic level, i.e. at cellular or subcellular levels since it may result in the elucidation of underlying biophysical mechanisms that are still missing,	Medium
	R35	Dielectric spectroscopy measurements of - preferably - human tissues from subjects of different ages, gender or physiological conditions.	High
	R36	Researching in the manufacturing of new affordable instrumentation or the improvement of existing specialized exposure meters to be used in prospective epidemiological studies.	Medium
	R37	New methodologies in collecting exposure data at a personal or an environmental level with the use of simple everyday equipment, like mobile electronic devices, and techniques like crowd-sensing.	Medium

Of the recommendations given by the Committee, it is worth highlighting the one that refers to studies that evaluate the effects of exposure to combined electromagnetic fields, as well as the development of simple equipment that can be used on a daily basis. This equipment includes mobile devices and crowdsensing[15] techniques that are used for data collection purposes regarding human exposure, or exposure levels in the environment.

It can be concluded that, with the exception of what is cited in the previous paragraph, the specific Internet of Things working groups do not seem to consider aspects related to the effect of electromagnetic emissions on health.

Furthermore, legislation aimed at analysing and counteracting EME risks for the general public seem very outdated, considering that the last European Directive in this regard is from 1999. However, it is important to note that the International Commission on Non-Ionizing Radiation Protection - ICNIRP published in May 2020 the guidelines for limiting exposure to electromagnetic fields (100 kHz to 300 GHz) [37b]. This range already covers all the predicted frequencies of 5G, but, as of the date of publication of this paper, this has not been reflected in EU legislation.

[15] Measurement and collection of data through different kinds of sensing devices (e.g., smartphones) by a large mass of users.

CHAPTER 4. ICTs IN HEALTH CARE AND IN THE PREVENTION OF MEDICATION ERRORS: IoT CONTRIBUTIONS

Internet of Things is advancing and with this it is possible to provide uninterrupted and personalized health services to the needs of the patient wherever they are, although it remains to be seen whether IoT or, more specifically, IoHealthT or IoMedicalT, will lead to the prevention of medication errors.

So far, the most widely used indicator to illustrate the level of development of the Internet of Things has been the number of objects connected to the Internet. When we use the Internet for any activity, be it email, web browsing, downloading files, or any other service or application, communication between the different elements of the Internet and our own computer or telephone uses a protocol that we call Internet Protocol - IP.

Ever since the Internet has had a commercial use, the version of this protocol is 4 (IPv4), allowing for only 232 addresses (addresses with a length of 32 bits, that is, 4,294,967,296 addresses) it has proved to be insufficient to support the massive growth of simultaneously connected devices that IoT implies.

For this reason, and anticipating the lack of IP addresses, the body in charge of Internet protocol standardization, the Internet Engineering Task Force - IETF, designed a new version of Internet Protocol, specifically IPv6, which assigns addresses that are 128 bits in length, providing 2^{128} possible addresses, or, to put it another way, a total of 340 sextillion.

The deployment of IPv6 is being done gradually, in an orderly coexistence with IPv4, which it is displacing as client devices, network equipment, applications, content and services adapt to the new version of the Internet protocol. Henceforth, the IPv6 protocol will allow all objects to be instantly identified by means of a unique and unequivocal code, something that could not be done with the previous IPv4.

But the fact that the connections between objects are increasing exponentially makes it impossible, in the opinion of the authors, to predict the potential impact of this technological deployment on the safe administration of medication. Consequently, in order to know where the interests of researchers in IoT were focused, it was considered necessary to go to the scientific literature and find commercial devices or systems whose purpose was to prevent medication errors.

LITERATURE REVIEWS

Figures 4.1. and 4.2., show the results obtained in two reviews carried out by the authors on works indexed in different databases of scientific publications, until July 2012 [25] and until February 2016 [47] respectively. The authors used as search criteria the radiant technologies considered proper or essential for the Internet of Things, such as Radio Frequency Identification - RFID, and the already referenced remaining Short-Range Devices - SRD. Subsequently, and depending on its purpose, each study was classified into one of the following categories:

- Assessment of technologies.
- EM Compatibility.
- EM Effects on the biological tissue.
- EM Health Risks.
- Monitored Environments.
- Ambient Assisted Living.

Figure 4.1. Papers related to SRD technologies organised in thematic categories. From January 1, 2001 to July 25, 2012 (n 275) and from July 1, 2012 to February 23, 2016 (n 204).

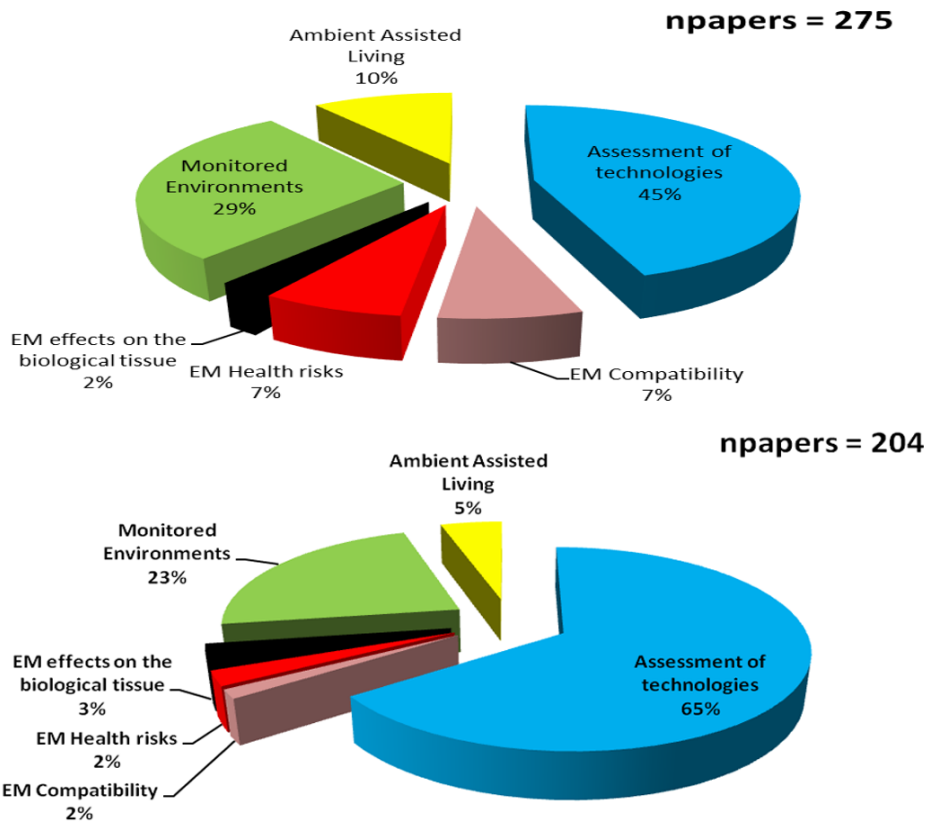
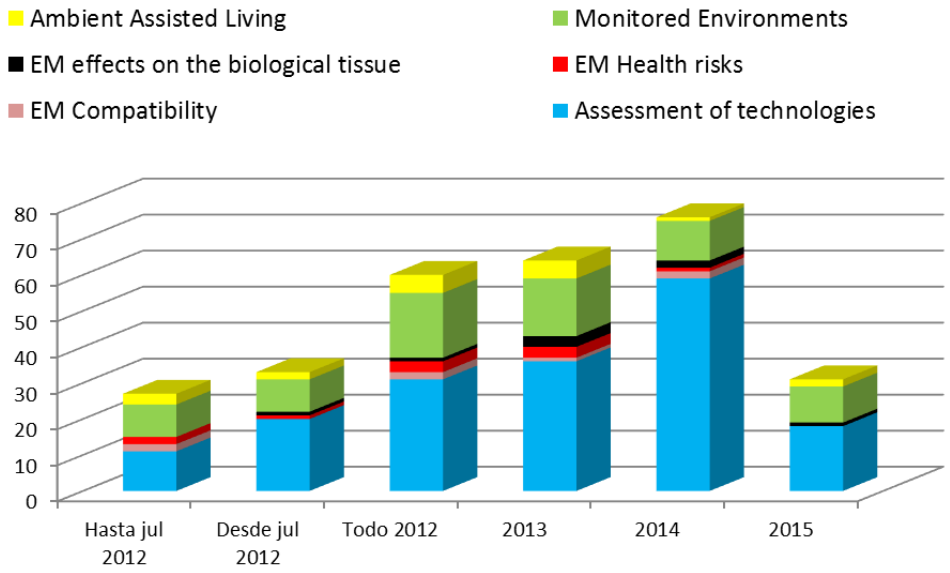


Figure 4.2. Subject matter of the papers by years, from July 1, 2012 to February 23, 2016 (n 204).



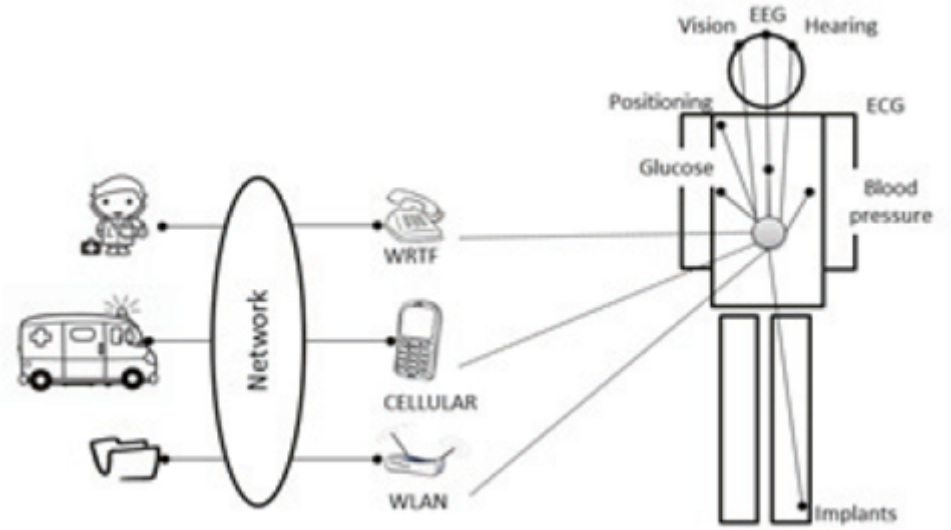
In the first review, most of the published works were prospective pilot projects that did not seem to have any immediate application in real settings, a conclusion supported by other reviews [45].

However, the second review showed that the number of publications related to IoT was significantly higher than the first, despite the fact that the time interval considered was much shorter (three years compared to practically twelve).

In the reviewed time period, an expansion of mobile Health or mHealth could already be noted, using on many occasions a Wireless Body Area Network or WBAN, with the ability to transmit, quickly and accurately, biometric, or behavioural data of users to other objects or people, thus allowing for remote health monitoring (Figure 4.3.). These networks, in combination with intelligent objects capable of interaction with other objects or people, would allow the creation of ubiquitous assisted environments that are no longer limited to a specific and static physical space, but capable of accompanying the patient wherever they are [46].

However, the risks that radiant technologies can entail for people, by direct exposure or by compromising the operation of other electronic devices or systems, were scarcely mentioned. This was despite the massive use of devices that were permanently connected to data transmission networks, and that in many cases, worked in close proximity to the body thanks to their progressive miniaturization. The publications dealt mainly with the evaluation and improvement of technology, to the detriment of areas more related to environmental and biological safety, whilst the concerns regarding personal safety focused on the protection of stored data, and the integrity and non-repudiation of the transmission.

Figure 4.3. Ubiquitous health monitoring: Body Area Network (BAN), wireless sensor nodes, biomedical signal monitoring and remote healthcare (WRTF: wired telephony service). Source: Marcos MD, Bardasano JL. Short-range devices for assisted health care settings 2013.



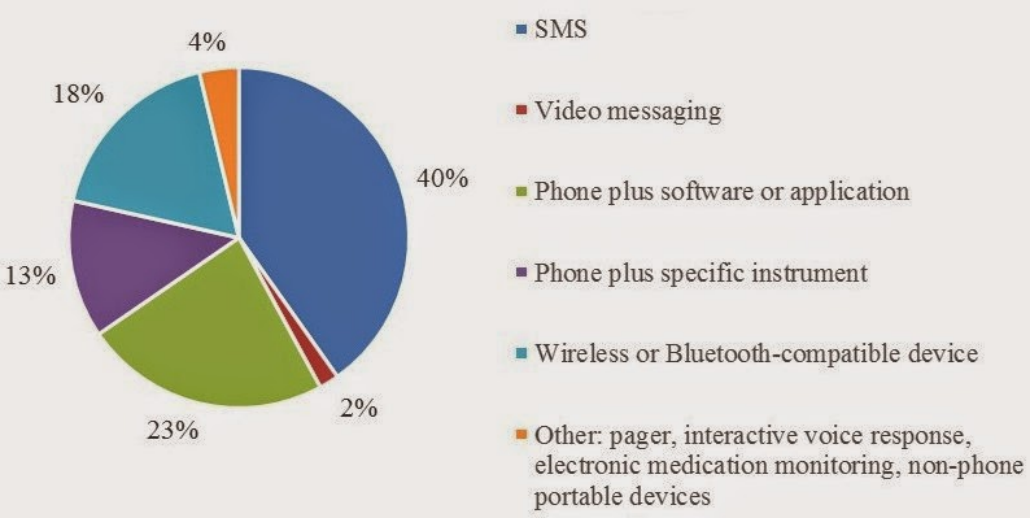
Regarding the prevention of medication errors, the authors found and classified a greater number of publications [47] with a focus on ICTs:

- The setting up of ambient assisted living - AAL to avoid medication errors during administration that can be attributed to the patient or informal caregiver, such as missing a dose or taking an inappropriate dose. Mobile phones were included as AAL, but only when they provoke, either in other objects or in people, a programmed reaction, for example, causing other devices to act after something is forgotten, or there is some kind of omission, such as starting the monitoring of physical parameters, or informing third parties to register an incident or make a reminder call. Phones that only inform or notify the user have not been considered as AAL.
  - Technological improvements, such as those related to the verification of communication protocols, to achieve greater integrity of the information, to favour usability, etc.
  - Environmental or personal safety studies on the effects of exposure to electromagnetic fields.
  - User satisfaction studies regarding the use of technology.
  - Studies on the adherence and compliance with treatments that facilitate the development of more effective technologies in order to achieve their intended purpose, for example, social or emotional considerations such as the importance of social support.

It has been observed that there were already numerous mHealth systems contributing to the correct administration of drugs, in particular for the self-management of medication, but these were often found to be complex for the user and not too effective, coinciding with other rigorous reviews that were carried out by different authors, including those published in the *Cochrane Database Syst Rev* by Nieuwlaat Ren et al in 2007 and 2014 [48]. The consequence is that these technological solutions would not contribute to realizing the expected benefits of the prescribed treatment, at least in chronic pathologies that require lifelong treatments, and which are currently one of the main causes of disability and death worldwide. The authors concluded that research in this field needs, among other aspects, to improve the design of long-term interventions and to have objective and real adherence measures.

Along the same lines was the systematic review carried out in 2015 by Saee Hamine et al., on publications indexed from 1984 to 2014 in the PubMed, Embase and EBSCO databases [49], and in which, whilst recognizing the potential benefits of these technologies, it was pointed out that neither their implementation nor successful adherence had been sufficiently established (Figure 4.4.).

Figure 4.4. Types of mobile tools used in mAdherence. Source: Hamine, S. et al. Impact of mHealth Chronic Disease Management on Treatment Adherence and Patient Outcomes: A Systematic Review. Ed. Gunther Eysenbach. *Journal of Medical Internet Research* 2015; 17.2: e52.



However, based on the reviewed literature, it has been possible to identify some good practices that could contribute to improving the effectiveness of future developments:

- There seems to be enough evidence to suggest that technologies that incorporate some form of warning system, regardless of its complexity, (lights, sounds, text messages ...) avoid involuntary forgetfulness and therefore contribute to the completion of treatment. They are also useful for all types of pathologies and groups, irrespective of their socioeconomic status, age, or cognitive disabilities (psychiatric disorders, alcohol use, etc.).

- It has also been shown that text messages are one of the most used and valued resources because of their universality, user friendliness and low

cost, and that they can be automated, personalized, and easily integrated into existing health systems, even in developing countries. In addition, they provide social reinforcement for the patient, an element that also seems key to improving adherence in chronic treatments [50].

- It is worth noting that the current limitation on text messages lies in the fact that they are subject to the telephone provider, and also to the commitment and bond established between the patient and the healthcare professional, especially in maintaining an ongoing fluid and continuous communication. Consequently, the possibility that messages can be generated and interpreted automatically by a computer system would undoubtedly represent a great advance, as has already been suggested by some authors [51].
- Training the patient to understand their illness also seems to contribute favourably to medication monitoring. Consequently, the technological innovations that could prove to be most beneficial for correct medication monitoring could be those that consider patient perceptions regarding their disease and the burden that it implies for them, as well as their beliefs about the medication, aspects which together play a significant role in predicting adherence [52].

Also, omissions or shortcomings have also been detected that, if corrected, could positively contribute to the development of efficient ICTs for the prevention of adverse drug events.

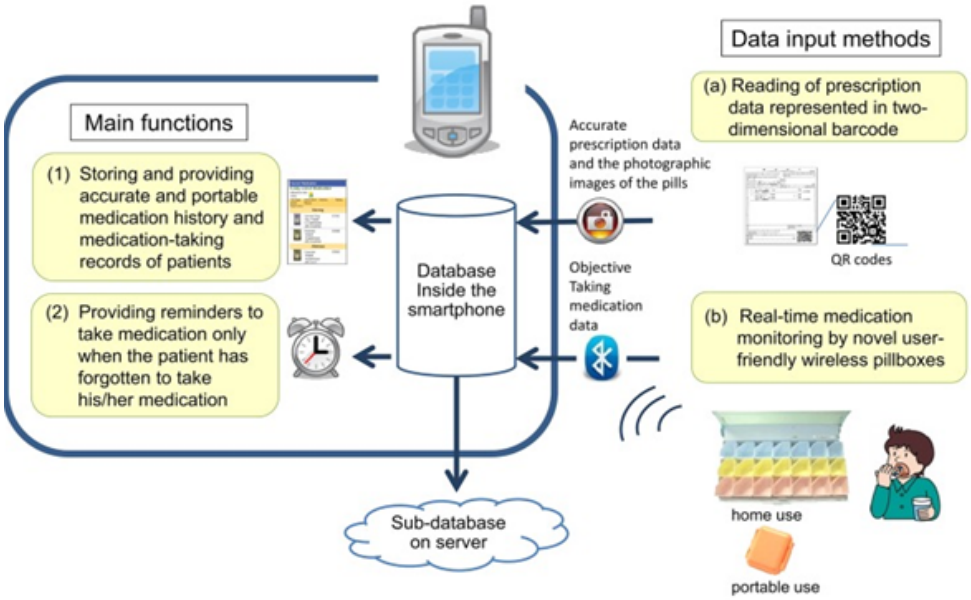
- A large body of research focuses on avoiding only certain types of medication errors, assuming perhaps that they are the most common, such as errors in the frequency of administration of the medication or use of the incorrect drug. As a solution, and interesting for future developments, automating the prescription registration process is proposed, for example, through Quick Response Codes- QR (Figure 4.5.), and making the mobile system itself responsible for telling the user which drug take, and when to take it.
  In addition, the system should have the ability to automatically record medication intake and inform, in real time, the healthcare professional (Figure 4.6.), thereby avoiding the patient reporting verbally on adherence , something which is often found to be inaccurate.
- It seems to be normal to commercialize devices without any guarantee of their usefulness or long-term use. As a consequence, in order to estimate interest in the technology and its possible future use, it would be essential to evaluate user satisfaction, but there are very few studies that explicitly deal with this issue.
- It should also be noted that there are few works aimed at developing new systems that have offered potential users the possibility of expressing their needs and preferences before their commercial use. This participation during the design and development phase also seems key to achieving the continued use of the technology.

Including the participation of potential users is not only desirable but essential, for example, when they present some kind of physical disability. In patients with visual impairments the risk of taking the wrong drug is high, however, the images or written text that are used with patients without vision problems are not sufficient to avoid these mistakes, and other methods of communication with devices must be implemented for these users.

- Finally, with regard to personal safety, allusions to the risks derived from EMF are practically non-existent, whether dealing with incompatibility between devices, incorrect use by users or simply due to the electromagnetic emissions themselves, even when the device is being used correctly.

Figure 4.5. Scanning a QR code on pharmaceutical packaging with smartphone. Source: DIARIOFARMA. https://www.diariofarma.com/2015/11/12/la-aemps-regula-el-uso-de-codigos-qr-para-informar-al-paciente.

Figure 4.6. Architecture of the smartphone-based medication self-management system (SMSS). Source: Hayakawa M et al., "A smartphone-based medication self-management system with realtime medication monitoring". *Appl Clin Inform*. 2013 Jan 30; 4(1):37-52.



FEATURES OF COMMERCIALIZED SYSTEMS FOR THE PREVENTION OF MEDICATION ERRORS

In addition to mobile applications or apps, which will be specifically referred to, there are many devices or systems on the market that use ICTs to monitor and control illnesses and diseases. Among their objectives, to favour independent living for the elderly and outpatients, reduce the readmission of chronic patients and allow remote monitoring of healthcare in general, including, of course, adequate compliance with pharmacological treatments. Many have been financed through publicly funded research programs and are sometimes certified by government health agencies or bodies. The most notable features are listed below:

- Monitoring activity patterns (eating, possible falls, sleep walking, excessive time in bed or in the bathroom, etc.), by using sensors in the home itself.
- Real-time clinical consultation via videoconference (Figure 4.7.).

Figure 4.7. InTouch Health virtual care platforms.

- Social interaction, with family, friends and / or caregivers, through telepresence (Figure 4.8).

Figure 4.8. Giraffe video conferencing robot.

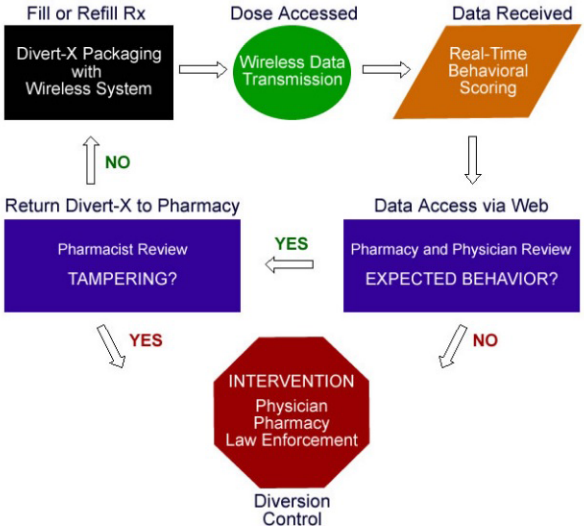
- Monitoring and recording of health data, both objective data that is provided by other devices, such as scales, oximeters, blood pressure monitors or medication dispensers, as well as subjective data that comes from the patient's responses to health questionnaires.
- Comprehensive management of health and social interaction, with reminders of dates, tasks or medication, photos, audio and video storage, possibility of exchanging text messages in real time - chat, and remote alarm systems.
- Home monitoring of adherence with the medication via alerts on the taking, dosage and control of the drug itself, as well as stock management, and the possibility of notifying third parties to give information on the medication taken (voice calls, messages, or emails) (Figures 4.9. y 4.10.).

Figure 4.9. Philips Automated Medication Dispensing Service.

Figure 4.10. Med Minder pill dispenser.

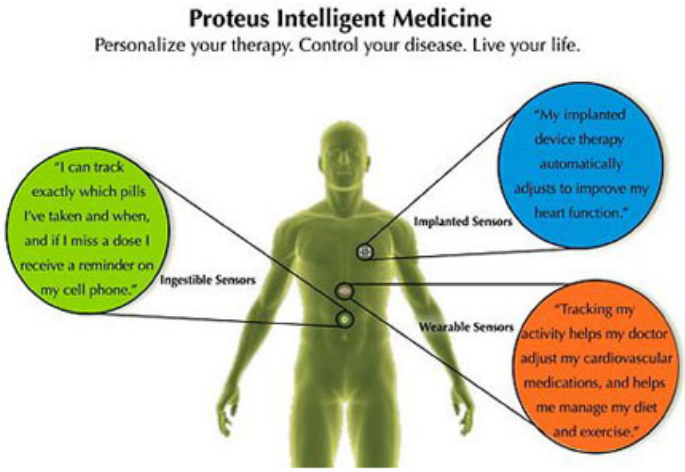
- Adherence monitoring through the pharmacy, via containers that store prescription data and have a GPS locator installed, to avoid trafficking and / or substance abuse (Figure 4.11.).

Figure 4.11. Divert-X functioning scheme.



- Ubiquitous monitoring of medication and other health guidelines (meals, physical activity goals, etc.) through wearables. The device shows the patient previously recorded data, although in some cases they have the ability to obtain biometric data, for example, blood glucose levels. The patient is then able to adjust food intake, exercise and medication recommendations based on these values.
- Ubiquitous medication tracking through Ingestible Event Monitors - IEM that communicate with a sensor attached to a smartphone when the medication is in the patient's digestive system. This sensor records the date, time and other biometric data that is transmitted to the doctor via the Smartphone (Figure 4.12.).

Figure 4.12. IEM functioning scheme.



An exponential growth has been seen in apps aimed at the therapeutic administration of drugs, as they are considered a valuable tool in improving adherence and avoiding medication errors. For this reason, initiatives such as the one carried out by the Andalusian Agency for Healthcare Quality, which has been working for several years in the field of regulation and app evaluation through its *Safety and Quality Strategy in Mobile Health Apps* [53], are especially relevant. This initiative is both a national and international pioneer in the Spanish language and was developed to regulate the market in mobile health applications, enhancing their benefits, driving their improvement, and minimizing the risks derived from incorrect use. They have created the AppSaludable Quality Seal, the first seal in Spanish that recognizes the quality and safety of health apps. This seal is based on the 31 recommendations published in the Recommendations *Guide on design, use and assessment of mobile health apps* [54], launched in 2012, and which is structured into four sections:

- DESIGN AND APPROPRIATENESS
- PROVISION OF SERVICES
- QUALITY AND SAFETY OF INFORMATION
- CONFIDENTIALITY AND PRIVACY

Its list of recommendations is very complete (Table 4.1.), among which those related to patient safety stand out, requiring developers to use a proven methodology to identify the possible risks derived from the use of the app, as well as the need to offer an incident or near-incident notification system, in addition to taking responsibility for adopting the appropriate corrective measures.

Also noteworthy are the observations on the suitability and usability of the app when considering its intended audience. Special emphasis being given on the need for testing, prior to release, by representative users of the intended group, and in addition, that any detected problems have been corrected.

Table 4.1. Recommendation Guide on design, use and assessment of mobile health apps. 2012. Source: The Andalusian Agency for Healthcare Quality.

DESIGN AND APPROPRIATENESS
Appropriateness
Recommendation 1. The health App clearly defines its functional reach and its purpose, identifying the target groups of information and the aims pursued regarding these groups.
Accessibility
Recommendation 2. The health App follows the Principles of Universal Design, as well as reference accessibility standards and recommendations.
Design
Recommendation 3. The health App follows the recommendations, patterns and directives included in the official manuals of the different platforms.
Usability/Testing
Recommendation 4. The health App has been tested by potential users before its availability to the public.

QUALITY AND SAFETY OF INFORMATION

Suitability for the Audience

Recommendation 5. The health App adapts itself to its target audience.

Transparency

Recommendation 6. The health App offers transparent information about its owners' identity and location.

Recommendation 7. The health App offers information about its funding sources, promotion and sponsorship, as well as about possible conflicts of interests.

Authorship

Recommendation 8. The health App identifies the authors of its content and their professional qualification.

Information Update/Revisions

Recommendation 9. The health App includes the date of the last revision made in the published material.

Recommendation 10. The health App warns of those updates which modify or influence the functioning of health-related content, as well as other sensitive data.

Content and Information Sources

Recommendation 11. The health App is based on one or more reliable information sources, and takes into account the available scientific evidence.

Recommendation 12. The health App offers concise information about the procedure used in order to select its content.

Recommendation 13. health App is based on ethical principles and values.

Risk Management

Recommendation 14. The possible risks for patient safety caused by the use of the health App are identified.

Recommendation 15. The known risks and adverse events (near misses) are analysed, and the convenient actions start to be developed.

PROVISION OF SERVICES

Technical Support/Inquiries

Recommendation 16. The health App has a support system about its use.

Recommendation 17. The health App offers a contact mechanism for technical support with an assured and fixed response time.

E-Commerce

Recommendation 18. The health App informs about the terms and conditions on its products and services' commercialisation.

Bandwidth

Recommendation 19. The health App makes an efficient use of communications bandwidth.

Advertisement

Recommendation 20. The health App warns of the use of advertisement mechanisms and allows deactivating or skipping it.

CONFIDENTIALITY AND PRIVACY

Privacy and Data Protection

Recommendation 21. Before downloading and installing, the health App informs about the kind of user's data to be collected and the reason, about the access policies and data treatment, and about possible commercial agreements with third parties.

Recommendation 22. The health App clearly describes the terms and conditions about recorded personal data.

Recommendation 23. The functioning of the health App preserves privacy in the recorded information, collects express consents granted by users, and warns of risks coming from the use of online mobile health Apps.

Recommendation 24. The health App ensures pertinent security measures when users' health information or sensitive data has to be collected or exchanged.

Recommendation 25. The health App informs the users when it has access to other resources of the device, to users' accounts and to profiles in social networks.

Recommendation 26. The health App ensures the right of access to recorded information and the updates regarding changes in its privacy policy.

Recommendation 27. The health App has measures regarding minors' protection in accordance with the current legislation.

Logical Security

Recommendation 28. The health App neither presents no sort of known susceptibility nor any type of malicious code.

Recommendation 29. The health App describes the security procedures established in order to avoid unauthorised access to personal data collected, as well as to limit the access by third parties.

Recommendation 30. The health App has encryption mechanisms for the storage and exchange of information, as well as mechanisms for passwords management.

Recommendation 31. When the health App uses services from the Cloud (cloud computing), the terms and conditions of those services are declared, and the pertinent security measures are ensured.

Another initiative to highlight in the regulation of apps is the one carried out by the FDA in the United States, with the *Mobile Medical Applications. Guidance for Industry and Food and Drug Administration Staff* originally published in 2013 and updated in 2019 [55].

However, this guide focuses mainly on regulating computer programs that allow smartphones, tablets, and PCs, with or without a wireless connection, to behave as regulated medical devices, or to be used as an accessory to these, in the diagnosis, prevention, monitoring and treatment of diseases.

Regarding the apps created to help pharmacological adherence, although they are also considered medical devices, the FDA proposes a different degree of control for them, as they consider that the risks to patient health are less when the apps don't work correctly.

It can be concluded, based on the revised technological solutions - that irrespective of whether they are devices and systems, or programs to install on mobile phones, tablets, and laptops - the apps to a large extent try to avoid the typical errors made by the patients themselves in the administration of drugs, these include forgetting to take of one or more doses, taking the wrong dose, or confusion between different medications. But it has been found that in the monitoring of pharmacological therapies the support of family, Friends, or other patients is another increasingly popular factor. The technology itself is the one that reports omissions as soon as they occur so that they can be corrected as soon as possible, or periodically sends reports on adherence. There is also a growing trend to involve pharmacies, nurses, and the doctors themselves in the real-time monitoring of medication. In addition, new features are being incorporated, mainly in the apps, that allow patients to know the need for and benefits of the prescribed treatment, as well as its possible side effects and interactions.

However, it is noteworthy that there is practically no data on their real effectiveness regarding adherence, nor on user satisfaction, to try to infer whether devices and apps will continue to be used in the longer term. Furthermore, it is difficult to find data on the validation tests on both types of products before commercial use, or information to determine the authority and competence of those who have developed them.

With regard to apps, the main difficulty for users is knowing which of all the existing ones would best suit their needs. Other factors are the apps longevity and sustainability in the marketplace, the company that sells it, or the degree of technical support it will have. There is also concern that when changing a mobile device - another brand, model, or a different version of the operating system - stored information or other features, such as communication and data exchange with third parties, will be lost. Nor are there usually any references to the effects that a change of telephone service provider could have on the operation of the app.

And with regard to personal safety, although conditioning factors are mentioned, such as defective or poorly programmed devices, inappropriate use by the user, or incorrect diagnosis by the health professional based on erroneous data, again no allusion to electromagnetic emissions has been found.

CHAPTER 5. A MORE EFFECTIVE AND SAFER ALTERNATIVE APPROACH

Determining whether ICTs are helping to avoid or minimize preventable medication errors does not appear to be an easy task. There are still too many variables to be able to give a correct evaluation, even if the field of study is narrowed as much as possible by focusing exclusively on problems derived from the administration of medication outside hospital settings.

It is worth noting that, although most of the studies consulted and commercial products justify their necessity by referring to the serious inconveniences that non-adherence entails, it has been found that there is no unanimity in the meaning attributed to these terms.

Other effects that hinder analysis, even more so when comparing technologies in the area of ADE prevention, are those stemming from the patients themselves. Individuals already introduce different variables, difficult to control, that condition the effectiveness of all technological development. This could be in the way in which they use the systems, devices, or appliances, which may be very different from what is planned, or by other physical, cognitive or personality differences, or indeed differing cultural, sociodemographic levels, etc. But in the context that concerns us, variability is even greater due to the different diseases or illnesses, individual or combined, that exist, as well as the myriad of treatments that can be prescribed.

The Internet of Things, for its part, is not designed to answer any of the aforementioned questions. It is likely that to solve the serious health problems arising from adverse events caused by medication, the simultaneous and sustained participation of different technologies is recommended and even necessary, and that they use, at least for the moment, wireless communication systems based on EME. The immediate consequence is that the effectiveness of ICTs that work under this concept will be conditioned by one more additional factor, and that is the risks associated with electromagnetic fields.

Despite everything, it is more than likely that technologies will become an increasingly common resource and it is therefore convenient to try to determine which factors would contribute to achieving higher degrees of efficacy and safety, something that will be discussed throughout this chapter.

DEFINING NON-ADHERENCE

Non-adherence is often cited as one of the greatest concerns for healthcare professionals in regard to outpatient medication and is therefore the intended purpose of many of the devices, systems or platforms that are designed and marketed. After reviewing the literature, it has become evident that no single reason exists for this non-adherence, thus making it difficult to establish to a degree of certainty whether the available technologies are effective in preventing it.

The very definition of the term can also be misleading, as with the case that describes non-adherence as inappropriate adherence, in this case the difficulty lies in determining what we should understand as inappropriate. To resolve this ambiguity, it is proposed that inappropriate adherence should include one or more of the following errors during the administration phase:

- Omitting a dose.
- Omitting the medication.
- Confusing one medication with another.
- Changing the time of the dose.
- Altering the dose.
- Mistaking the route or the form of administration.
- Altering the duration of the treatment.
- Not having the medicine at hand at the prescribed time (forgetting it and leaving at home, not having planned its purchase in advance, not finding it in the usual pharmacy ...).
- Not carrying out any other routine or activity that is directly involved with the medication and that is required in order to take it (for example, food intake, exercise, etc.).

With this approach, the ideal technological solutions to avoid non-adherence would be those that foresee each and every one of the circumstances previously set out Those that only partially do so could not be considered adequate in resolving the issue of non-adherence, although they could be qualified and compared, using as a parameter the number of errors that they are able to resolve.

THE USER FACTOR

One of the most sensitive aspects when talking about technologies is that its effectiveness will depend very much on the intended recipient, the person who is ultimately responsible for accepting it and using it appropriately.

Resolving these difficulties is the goal of user-centred developments. These are seen as a joint design work alongside patients in order to ensure that the procedures and decisions taken respect their needs and preferences.

The user-centred approach also focuses on integrating usability factors that respond to the physical, mental, and even emotional conditions of those who are going to use them, which is fundamental if our potential users have a certain hemispheric dominance or certain disabilities: visual, motor, cognitive, etc.

It is common for users to adopt a more participatory and closer technological role during the design and testing phase than when actually using the technology, in this case without the support of development technicians, and which may lead to eventual abandonment. To avoid this happening, it is considered essential to analyse, in the design phase itself, the perception that potential users have of the following aspects:

- User-friendliness
- Adaptability to changing needs.
- Impact or disruption on their lifestyle.

- Additional burdens implied by the use of the technology that, in itself, produces the treatment.
- Feeling of control.
- Degree of confidence in the correct functioning of the device.
- Concerns about financial costs.

However, with regard to the prevention of adverse medication events derived from non-adherence, an aspect that could be very relevant, but which the world of technology does not seem to share, is that there exists, as some authors maintain, personality variables that make us more prone to this non-adherence. To evaluate this aspect, we already have at our disposal questionnaires such as the Haynes - Sackett test or the Morisky - Green - Levine test. These, in addition to being able to be used in consultations, could be integrated into the technologies that are being developed, adapting their features to the results derived from the application of said questionnaires. For example, they could provide the patient with training, or promote greater family or professional support if shortcomings regarding adherence are detected, since the suitability of both strategies to improve adherence has already been sufficiently proven.

SEARCHING FOR LOYALTY

If medication errors attributable to the patient can be avoided thanks to ICTs, it is essential that the patient uses the technology continuously and over a sustained period of time, at least for as long as they must continue medicating. However, never getting to use the technology or abandoning it is a very common occurrence, even when the technology itself works correctly. Usually, the only problem that this causes is the useless occupation of space, and therefore any risk analysis of the technology tries to anticipate, exclusively, manufacturing errors or operating errors, but not underuse. However, if the device is designed to prevent non-adherence, not using it is, in itself, a risk that should be minimized before marketing.

Consequently, it is essential to establish, as far as possible, the characteristics that could contribute to the non-abandonment of a technology when it has proven to be effective in solving a specific problem, for example, correct adherence with the prescribed treatment. This aspect, which we can call loyalty, acquires enormous importance in long term or chronic treatments, however, it is not usually studied, either during the development phase, or during the testing phase of technological devices or systems.

Loyalty is the phenomenon by which a certain group remains loyal to a product or service, giving rise to a stable and lasting relationship with users, and is one of the greatest ambitions and challenges of the technology industry. Already in the 80s Mark Weiser, pioneer of ubiquitous computing, mentioned loyalty as the second stage of future technological environments, in which devices of different sizes and functionalities could be connected and used together to manage information, in such a way that people will be able to carry out their activities in the everyday world more easily.

One of the characteristics that researchers in technology consider essential to achieve long-term acceptance and use is being a regular user of a certain type of product, or, in other words, how familiar the product is to the user. Consequently, the widespread use of smartphones and tablets in all sectors of the population has led to them being considered as the ideal support in which to implement mHealth, and also for the prevention of errors in the therapeutic administration of drugs, the majority of the time through apps.

To avoid underuse or abandonment, it is proposed that the technology itself be responsible for attracting the user, and not just wait to be used. We are talking here of persuasive technologies, understood to be those that turn to consumer psychology in order to capture interest, being able to change attitudes and even behaviour.

One of the sectors that uses these techniques the most is video games, where gamification can use techniques, elements, and dynamics typical to games and leisure in other non-recreational activities and settings. This is done in order to enhance motivation and reinforce behaviours with the aim of problem solving or reaching a certain objective. Gamification also emanates from known principles regarding the way human beings relate to the group, such as the need for integration or to belong to said group, the interest to compete, the ability to collaborate, and the desire for recognition. Although this is not a new concept, it has become especially popular since 2010, and you can already find references to its use in the health sector.

COMMUNICATING ELECTROMAGNETIC RISKS FOR THE SAFE USE OF RADIANT TECHNOLOGIES

Society, thanks to the effort undertaken by public administrations to introduce the Internet into all areas and environments and the rise of more user-oriented online services, is now more willing and inclined to use wireless technologies for health care. For many elderly people and other dependent groups, as well as for their caregivers, the Internet is already the window through which they communicate with the world, obtaining entertainment and information.

In addition, a new horizon is emerging in health care via what has come to be known as the Internet of Things. Up to now it has been the user who voluntarily sends or receives information through the Internet, but this has now shifted to the objects that surround us in our daily lives since they will be able to send and receive information virtually autonomously.

It would therefore not be surprising, with regard to the well-being of patients, if the possibility of using the Internet for much more practical and value-added purposes were welcomed, and soon could become a requirement of health administrations.

Health professionals, undoubtedly, must become used to dealing with the working models derived from the application of these technologies in all areas of health, be it for the purposes of prevention, diagnosis, or treatment. But they may also be required to engage in how their patients use these technologies, and where appropriate they should recommend safe user guidelines, also aimed at avoiding, as far as possible, the problems derived from electromagnetic exposure.

Although electromagnetic emissions have been the subject of controversy and cause of fear among the general population, the mass introduction of wireless devices on the market, and in particular the multiple services offered through mobile phones, could lead to a reversal of this situation, even resulting in risky behaviour. The truth is that rejection and compulsive use are both extreme positions that can equally compromise public health.

Therefore, and without underestimating the value and need to establish standards and controls that monitor radiation levels or electromagnetic incompatibility, users, with their opinions and behaviour are creating a situation that could seriously compromise the application and effectiveness of the adopted security measures.

From this perspective, an essential aspect in their relationship with patients, as potential users of these technologies, is to avoid considering them as passive recipients of instructions or recommendations, even when these are aimed at providing them with, according to the objective data, the maximum benefits and minimum level of risk.

Risk communication is one of the eight basic functions that the WHO includes in the International Health Regulations-IHR, a legally binding international instrument in 196 countries around the world, including all Member States of the WHO and which came into force in June 2007.

This body considers that competence in risk communication is as essential as training in epidemiology or in laboratory techniques. However, whilst authority and knowledge are factors that are valued very positively in those giving or reporting information, they do not seem to be decisive in ensuring adherence. In interactions with the patient, their own risk perception intercedes, that is, the consequences in terms of damage or harm that they attribute to these devices, or the risks associated with following, or not, the expert's instructions [56].

Risk perception has been incorporated as a decisive element in communication strategies, together with some variables that condition it: source of the risk, degree of control over it, whether the use of the device or appliance that causes the risk is voluntary or has been imposed on the user, fear of its effects or cost-benefit ratio, among others. Risk perception is an insufficiently known characteristic and is often incorrectly quantified, perhaps due to the techniques and instruments that are used to detect and measure it, mainly surveys or questionnaires.

A characteristic of risk perception is that, although it seems to depend on very personal knowledge and experiences, it is homogeneous in groups that are linked in some way, be it geographic, cultural, age, etc., and therefore can be used to design communication strategies aimed at groups and not necessarily specific to each individual [57]. It also appears that it may be affected by the information that it provides.

Determining the content of precautionary messages to avoid increasing risk perception is still the object of study [58], [59], this is because a particularity of communications regarding health risks is that they correlate positively with greater concerns or worries, leading to a higher demand for corrective or preventive measures by the general public.

Therefore, it is not unlikely that, in the near future, patients will request information on mHealth technologies from medical, nursing, or pharmaceutical personnel. Consequently, ensuring that the guidelines for use are adequate, without any errors or excessive information, would also be the responsibility of health professionals, mainly those most closely linked to primary care. It is therefore appropriate to provide this group with adequate training to ensure the safe use of these applications.

CHAPTER 6. TECHNOLOGICAL PROPOSAL

The previous chapters have allowed us to identify elements that could contribute to the development of more effective technological devices, platforms or systems for the prevention of medication errors in general, but also within the context of Internet of Things. Consequently, the following considerations are intended to justify a technological development proposal that, in addition to integrating those characteristics sufficiently verified to address the problem of harmful medication errors, will incorporate others that have proven validity in other areas, or for other purposes, even if they are ground-breaking in the context that concerns us.

APPLICATIONS WITH A GENERAL OR SPECIFIC PURPOSE?

Just as medication by itself can prove to be insufficient in treating a disease, perhaps the technology that is designed for the correct administration of the medication could, or even should, provide some additional benefit, contributing not only to the intended aim but also to increase the physical, mental, and even emotional well-being of those who use it.

Furthermore, forcing patients to focus attention on their own disease or illness, even if the intention is good, could have a negative impact on social, occupational, and cognitive skills, a situation that in turn will condition their well-being and recovery. Therefore, it may be useful to have a technical proposal that manages to prevent medication errors, but not necessarily in an explicit and manifest way, or at least, that does not focus exclusively on this particular issue.

According to the reviewed studies, correct self-management of the medication seems to occur in situations where the patient has access to their doctor or personal caregiver. They are able to raise doubts they have regarding the taking of the drug itself, their illness, or other associated questions, and this leads to other desirable effects, such as a reduction in urgent visits [60]. Consequently, it is proposed that the mobile application or system be capable of simulating this type of interaction.

CHOICE OF PLATFORM

When developing a new mHealth intervention there are a wide variety of mobile platforms and systems to choose from. Smartphones are one of the most widely used options to try and minimize possible technical and functional difficulties that could lead to technological failures when trying to prevent medication errors. These are commonly used devices, incorporated into our daily lives and nearly always carried by the user. This portability makes them ideal candidates for configuring ubiquitous assisted environments, and the most valued option by potential users.

Therefore, a portable computer application is proposed using a smartphone, at least as one of the possible platforms. However, keeping the user's data on the phone has been ruled out after considering the following vulnerabilities: fraudulent capture of the stored information and high probability of loss, theft or replacement of the data terminal due to the emergence of another with new and improved features.

On the other hand, within the home, we could choose to use other more ergonomic platforms, mainly with regard to the image size and sound quality, for example, those that use the television as an interactive means to access health information and that can also be easily integrated with new services or external platforms [61].

CONTROLLING THE RISKS OF ELECTROMAGNETIC EXPOSURE

The appearance of smartphones has been an important advance in the Wireless Personal Area Networks - WPANs, essential for the widespread implementation of IoT applications.

But, as has been shown, its potentially harmful effects cannot be completely ruled out, at least because of their possibility in interfering with the correct functioning of electromedical devices.

Consequently, it would be appropriate to resort to the Precautionary Principle, as advised by the World Health Organization itself.

The Precautionary Principle aims to guarantee a high level of environmental protection through preventative decisions in cases of risk. Its scope is very broad and extends to consumer policies, European legislation on food, and human, animal and plant health.

The precautionary principle is detailed in Article 191 of the Treaty on the Functioning of the European Union. It aims at ensuring a higher level of environmental protection through preventative decision-taking in the case of risk [62]. According to the European Commission "the precautionary principle may be invoked when a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty".

In relation to mobile phones, the precautionary measures have concentrated, for quite some time, on providing recommendations for use: mainly ensuring good coverage conditions, reducing usage time, and keeping them a sufficient distance from the body, especially in the case of implanted electromedical devices. With regard to wireless networks, the most common recommendation has focused on keeping the connection point away from the areas where we spend most time and even turning it on only when necessary. The use of Power Line Communications-PLC, which uses the power grid for data transmission, has also been proposed as an alternative to wireless connections, although it is also controversial. The option that, in general, is considered the safest to use in closed spaces, continues to be a shielded cable with protective covering or fibre optics.

However, the previous recommendations seem impractical at the present time, given the massive use of ubiquitous personal technologies and the enormous popularization of wearables, whose main characteristic is permanent connectivity to the body itself or from somewhere in close proximity. In fact, any mHealth technical solution focused on promoting adherence with the prescribed treatment will work with a permanent connection, accompanying the patient wherever they may be. It is therefore considered essential that, as a minimum, a study of the patient's immediate electromagnetic environment should be carried out to control direct personal risks or those derived from interferences between devices. In addition, electromagnetic contamination detectors should be incorporated, in the mobile technologies themselves, as they provide new recommendations for use that are more adjusted to the current situation.

INTERACTION WITH TECHNOLOGY: USER INTERFACES

In the 1980s, computers started to play a very important role in people's lives with the appearance of what we call today a PC or a Personal Computer. Different research related to the Human Computer Interaction or HCI, led to the implementation of the Windows, Icons, Menus and Pointers-WIMP paradigm, which has prevailed over other possible graphical interfaces until the current era, even though they are not unanimously considered to be the most accessible and intuitive form of interaction.

User Interfaces-UI is a fundamental characteristic in human-machine interaction and is therefore something that mobile healthcare should not ignore. It is so decisive that it can even cause the success or failure of a technology.

Although the popularity of the WIMP paradigm has slowed down user interface research, with the advent of 3D graphics, virtual reality, and speech or natural language technologies, a new approach to interaction, called multimodal interaction, is spreading.

When designing a multimodal interaction system, it is important to consider the most common way in which people interact with each other in their daily lives, which is through words, that can be supported by facial and / or body language or expressions.

Therefore, to achieve a natural type of interaction, it is important to provide the interaction interface between the user and the electronic device (computer, tablet, smartphone, TV, etc.), with a communication system just like the one used by people, based on spoken and body language.

Ella4Life Project, co-financed under the Ambient Assisted Living Joint Programme of the European Commission and the National Funding Agencies of Switzerland, Netherlands, Poland and Romania [63] exemplifies this type of interaction. Ella4Life is the integration of Emma, a mobile solution which has a working connection with several e-health self-management solutions, Anne, an avatar that supports - by speech - elderly people with their daily life (Figure 6.1.) and specially developed sensor technology from the University of Gdansk.

Figure 6.1. Anne avatar. Source: Ella4Life, your virtual personal assistant for home and on the road, project. AAL Programme. Call 2017.

Avatars have aroused enormous interest, giving rise to different studies and projects such as Avatars @ Home, which, among other actions, assesses the interest of these interfaces in comparison to others, mainly for the elderly, children and other groups with disabilities or specific pathologies [64].

They can act as virtual assistants, adopting different appearances, even including those of real people who are close to the patient, with a degree of similarity that makes them perfectly recognizable. In addition, they have the ability to interact with the user through written, but also spoken language. In their current state of development, they can modify their communication style (controlling, empathetic, assertive ...), adjust facial expressions and tone of voice according to what they are expressing. They can even answer a diverse range of questions, although their answers will be more suited to questions that refer to the topics for which they have been previously programmed.

What is undeniable is that they offer a natural form of interaction, as well as multifunctionality. In this regard, the research carried out by Stanford University on the ability of avatars to achieve better results in education and training becomes relevant [65]. This is a characteristic that may be of great interest in applications designed to improve adherence, if we consider that, according to the literature review that has been carried out, providing patients with health training seems essential.

From this research there are several relevant conclusions that should be mentioned:

1. The importance of social skills as a critical factor for success in teaching, business and interpersonal relationships. Social intelligence manifested through facial expressions, body language, tone, rhythm, and other language characteristics is the key to communication. It is also the origin and cause of learning, bonding, care, and above all, because of its relevance in establishing permanent relationships, an aspect of great interest for enhancing loyalty to technology.

2. The same social skills that facilitate communication between humans also determine success between people and technological means, mainly those of an interactive nature. The reason lies in our own brains as, although everyone understands that computer-generated images are not authentic, they automatically elicit social responses as if the characters were real. In addition, when a face appears on the screen, it is no longer necessary to explain how to interact with it, since it is enough to reproduce what we know and use when dealing with other people.
3. Interfaces with social intelligence promote continuity in interaction. People feel safer and more comfortable, the persuasiveness of technology is increased, and a longer-term relationship is fostered by incorporating words of greeting and information from previous conversations, which makes the user feel recognized and special.
4. Interactivity, understood as the ability to listen to understand, increases perceived realism and effectiveness. Interactivity will be all the more realistic when it is observed that each interlocutor, whether human or machine, modifies their dialogue based on what is expressed by the other, something that also must be done in real time without undue delays or uncomfortable silences.
5. At the present time, interfaces with social intelligence are very realistic and customizable in their appearance and dialogue to adapt to multiple needs and uses. They are generated to be used on multiple platforms without suffering distortion, and thus preserving their identity.
6. Virtual characters can modify the behaviour of the people who interact with them leading to less harmful, more appropriate, or adaptive behaviours [66].

PROPOSAL

In 2004, Michel Beaudouin - Lafon, member of the Special Interest Group in Computer - Human Interaction of the Association for Computing Machinery, identified three paradigms of interaction between people and devices [67]: the device as tool, devices as companions and devices as a medium for interaction, and that in the author's opinion they should be unified:

- The device-as-a-tool paradigm expands people's skills, using the device as a tool to help them do their job. Direct manipulation and WIMP interfaces fall within this paradigm.
- The device-as-a companion paradigm implies an interaction with the device in a natural way, as occurs with agent-based interaction or voice-based interfaces.
- The device-as-medium paradigm uses the device as a medium to communicate with other people, for example through email, chats, videoconferences, etc.

Along the same lines is the work of María del Puy Carretero Carrasco [68], who focused her research on architectures capable of displaying virtual characters on different devices, but without losing their identity, so that they can establish gestural communication and emotional ties with the users. Such characters could adopt a virtual assistant role, for example, helping elderly people in their daily lives, reminding them of their medical appointments, the medications they must take, advising them that they have left food cooking, etc.

Based on both the literature review and the products in the marketplace, there are practically no examples of using avatars in the area of adherence. However, intelligent virtual assistants integrated into operating systems, with a strong market presence, are popularizing a human-machine interaction model based on natural language.

Considering the above, the development of a multimodal and cross platform approach is proposed, which contributes to the correct monitoring of medication therapy by preventing administration errors attributable to the patient or informal caregiver, but not focused exclusively on the said objective, since it should be able to adopt the aforementioned three paradigms of interaction between people and machines identified by Michel Beaudouin-Lafon.

Functionalities of the proposal:

- Storage of information in order to carry out the typical functions of any agenda (appointments, birthdays, contact list ...), but also able to register any other requirement to properly monitor medication therapies, that is, the data related to the identification of the drug - name and appearance, and treatment data - dose, frequency, schedule, and duration. Additionally, it will keep a record of consumption to report adherence and renew stocks.
- It will also be able to gather information from the patient's environment to inform the patient or transmit this to third parties as appropriate, for example, notification of the sound of a doorbell, a phone call or other information collected by environmental or wearable sensors. The aim is for technology to be integrated into the daily dynamics of the patient's life by providing additional services beyond its use in medication therapy. An additional feature, of interest in the scope of this thesis, will be the ability of technology to report on any surrounding electromagnetic disturbances that, by exceeding the basic restrictions, may put patient safety at risk.
- For the early detection of conditions that could lead to non-adherence, the application will integrate adherence control questionnaires, such as those already mentioned, to adopt reinforcement measures and inform third parties of the results.
- In addition, to improve adherence, technological development should be able to educate and train the patient regarding their pathology and the benefits of the prescribed treatment. The technology would have the capacity to answer questions or even provide information without being requested, consulting previously stored content or information that can be found on the Internet.
- The computer application may work using different platforms (telephone, television, computer, or others) without changing its functionalities.

- The information will be recorded in the cloud to ensure independence from the platform. In addition, it can be viewed and controlled by other suitably authorized users (health professionals, family members, informal caregivers, etc.).
- Loyalty to the technology will be sought by adopting gamification measures.
- As an interface or means of interaction with the application, an avatar with a human or anthropomorphic appearance is proposed, with the ability to communicate in written and spoken natural language and with social intelligence.

  Social intelligence is understood as

  - Gestures that give the feeling that the character is alive, such as natural blinking, eyebrow movement, swaying as a sign of waiting, etc.
  - Synchronization of speech with lip movements (lip-synching).
  - Facial expressions that reflect what is being expressed.
- For each patient, the avatar with the most convenient appearance will be generated.
- The interaction will take place in real time, simulating a conversation between humans.
- From the registered data, the avatar will be able to call or send a message to health professionals or other people, so that they, or the avatar itself, can try to modify the patient's inappropriate behaviour.
- The avatar, in their role as a companion, may also propose other activities to be carried out jointly with the patient, for example, looking at previously scanned photos of people or familiar places, read books, listen to music or be the opponent in board games with an electronic format.
- In any event, a development focused on the user is proposed, with collaboration from the design phase, that will have to be validated in an experimental trial situation to verify its effectiveness, both regarding adherence and for other planned uses.

7. CONCLUSIONS

Considering the above, it is possible to affirm that the health sector recognizes the problems posed by errors in the administration of drugs and that it is interested in wireless ICTs to support ubiquitous mHealth systems. This is also the preferred option for non-hospitalized patients when it comes to ensuring a correct adherence with treatments and preventing medication errors.

Literature reviews and commercialized products have revealed that there are numerous devices and apps to assist the patient in the taking of medication, but also, that they are usually complex, and their success in achieving the desired objective is not sufficiently proven. Along with effectiveness, their safety is also questioned. For example, the fact that the FDA does not consider them medical devices leads one to think that the surveillance and monitoring of this technological sector is less demanding in nature, although the aforementioned institution reserves the right to exercise some kind of authority, if it deems it necessary. In Spain and Europe, the need for public administrations to become involved in the monitoring and control of health care apps has also been recognized and there are already some initiatives, but these are aimed at giving recommendations on the design, use and evaluation of these programs, rather than controlling their commercialization.

With regard to their effectiveness, firstly, the need to give objectivity to the term adherence is proposed, so that it can be interpreted as the sum of certain preventable errors, avoiding definitions such as inadequate adherence, which are ambiguous and difficult to measure. Among their main objectives, it is also necessary that the technological proposal aims to avoid underuse or abandonment, an especially critical aspect in long term or chronic treatments. To this end, they must be able to adapt to possible variations in patient pathologies and treatments, as well as to other personal circumstances, including the patient's loss of interest or confidence in the prescribed medication. To promote loyalty, that is, the long-lasting and consistent use of the technology, it is considered essential that potential users participate in the design and development phases, evaluate their satisfaction with the final result, and include gamification strategies. Likewise, it is recommended that the technology should not focus exclusively on the administration of medication, but rather adopt a triple model of human-machine interaction, as a tool, as a medium for interaction, and above all as a "companion", with a multimodal and cross-platform interface. To adapt to the different cognitive and sensory capacities of patients, it is proposed to use anthropomorphic avatars that can interact in a similar way to humans, using spoken and gestural language. Due to its proven effectiveness in improving adherence, the system should be able to train the user regarding their disease and prescribed drugs and facilitate social support by integrating communication systems with peers, family members, caregivers and / or health professionals. The health sector has also shown interest in wireless technologies for the configuration of ambient assisted living environments for health care.

What has been verified is that many patients already have multiple radiant technologies in their homes, such as telecare devices and others based on Bluetooth and Wi-Fi. Laboratory tests have revealed that in general the levels of Electric field strength and the Equivalent of Effective Isotropically Radiated Power - EIRP are apparently safe, both for users and for the operation of other devices. However, the Electric field strength of the Wi-Fi module, measured in near field conditions, significantly exceeded the basic restrictions established by the IEC - EN 60601-1-2 standard to ensure the correct operation of electrical medical devices.

The use of wireless technologies is not only accepted, but is also promoted by industry and government, who jointly propose a new horizon characterized by simultaneous and continuous emissions, that operate at different frequencies and come from the everyday objects in our close proximity. This approach, called Internet of Things or IoT, requires different transmission technologies for its deployment, that in many cases will emit radiation when transferring data from distances that are very close to people, as is the case with wearables, and in some cases actually from within the body.

The report *Internet of Things in 2020: a roadmap for the future*, prepared jointly by DG INFO (now DG CONNECT) and the EPoSS platform in 2008, set out a series of milestones to be achieved at specific time intervals so that by 2020 IoT would become a reality.

Except for the fact that RFID technology is not ubiquitous, other predictions in the aforementioned report have materialized at the predicted rate. This is the case with the rise of smart devices and the ultra-speed that 5G allows, but also when considering standardization, authentication, trust, and verification.

However, with regard to electromagnetic emissions, it has been found that neither in the increasingly numerous pieces of news on IoT, nor in reports supported by official institutions dedicated to this technological approach, is there any allusion to its possible direct or indirect effect on personal safety. The exception is if privacy of information is compromised by loss, malware, unauthorized access to personal data, intrusive use of portable devices and illegal surveillance, or by the harmful effects derived from device or communication failures.

It is worth noting that other institutions that collaborate regularly with the European Commission continue to work on evaluating the risks that electromagnetic fields can pose to human health. This is the case of the Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR, which, in its last opinion, in 2015, concluded that, in general, the results of scientific research indicated that there were no obvious adverse effects for health when exposure to electromagnetic fields remained below the levels recommended by the European Union legislation.

Nevertheless, it also recommended that the effects of combined exposure to both low and high frequencies be examined as people are subjected to multiple frequencies, at different bandwidths, in their everyday environment. It also pointed out that there are practical limitations and difficulties that are common to all lines of scientific research on the possible effects of EMFs on biological activity and health. As a consequence of these limitations, the data obtained is inadequate, or cannot be used for a correct risk assessment, so research should be focused on achieving more affordable instrumentation, improvements in dosimeters and also in crowdsensing techniques.

The levels of electromagnetic disturbance must be taken into consideration in homes, especially if there are patients with implanted electromedical devices. It is therefore recommended that both homes and personal mobile technologies have sensors that, through light or acoustic signals, report the times when critical levels are being exceeded.

The apparent benefits of Ambient Assisted Living could be compromised, if acceptable thresholds for human exposure to electromagnetic fields, operating simultaneously and at different frequencies, are not accurately determined beforehand. Likewise, it is essential to unequivocally establish the technical conditions that would avoid interference with other devices or systems, mainly electromedical ones. The incorporation of IoT into healthcare applications, and its acceptance or rejection by providers, professionals, and patients, may depend on how these factors are addressed.

Precautionary measures aimed at avoiding the risks of personal mobile technologies have traditionally focused on trying to reduce usage time and keeping them at a sufficient distance from the body. Today however, given the increasing and continuous use of these devices in all areas, including health, these measures seem impractical, or unknown. Also, the security measures focusing on Wi-Fi connections have been questioned. This is the case of Power line communications PLC due to its vulnerability to intrusion and interference, and because it does not eliminate electromagnetic contamination in near field conditions. Other measures, such as limiting use, turning off the access point, or reusing the cable connection do not seem feasible if what is being promoted is the permanent and ubiquitous monitoring of patients. That is why safety guidelines must be revised to adapt to new scenarios.

Given that it is foreseeable that the use of personal technologies for health care, including those aimed at achieving therapeutic adherence, will become widespread, patients may require advice from health professionals. Therefore, it would be essential to provide these professionals with adequate training so that they can correctly communicate the risks associated with EMFs, as well as the measures to control them.

Finally, it is important not to forget that the success of any measures aimed at avoiding adverse events due to medication, including those involving technology, will depend above all on the existence of a prior safety culture that must be promoted by public administrations. Internet of Things, for its part, is not designed to answer any of the above questions. It is likely that to solve the serious health problems posed by adverse drug events, the simultaneous and sustained participation of different technologies is recommended, and that these use, at least for the moment, wireless communication systems. The immediate consequence is that the effectiveness of ICTs that work under this concept will be conditioned by one more additional factor, and that is the risks associated with electromagnetic fields.

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Tables and figures

Glossary of acronyms

AAL.	Ambient Assisted Living.
AAL Program.	Assisted and Active Living Program.
ADE.	Adverse Drug Event.
ADR.	Adverse Drug Reaction.
AENOR.	Asociación Española de Normalización y Certificación.
AFH.	Adaptative frequency hopping.
App.	Application.
A/m.	Ampere per meter.
B.	Magnetic flux density.
CEN.	European Committee for Standardization
CENELEC.	European Committee for Electrotechnical Standardization
BMI.	Body Mass Index.
DECT.	Digital Enhanced Cordless Telecommunications.
DG CONNECT.	Directorate General for Communications Networks, Content and Technology.
DG INFSO.	Directorate General Information Society and Media.
DL.	Down Link.
DSSS.	Direct Sequence Spread Spectrum.
E.	Electric field intensity.
EDR.	Enhanced Data Rate.
EIRP.	Equivalent of Effective Isotropically Radiated Power.
ELF.	Extremely Low Frequency.
EMC.	ElectroMagnetic Compatibility.
EME.	ElectroMagnetic Emission.
EMF.	ElectroMagnetic Fields.
EMI.	ElectroMagnetic Interferences.
EPoSS.	European Technology Platform on Smart Systems Integration.
ETSI.	European Telecommunications Standards Institute.
FDA.	US Food and Drug Administration.
GPS.	Global Positioning System.
GSM.	Global System for Mobile Communication.
H.	Magnetic field intensity.
HCI.	Human Computer Interaction.
IC.	Contact Current.
ICNIRP.	International Commission on Non-Ionizing Radiation Protection.
IEC.	International Electrotechnical Commission.
IEEE.	Institute of Electrical and Electronics Engineers.
IEM.	Ingestible Event Monitors.
IETF.	Internet Engineering Task Force.
IHR.	International Health Regulations.
IF.	Intermediate frequency.
IoE.	Internet of Everything.
IoHT.	Internet of Health Things.
IOM.	Institute of Medicine.
IoMT.	Internet of Medical Things.
IoT.	Internet of Things.
IP.	Internet Protocol.
ISO.	International Organization for Standardization.

ITU.	International Telecommunication Union.
J.	Current density.
LCD.	Liquid Crystal Display.
MAC.	Medium Access Control.
Mbps.	Megabits per second.
MIT.	Massachusetts Institute of Technology.
MRI.	Magnetic Resonance Imaging.
NB-IoT.	Narrow-Band Internet of Things.
NCC MERP.	National Coordinating Council for Medication Error Reporting and Prevention.
NFC.	Near Field Communication.
OFDM.	Orthogonal Frequency Division Multiplexing.
PC.	Personal Computer.
PLC.	Power Line Communications.
QR.	Quick Response.
RED.	Radio Equipment Directive.
RFID.	Radiofrecuency Identification.
R&D&I.	Research, Development and Innovation.
S.	Power density.
SA.	Specific energy Absorption.
SAM.	Specific Anthropomorphic Mannequin.
SAR.	Specific Absorption Rate.
SCENIHR.	Scientific Committee on Emerging and Newly Identified Health Risks.
SIM.	Subscriber Identity Module.
SMS.	Short Message Service.
SRD.	Short Range Devices.
T.	Tesla.
ICTs.	Information and Communication Technologies.
3D.	Three-Dimensional
UI.	User Interface.
UL.	Upper Link.
UMTS.	Universal Mobile Telecommunication System.
UWB.	Ultra-Wide Band.
V/m.	Volts per meter.
WHO.	World Health Organization.
Wi-Fi o wifi.	Wireless Fidelity.
WHO.	World Health Organization.
WIMP.	Windows, Icons, Menus and Pointers.
WLAN.	Wireless local area network.
W/m².	Watt per square meter
WPAN.	Wireless Personal Area Network.

Glossary of key terms

Actuators: component of a machine that is responsible for moving and controlling a mechanism or system. It is a part of a device or machine that helps it to achieve physical movements by converting energy, often electrical, air, or hydraulic, into mechanical force.

Adverse Drug Reaction: any response to a drug which is noxious, unintended and occurs at doses normally used for prophylaxis, diagnosis, or therapy. ADRs are therefore unwanted or unintended effects of a medicine, including idiosyncratic effects, which occur during its proper use.

Adaptative Frequency Hopping: system that incorporates Bluetooth technology to avoid interference between devices and forces the signal to jump, randomly, between 79 frequencies in 1 MHz intervals.

Adherence (definition from *Adherence to long term therapies: evidence for action*. WHO 2003): the extent to which a person's behaviour - taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider.

Ambient Assisted Living: use of ICTs to contribute to the care and well-being of both the environment and people, with a practically autonomous operation and total integration in the daily life of users without disturbing it.

App: an application, especially as downloaded by a user to a mobile device.

Active and Assisted Living Programme: funding instrument co-financed by the member countries and the European Commission. AAL projects aim to create better quality of life for older people and to strengthen industrial opportunities in the field of healthy ageing technology and innovation.

Avatar: computer (animated) character representing a real life person, concept or artificial entity. Quite often this term is used to address human-like online assistants representing organizations, commercial firms and brands. These virtual assistants are able to answer questions and perform tasks through conversational dialogs with humans.

Basic restrictions: Restrictions on exposure to time-varying electric, magnetic, and electromagnetic fields which are based directly on established health effects and biological considerations. Depending upon the frequency of the field, the physical quantities used to specify these restrictions are magnetic flux density (B), current density (J), specific energy absorption rate (SAR), and power density (S). Magnetic flux density and power density can be readily measured in exposed individuals.

Contact Current IC between a person and an object is expressed in amperes (A). A conductive object in an electric field can be charged by the field.

Crowdsensing: measurement and collection of data through different kinds of sensing devices (e.g., smartphones) by a large mass of users.

Current Density J: current flowing through a unit cross section perpendicular to its direction in a volume conductor such as the human body or part of it, expressed in amperes per square metre (A/m^2).

Customer loyalty: act of choosing one company's products and services consistently over their competitors.

Domotics or home automation: involves the integration of various products, systems and services which allow the automation of domestic functions, even with equipment (home appliances, boilers, lamps, audio/video devices...) which already has a traditional place in the home.

Electric Field Strength E: vector quantity that corresponds to the force exerted on a charged particle regardless of its motion in space. It is expressed in volts per metre (V/m).

Electromagnetic Compatibility EMC: concept of enabling different electronics devices to operate without mutual interference.

Electromagnetic Fields EMFs: invisible areas of energy, often referred to as Radiation, that are associated with the use of electrical power and various forms of natural and man-made lighting. EMFs are typically grouped into one of two categories by their frequency:

- **Non-ionizing**: low-level radiation which is generally perceived as harmless to humans.
- **Ionizing**: high-level radiation which has the potential for cellular and DNA damage.

Equivalent of Effective Isotropically Radiated Power EIRP: a power that would have to be radiated by a hypothetical isotropic antenna to achieve identical signal level in the direction of maximum radiation of a specific antenna.

5G: fifth generation technology standard for broadband cellular networks.

Frequency: magnitude that characterizes electromagnetic fields. Describes the number of oscillations or cycles per second. The term "wavelength" refers to the distance traveled between two consecutive maxima of the wave.

Gamification: use of techniques, elements and dynamics typical of games and leisure in other non-recreational activities, in order to enhance motivation and reinforce behaviors aimed at solving a problem or obtaining a goal.

Immotics: monitoring of the general operation of buildings.

Internet: Worldwide network of interconnected computer networks, based on a standard communication protocol, the Internet TCP / IP suite.

Internet of Things: It is the global network of objects interconnected by standard communication protocols with the ability to detect or perceive, identify and understand the world autonomously and without the need for human beings to enter data.

Magnetic field strength H: together with the magnetic flux density, specifies a magnetic field at any point in space. It is expressed in amperes per metre (A/m).

Magnetic Flux Density B: vector quantity resulting in a force that acts on moving charges, it is expressed in teslas (T).

Malvare: collective name for a number of malicious software variants, including viruses, ransomware and spyware.

Megabits per second: unit of measurement for bandwidth and throughput on a network.

Mobile Health or mHealth (definition suggested by the WHO Global Observatory for eHealth): medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices. mHealth is a component of eHealth.

Multimodal Interaction: man-machine communication modality that uses multiple channels, be they auditory, visual, tactile and gestural, enhancing human modes such as speech.

Persuasive Technology: interactive computing products designed to change attitude or behavior of the users.

Power Line Communications PLC: provides broadband data communications on conductors already used for electric power transmission using a modular signal.

Power Density S: is the appropriate quantity used for very high frequencies, where the depth of penetration in the body is low. It is the radiant power incident perpendicular to a surface, divided by the area of the surface and is expressed in watts per square metre (W/m^2).

Precautionary Principle: also called caution, it aims to guarantee a high level of protection of the environment through preventive decision-making in the event of risk. However, in practice, its scope is much broader and also extends to consumer policy, European legislation on food and human, animal and plant health.

Preventable adverse drug event: result from a medication error that reaches the patient and causes any degree of harm and which can happen in the course of prescribing, transcribing, dispensing, administration and monitoring practices.

Radio Equipment: electrical or electronic product that intentionally emits or receives radio waves for radiocommunication or radiodetermination purposes. Also electrical or electronic product that must be completed with an accessory, such as an antenna, to intentionally emit or receive radio waves for radiocommunication or radiodetermination purposes.

Risk Perception: subjective judgement that people make about the characteristics and severity of a risk.

Sensors: devices that collect real-world information - temperature, status of a door (open / closed), humidity, air speed, CO2 level, etc. And they deliver it to the control system so that the control system 'understands' and can process and make decisions. Its function is to transform a parameter or physical state of the environment that surrounds us into information translated into electrical signals that we will provide to the control system.

Short Range Devices SRD: technologies capable of transmitting information at a short distance using electromagnetic waves. They work with different standards that will determine some of their characteristics, such as the data transfer rate, the transmission range or distance, and the type of modulation used.

Specific Absorption Rate SAR: rate at which energy is absorbed per unit mass of body tissue and is expressed in watts per kilogram (W/kg). Whole body SAR is a widely accepted measure for relating adverse thermal effects to RF exposure. Besides the whole body average SAR, local SAR values are necessary to evaluate and limit excessive energy deposition in small parts of the body resulting from special exposure conditions. Examples of such conditions are: a grounded individual exposed to RF in the low MHz range and individuals exposed in the near field of an antenna.

Specific energy Absorption SA: the energy absorbed per unit mass of biological tissue, expressed in joules per kilogram (J/kg). In this recommendation it is used for limiting non-thermal effects from pulsed microwave radiation.

Tesla T: unit of magnetic flux density.

Unique Identifier UID: numeric or alphanumeric string that is associated with a single entity within a given system. UIDs make it possible to address that entity, so that it can be accessed and interacted with.

Wearable: electronic device that is worn over, under or included in clothing and that is always active or on. Other of its characteristics is that it allows multitasking so it does not need to stop doing something else to be used and it can act as an extension of the user's body or mind.