

National Health System Patient Safety Strategy

2025-2035

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Note:

Throughout the text, the term “Autonomous Communities” is used to refer to Spain’s 17 Autonomous Communities and to its two Autonomous Cities, Ceuta and Melilla (National Institute of Healthcare Management (INGESA)).



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National Health System Patient Safety Strategy

2025-2035



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Spanish Allergy and Clinical Immunology Society
Spanish Society for Quality of Care

Spanish Society for Endocrinology and Nutrition
Spanish Oncology Nursing Society
Spanish Society for Intensive Care and Coronary Unit Nursing
Spanish Society for Epidemiology
Spanish Society for Medical Physics
Spanish Society for Geriatrics and Gerontology
Spanish Society for Haematology and Haemotherapy
Spanish Society for Paediatric Haematology and Oncology
Spanish Society for Laboratory Medicine
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1. Introduction

The Ministry of Health has developed and built upon the National Health System Patient Safety Strategy since the first version was prepared in 2005 in collaboration with Spain's Autonomous Communities and numerous different professionals through their respective professional organizations.

The objectives of that first version were to promote and improve the safety culture of healthcare organizations, to incorporate healthcare risk management into their practices, to train professionals and patients in basic aspects of patient safety, to implement safe practices and to involve patients and the broader public.

After ten years in place, that first Strategy was updated for the 2015-2020 period to consolidate the strategic lines of action implemented; to compile international recommendations on patient safety; to incorporate achievements and strengths; to propose objectives and recommendations based on the best evidence available; and to establish an evaluation system agreed with Spain's Autonomous Communities to enable standardized measurement of the implementation of the update.

Following an evaluation in 2021, work began on this new edition of the Strategy for a longer period (2025-2035), to enable the pursuit and achievement of all the objectives considered, and in particular the following: reduce potential healthcare-associated harm as far as possible; prioritize patient safety in all health plans as a cross-cutting aspect of quality of care; and foster patient safety at all levels and in all areas of care of the National Health System.

The construction of a framework broad enough to encompass all of the actions proposed was made possible by the efforts and involvement of the members of the Institutional Committee on Patient Safety and of numerous professionals committed to this issue. I would like to express my sincere gratitude for their dedication and hard work.

We trust that the application of this Strategy will minimize healthcare-associated harm and improve quality of care and safety for all National Health System patients.

2. Technical note

This document contains five discrete parts:

1. General aspects: This section sets out the need for this Strategy through situation analysis, as well as the methodology used to implement it and achieve its purpose.

- a. Situation analysis
- b. Methodology
- c. Purpose of the Strategy: mission, vision and general aims
- d. Target population
- e. Guiding principles

2. Strategic lines of action: These are founded on the basic principles underpinning the existing Patient Safety Strategy while incorporating updated objectives and a new strategic line of action.

Strategic line of action 1: Safety culture, human and organizational factors and training

- General objective 1.1. Improve the National Health System safety culture in all areas and at all levels
- General objective 1.2. Encourage health professionals to take the lead on patient safety
- General objective 1.3. Training

Strategic line of action 2: Safe clinical practice

- General objective 2.1. Promote medication safety
- General objective 2.2. Promote safe practices for preventing and controlling healthcare-associated infections
- General objective 3.2. Promote the implementation of safe surgical practices
- General objective 2.4. Promote the implementation of safe practices in patient care
- General objective 2.5. Promote the correct identification of patients, samples and clinical documents
- General objective 2.6. Promote communication among professionals and between professionals and patients

- General objective 2.7. Promote the design and development of strategies for dealing with serious adverse events at healthcare facilities
- General objective 2.8. Promote the safe use of ionizing radiation in medical-radiological procedures and ensure that comprehensive quality assurance programmes are implemented pursuant to legislation
- General objective 2.9. Promote the abandonment of low-value practices through the implementation of do-not-do recommendations

Strategic line of action 3: Risk management and systems for reporting and learning from incidents

- General objective 3.1. Promote risk management at healthcare facilities
- General objective 3.2. Promote the implementation and development of systems for reporting and learning from healthcare-related incidents

Strategic line of action 4: Participation of patients, families and the broader public in patient safety

- General objective 4.1. Promote the participation of patients and their caregivers in patient safety

Strategic line of action 5: Research and innovation in the field of patient safety

- General objective 5.1. Foster greater knowledge about preventing healthcare-associated harm

Strategic line of action 6: National and international participation

- General objective 6.1. Foster international collaboration on patient safety
- General objective 6.2. Promote national collaboration on patient safety

Strategic line of action 7: Patient safety in all areas of care

- General objective 7.1. Guarantee patient safety in all areas

3. Evaluation

4. Abbreviations and acronyms

5. Bibliography

3. General aspects

A. Situation analysis

Evaluation report on the national health system patient safety strategy

The *National Health System Patient Safety Strategy* has been prepared, since 2005, by the Ministry of Health in collaboration with the pertinent authorities of the Autonomous Communities, and incorporates contributions from health professionals and patients through their respective societies and associations. The update of the strategy for the 2015-2020 period⁽¹⁾ set out objectives and recommendations divided between six strategic lines of action (*Figure 1*), based on available evidence and taking into account international guidelines on patient safety, to minimize healthcare-associated harm.



The Strategy's objectives were initially focused on promoting and improving the safety culture in healthcare facilities and organizations, incorporating healthcare risk management into their practices, training professionals and patients in basic aspects of patient safety, implementing safe practices and involving patients and the broader public in the matter.

The current Strategy proposes the development of an evaluation system agreed with the pertinent authorities of the Autonomous Communities to enable standardized evaluation of strengths and of progress made during the period, taking into account not only prevention of harm to patients—a fundamental aspect of patient safety—but also the risks to which they are exposed throughout their experience in the health system.

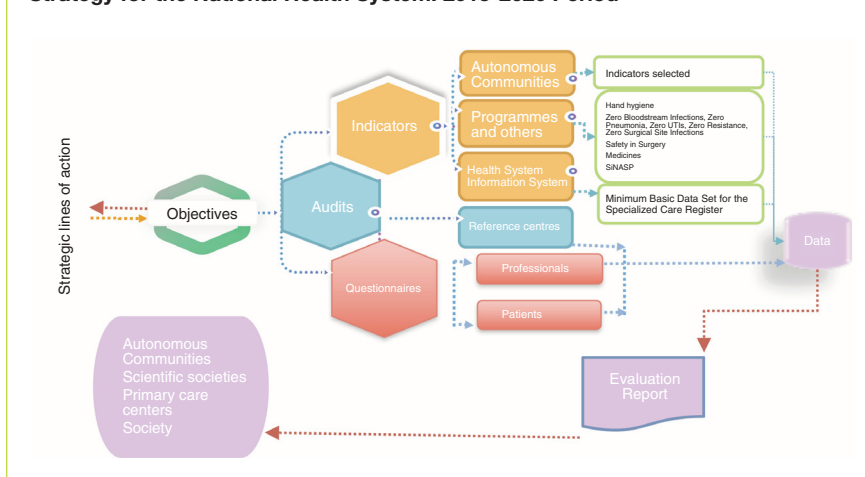
Such evaluation is key to obtaining the information needed to analyse the effectiveness of the Strategy and its programmes and actions to prevent and minimize healthcare-related risks and harm and to improving the performance both of professionals and of the system in which they work. Additionally, evaluation must enable identification of those improvements that will guide policies and healthcare management, as well as clinical practice.

The **evaluation of the Patient Safety Strategy for 2015-2020** afforded us an overview of the progress made and facilitated reflection and decision-making on patient safety in the National Health System. The next step is to use the information obtained to cultivate patient safety across the National Health System, foster transparent reporting, identify success stories, promote collaborative learning and spotlight areas for improvement in which to establish the innovations to guide a new period for the Strategy.

The Strategy was evaluated following the multifactorial methodology (Figure 2) defined in the *Evaluation handbook for the Patient Safety Strategy for the National Health System. 2015-2020 Period*,⁽²⁾ using a variety of indicators, audits and questionnaires to evaluate the progress made in implementing the **strategic lines of action and objectives established**.

The findings of the evaluation were included in the *Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period* (hereinafter, the Evaluation Report), which was **published in 2022**.⁽³⁾ It should be noted that the COVID-19 pandemic represented an exceptional crisis that overburdened the healthcare system and required a reorganization of human resources and healthcare services to respond to the consequent rise in demand. For this reason, it was not possible to obtain data in 2020 for certain evaluation indicators referring to 2019 and those indicators have therefore been excluded from the Report. Nevertheless, Section 6 of the *Evaluation Report* does set out a number of conclusions regarding data obtained during the health crisis for indicators relating to certain programmes.

Figure 2. Multifactorial methodology: Evaluation handbook for the Patient Safety Strategy for the National Health System. 2015-2020 Period



The main conclusions of the *Evaluation Report*, which form the basis for the approach adopted in the 2025-2035 Strategy, are set out below. The conclusions are divided between those relating to the strategic lines of action defined in the current Strategy and those relating to audits and questionnaires prepared ad hoc for the *Evaluation Report*.

Evaluation of the strategic lines of action

1. Strategic line of action 1: Safety culture, human and organizational factors and training

A strong **patient safety culture** at healthcare institutions is a key requirement for preventing and minimizing incidents, enabling individuals and organizations to learn from past mistakes and avoid repeating them.

Improving this culture entails informing and training all National Health System professionals about and in matters of safety, as well as training work teams in risk management, reporting and learning from incidents, and keeping professionals informed of the findings of evaluations conducted at their facilities, encouraging their participation in proposed improvements.

Such efforts fall within the scope of a single general objective for this strategic line of action: **to improve the safety culture and human and organizational factors.**

The *Evaluation Report*⁽³⁾ defines two indicators for determining the degree of implementation, both at primary care centres and at hospitals, of a

patient safety plan that specifies the person responsible for ensuring that the plan is implemented; the period covered; the content of annual reports; evaluation and dissemination of the plan.

Patient safety plans are tools that enable the fostering of a safety culture, facilitating the involvement of professionals in implementing and evaluating safe practices and in improving and promoting patient safety.

The *Evaluation Report* specifies that 78.8% of the primary care centres that contributed data had adopted a patient safety plan, as had 73.9% of hospitals. However, a breakdown of the data by Autonomous Community reveals that only 10 have a patient safety plan in place at 100% of their primary care centres and only 8 have such plans at 100% of their hospitals (*Figure 3*).

On the basis of these findings, a number of recommendations have been adopted at the national and Autonomous Community levels and at the level of healthcare facilities themselves (*Table 1*).

Previously, in 2008, the Government launched the **patient safety website** (<https://seguridaddelpaciente.sanidad.gob.es/>) to promote a safety culture and knowledge about safety among professionals and patients at all levels of healthcare, offering information, guides and resources based on scientific evidence. This interactive website, which is continuously updated, enables the identification and sharing of good practices and lessons learned with respect to patient safety.

Moreover, **GuíaSalud** (<https://portal.guiasalud.es/>), a National Health System body in which the pertinent authorities of the Autonomous Communities and the Ministry of Health participate, was created in 2002 as an instrument for improving the quality of healthcare. Its mission is to increase the range of evidence-based resources, services and products available to help inform the decision-making both of professionals and of patients. To fulfil this function, it applies pre-defined criteria to prepare clinical practice guidelines and other evidence-based products, including do-not-do recommendations encouraging the abandonment of low-value clinical practices that do not offer any clear benefits for patients, or that entail an unnecessary risk of causing them harm.

Figure 3. Breakdown of Autonomous Communities by percentage of primary care centres and hospitals that have adopted a patient safety plan and the percentage that said healthcare facilities represent out of the total number evaluated.
“Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.

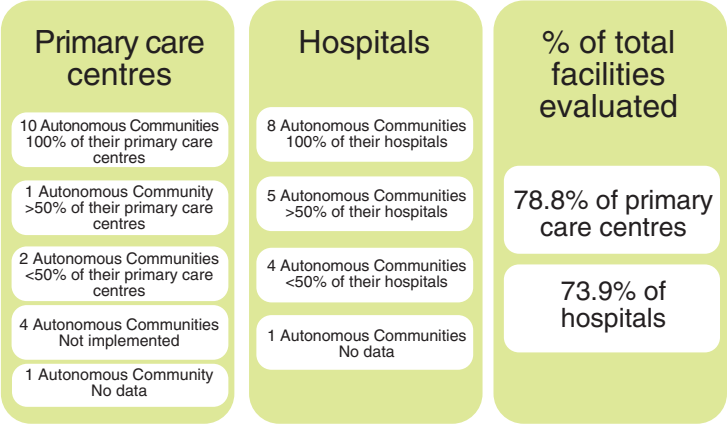


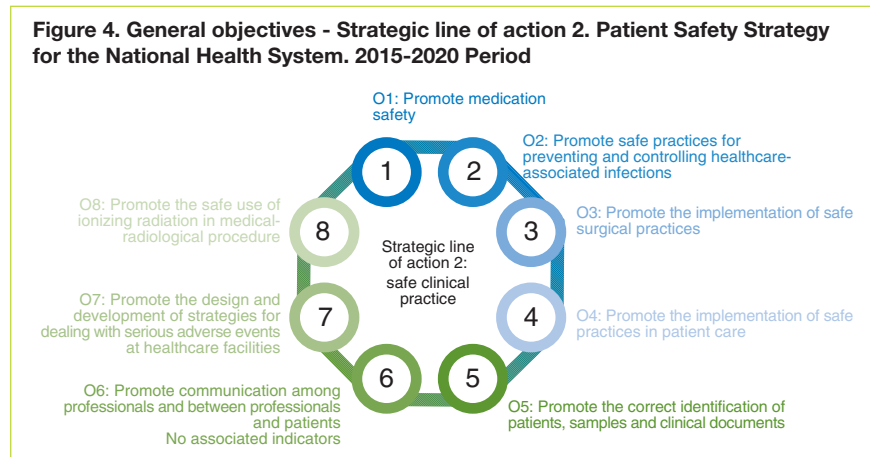
Table 1. Recommendations - Strategic line of action 1. Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period

Ministry of Health	Share the findings of the evaluation of the Patient Safety Strategy indicators, agreed with the relevant authorities of the Autonomous Communities
	Hold an annual Patient Safety Seminar to foster a safety culture and the sharing of experiences relating to the different strategies, programmes and plans adopted in each Autonomous Community
Autonomous Communities	As part of healthcare directorates' commitment to patient safety, encourage the definition and application of patient safety plans hand in hand with healthcare facility management teams, periodically evaluating their implementation
	Foster collaboration between the healthcare facilities of the different Autonomous Communities to facilitate the sharing and adoption of safe practices, and assess their inclusion in healthcare facilities' management agreements
Healthcare facilities	Adapt their working environments and adopt the patient safety plan of their Autonomous Community
	Appoint an individual/team to lead implementation and evaluation of the patient safety plan
	Prepare reports and distribute them to health professionals; involve health professionals in the plan and in establishing initiatives to adopt improvements

2. Strategic line of action 2: Safe clinical practice

This strategic line of action comprises internationally recommended safe clinical practices of proven effectiveness in preventing and controlling the factors most frequently associated with adverse events (AEs).

These practices have been developed under eight general objectives (Figure 4), which in turn encompass more specific objectives and recommendations for achieving them.



In line with the *Evaluation Report*, we will now examine different aspects of these objectives in greater detail:

General objective 2.1: Promote medication safety

As agreed with the relevant authorities of the Autonomous Communities, the **evaluation** of this objective focused on the key action areas identified by the World Health Organization (WHO), namely transitions of care, polypharmacy and high-risk situations.

The indicators **monitored** relate to the implementation of protocols for the use of high-risk medications (HRM) at hospitals and in patients with chronic conditions at primary care centres, for medication reconciliation on admission, and for low-value (do-not-do) practices regarding the use of medicines in primary care. The completion, by 77 hospitals, of a medication safety self-assessment for hospitals and the errors reported voluntarily to the Institute for Safe Medication Practices (ISMP-España) by practitioners were also taken into account.

The *Evaluation Report* revealed the **limited implementation of protocols for HRM** (Figure 5) and of other priority practices recommended

for medication safety. It also found that **few actions** had been carried out to **improve the use of medication in chronic patients on multiple prescriptions** (Figure 6) and that **only four Autonomous Communities** carry out **medication reconciliation** actions at 100% of their hospitals (Figure 7).

As regards **do-not-do practices**, the prescription of benzodiazepines for insomnia in patients over the age of 65 is that which is most commonly followed and that with the greatest potential for patient harm. Although this practice has declined in recent years, it is still applied in more than 50% of cases.

The **analysis of medication incidents** recorded in the Patient Safety Reporting and Learning System (hereinafter, SiNASP) and in the ISMP-España system show that some errors continue to occur repeatedly even though they could have been avoided through implementation of medication safety practices, including providing patients with all necessary information.

The *Evaluation Report* established a number of recommendations addressed to the Ministry of Health, the pertinent authorities of the Autonomous Communities and healthcare facilities (Table 2).

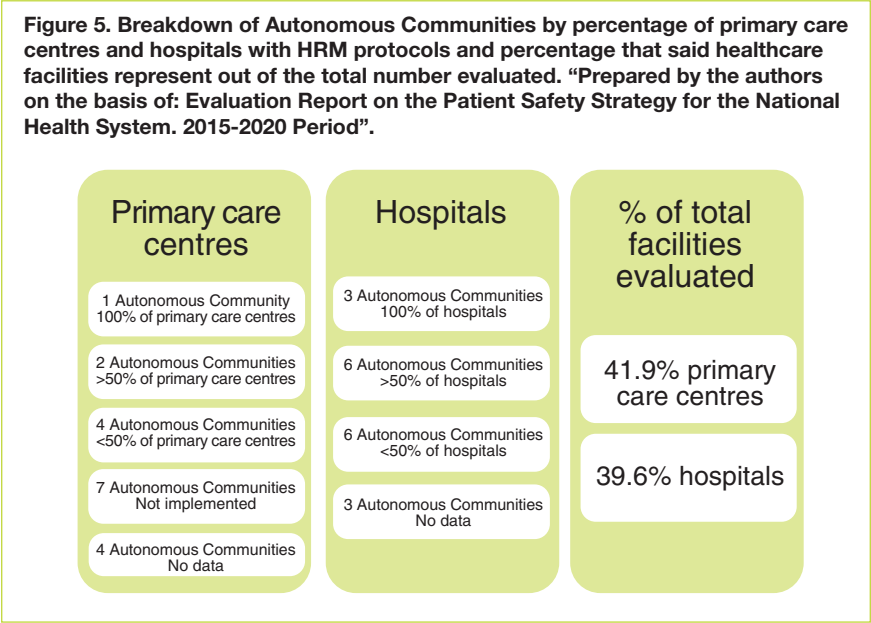


Figure 6. Breakdown of Autonomous Communities by percentage of hospitals that have adopted actions to improve the use of medication in chronic patients on multiple prescriptions and the percentage that said hospitals represent out of the total number evaluated. “Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.



Figure 7. Breakdown of Autonomous Communities by percentage of hospitals that have adopted medication reconciliation on discharge actions and percentage that such hospitals represent out of the total number evaluated. “Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.



**Table 2. Recommendations – Strategic line of action 2, General objective 2.1.
Evaluation Report on the Patient Safety Strategy for the National Health System.
2015-2020 Period**

Ministry of Health	Work with the Autonomous Communities to develop projects to increase safety in the use of different therapeutic classes and high-risk medication, especially as regards high-risk patients and areas
	Work with the Autonomous Communities to implement multidisciplinary programmes for medication reconciliation during transitions of care
	Develop and agree on recommendations for medication reconciliation in primary care with the Autonomous Communities
	Improve the visibility of medication safety actions by posting relevant content on the Patient Safety web page of the Ministry of Health's website
	Hold seminars to share safe practices
	Undertake periodic evaluations of actions agreed with the Autonomous Communities
	Produce information materials and tools targeted at patients and professionals to share and apply the 5 Moments for Medication Safety tool
	Improve information provided to professionals and patients on the risks of low-value prescribing practices
	Encourage the reporting of medication incidents through existing systems
Autonomous Communities	Distribute information on measures to remedy problems identified by reporting systems that require action due to the frequency or seriousness of the incidents recorded
	Inform healthcare facilities of medication safety projects, recommendations and materials
	Identify a coordination group of Autonomous Communities to lead the application and evaluation of projects and specific actions to increase medication safety
	Carry out projects to increase safety in the use of different therapeutic classes and high-risk medication at hospitals and primary care centres
	Foster implementation of programmes for medication reconciliation on hospital discharge and at primary care centres
	Consolidate the adoption of IT tools facilitating prescription and tools facilitating medication reconciliation
	Hold periodic meetings with local leaders/managers to review the implementation of projects and progress on objectives
	Prepare periodic reports on the findings of evaluations and measures to improve projects/actions
	Hold seminars to share safe practices
	Foster/carry out training actions
	Pursue actions to actively engage patients and caregivers
	Improve incident reporting and management
	Improve the transfer of data to the primary care database
	Promote do-not-do recommendations in management agreements with healthcare facilities and periodically evaluate them

**Table 2. Recommendations – Strategic line of action 2, General objective 2.1.
Evaluation Report on the Patient Safety Strategy for the National Health System.
2015-2020 Period**

Autonomous Communities	Analyse recorded incidents to establish measures to prevent recurrence
	Foster self-assessment/analysis of medication risks at healthcare facilities
Healthcare facilities	Identify healthcare facility leaders who favour the implementation of projects/ actions
	Share recommendations and safe practices with professionals at the facility
	Implement priority projects and actions at Autonomous Community level
	Implement multidisciplinary programmes for medication reconciliation
	Evaluate the projects and actions carried out
	Provide information to patients and their caregivers and foster a safety culture
	Analyse the incidents reported for each medication, establishing actions to reduce occurrence of the most common incidents

General objective 2.2: Promote safe practices for preventing and controlling healthcare-associated infections

Healthcare-associated infections (HAIs) are one of the **most easily preventable** causes of serious adverse events (SAEs) in hospitalized patients. Because of the **high morbidity and mortality rates and increase in healthcare costs caused by HAIs**, preventing and controlling them is a priority for improving the quality of care provided by healthcare facilities. The **prevention and control of HAIs** requires the following: robust surveillance systems that enable analysis of sufficient, high-quality data; the application of practices of proven effectiveness; and prudent and proper use of antibiotics.

The main types of HAIs are those related to invasive procedures. Examples include surgical site infections, catheter-associated urinary tract infections (UTIs), catheter-related bloodstream infections and ventilator-associated pneumonia.

Multimodal, interdisciplinary programmes and strategies, such as the **Hand Hygiene Programme and the Critical Patient Safety Programme** have proven effective in preventing HAIs.

The **monitoring** of general objective 2.2 covered in the *Evaluation Report* refers to various indicators pertaining to the two key programmes—the Hand Hygiene Programme and the Critical Patient Safety Programme—and to their different projects (Zero Bloodstream Infections, Zero Pneumonia, Zero UTIs and Zero Resistance).

WHO considers **hand hygiene** to be the most important measure for reducing HAIs and the transmission of multidrug-resistant organisms

(MDROs). The current National Health System Patient Safety Strategy highlights hand hygiene as a safe, simple, economical and effective practice and underscores the need to expand the Hand Hygiene Programme to include all healthcare facilities.

The *Evaluation Report* found that **point-of-care alcohol-based hand rubs (ABHRs)** were available in 97% of **Intensive Care Units (ICUs)** across the National Health System and 10 Autonomous Communities reported that they were in place at 100% of their ICUs (*Figure 8*). Of the hospitals evaluated, 80% reported that **ABHRs were available at points of care in inpatient wards** (*Figure 9*).

Overall compliance with hand hygiene measures stands at 60% and use of ABHRs at 52%. Monitoring compliance requires training and resources, which in turn require a safety culture and leadership from healthcare managers.

The conclusion of the evaluation of the **Hand Hygiene Programme indicators** is that the programme has been firmly established within the National Health System, but there is still plenty of room for improvement.

Hand hygiene was crucial to addressing the health crisis caused by the COVID-19 pandemic, and that must be taken into account when interpreting 2020 data.

As regards the **Critical Patient Safety Programme**, of all patients, those in ICUs are most at risk of suffering an AE, given the complexity of the care they receive. This is why the Ministry of Health is spearheading this programme, which includes a number of projects focused on implementing safe practices at ICUs: Zero Bloodstream Infection, Zero Pneumonia, Zero UTIs and Zero Resistance.

As with the Hand Hygiene Programme, different indicators were evaluated for all of these projects. It was found that rates of **bloodstream infection** (whether primary or catheter-related) have remained low and that **ventilator-associated pneumonia** rates continue to fall, as do UTI rates.

It was also determined that the percentage of **patients with one or more multidrug-resistant bacterial infections** when admitted to an ICU has increased in recent years; however, the number of infections suffered during ICU stays has fallen.

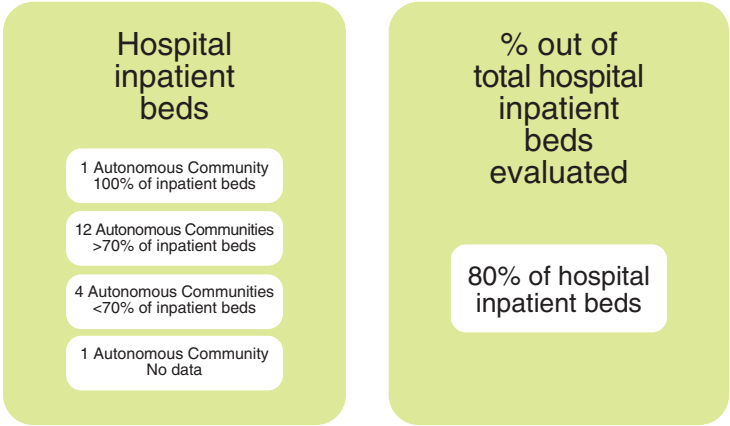
The findings show that the **ICUs that are participating in the Zero projects** present lower infection rates than those that are not. Despite the reduction in the rates of infection caused by medical devices in National Health System ICUs, **considerable variability** was identified in the analysis of the data contributed by the Autonomous Communities.

The monitoring of this objective resulted in a number of recommendations for different levels of action (*Table 3*).

Figure 8. Breakdown of Autonomous Communities by percentage of ICU beds with point-of-care ABHR dispensers and the percentage that said ICU beds represent out of the total number evaluated. “Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.



Figure 9. Breakdown of Autonomous Communities by percentage of inpatient hospital beds with point-of-care ABHR dispensers and the percentage that such beds represent out of the total number evaluated. “Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.



**Table 3. Recommendations – Strategic Line of Action 2, General Objective 2.2.
Evaluation Report on the Patient Safety Strategy for the National Health System.
2015-2020 Period**

Ministry of Health	Hold periodic meetings with the national coordination group for the Hand Hygiene Programme
	Review the indicators evaluated with the coordination group
	Analyse the variability among Autonomous Communities with the coordination group
	Strengthen hand hygiene in all patient safety programmes
	Hold specific seminars to improve hand hygiene
	Improve coordination with institutions to strengthen the messaging of annual hand hygiene campaigns
	Maintain/bolster collaboration with WHO
	Hold meetings with the Critical Patient Safety Programme Advisory Council
	Share findings and impediments to correct implementation identified on an annual basis
	Conduct an in-depth analysis of the factors associated with the variability of the rates of HAIs in ICUs among Autonomous Communities
	Carry out efforts in the framework of the National Action Plan against Antimicrobial Resistance to promote programmes to reduce antimicrobial resistance
Autonomous Communities	Align safety programmes for the prevention and monitoring of HAIs with national programmes for the surveillance of said infections
	Coordinate the monitoring of the Hand Hygiene Strategy at Autonomous Community level
	Identify the individuals responsible for the Hand Hygiene Programme at the Autonomous Community and local levels
	Ensure that point-of-care ABHR dispensers are in place in healthcare facilities, and especially in their ICUs
	Hold periodic meetings with healthcare facility managers
	Train teams to evaluate adherence to hand hygiene standards and recommendations in all Autonomous Communities
	Recognize the healthcare facilities that comply with the Programme
	Ensure that healthcare facility managers are committed to the Hand Hygiene Programme
	Hold seminars at Autonomous Community level on the strategy and its results
	Update programme leaders at Autonomous Community level
	Hold meetings with the coordinators of the Critical Patient Safety Programme in all Autonomous Communities
	Hold periodic meetings with the coordinators of the Critical Patient Safety Programme at hospitals
	Promote the training of healthcare staff in the Zero projects
	Share results at an annual seminar

Table 3. Recommendations – Strategic Line of Action 2, General Objective 2.2. Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period

Healthcare facilities	Apply the recommendations of the Hand Hygiene Programme
	Ensure that Hand Hygiene Programme data and indicators are properly recorded
	Conduct audits on compliance with hand hygiene guidance
	Establish the measures adopted to implement and evaluate the Zero projects in ICUs
	Ensure that Zero project leaders share data on HAs in their ICUs
	Ensure that Zero project leaders foster training of health professionals on this matter

General objective 2.3: Promote the adoption of safe surgical practices

In developed countries, surgery is one of the pillars of medical treatment. However, it is not without associated complications.

The **main complications** during surgical procedures are the result of factors such as poor communication between team members; errors regarding patient identification, the nature of the procedure to be performed, or the surgical site; problems with equipment; medication errors, especially during anaesthesia; unexpectedly high blood loss; and surgical items unintentionally left inside patients when closing wounds.

Measures must be taken to minimize these risks, including the use of a **Surgical Safety Checklist (SSC)** and actions to **prevent surgical site infections**. This requires specific multimodal and multidisciplinary strategies that address factors related to **improving the safety culture** in surgical units and the application of safe clinical practices to improve the quality of care received by surgical patients.

Safe surgical practices are included in the Safety in Surgery Programme, spearheaded by the Ministry of Health, which includes the **Safe Surgery** and **Zero Surgical Site Infection Projects**.

The aim of the **Safe Surgery Project** is to create a collaborative network of surgical units from different specialities that apply safe practices of proven effectiveness and share tools to foster safety. It primarily seeks to foster the **use of the Surgical Safety Checklist**, a simple, efficient measure of proven effectiveness for improving patient safety during surgical procedures, facilitating compliance with a universal protocol (correct patient, procedure and site). The Surgical Safety Checklist underscores the importance of good communication and teamwork and should be utilized, at minimum, for all scheduled surgeries.

The **Zero Surgical Site Infection Project**, which has been implemented across Spain since 2017, seeks to reduce surgical site infection rates at healthcare facilities and contribute to controlling such rates across the National Health System. It focuses on promoting a number of **preventive practices**, grouped into a bundle of five measures of proven effectiveness: antibiotic prophylaxis, use of alcoholic chlorhexidine, hair removal, perioperative normothermia and perioperative normoglycaemia.

Progress towards this objective was evaluated using indicators of the levels of implementation of the two projects and the performance over time of various National Health System indicators obtained from the Specialized Care Register Minimum Basic Data Set (RAE-CMBD).

According to the data contributed by the Autonomous Communities, only 51 hospitals (19.5%) were taking part in the Safe Surgery Project. Only four Autonomous Communities stated that 100% of their hospitals had adopted the guidelines of the Safe Surgery Project (Figure 10).

Only five Autonomous Communities reported that all surgical unit professionals at participant hospitals **had received training in the content of the programme**.

Application of the **Surgical Safety Checklist** in scheduled surgeries **was found to be rare**, with only one Autonomous Community using it for all surgeries. However, given the low rate of participation of the Autonomous Communities in the project and the lack of responses, the data obtained for this indicator cannot be considered representative of the National Health System.

The indicators regarding **practices to prevent surgical site infection** showed an encouraging trend, except for the indicator relating to normothermia. Surgical site infection rates have fallen, except in the case of minimally invasive thoracic surgery for aortic-coronary bypasses.

The data also reflected a decrease in the **readmission and repeat surgery rates** recorded in the Zero Surgical Site Infection Project. By contrast, the data obtained from the Specialized Care Register Minimum Basic Data Set (RAE-CMBD) showed an upward trend in readmissions. This is because the indicators do not refer to the same population group, the same surgical procedures or the same period.

A number of recommendations for making surgery safer have been put forward on the basis of the conclusions of the *Evaluation Report* (Table 4).

Figure 10. Breakdown of Autonomous Communities by percentage of hospitals participating in the Safe Surgery Project and the percentage that said hospitals represent out of the total number evaluated. “Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.

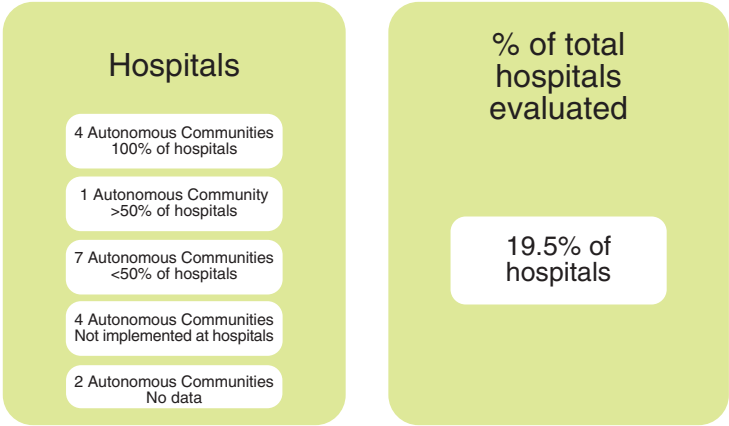


Table 4. Recommendations – Strategic line of action 2, General objective 2.3. Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period

Ministry of Health	Promote the recommendations of the Safety in Surgery Programme and align them with other National Health System actions to improve quality and safety
	Share the results of the programme and barriers to implementation identified with coordinators at the Autonomous Community and healthcare facility levels to identify measures for improvement
	Analyse the factors linked to variability in surgical site infection rates at participant hospitals
	Review, assess and update surgical unit managers on the indicators to be evaluated
Autonomous Communities	Review with the Autonomous Communities the key National Health System patient safety indicators referring specifically to surgery and their usefulness in clinical practice
	Update the leaders of the programme at Autonomous Community level
	Coordinate the rollout of the programme in the sphere of the Autonomous Communities
	Encourage all hospitals of the Autonomous Communities to join the programme
	Organize meetings with the regional coordinators of the programme to review implementation and the actions required to achieve objectives

**Table 4. Recommendations – Strategic line of action 2, General objective 2.3.
Evaluation Report on the Patient Safety Strategy for the National Health System.
2015-2020 Period**

Autonomous Communities	Promote health worker training
	Establish actions to foster the sharing of safe surgical practices among the hospitals of all Autonomous Communities
	Safeguard resources for controlling infection. Enrich surveillance of HAIs through the programme. Integrate, systematize and digitalize relevant documentation in the different electronic health records
	Share the results of the programme at Autonomous Community level
Healthcare facilities	Ensure that management and senior management committed to patient safety establish the necessary measures for the implementation, development and evaluation of the programme
	Ensure that programme leaders at each hospital foster training of professionals, gathering of data, sharing of results and proposal of corrective measures
	Ensure that the programme is incorporated into quality and patient safety plans
	Conduct internal audits on compliance with the programme guidelines

General objective 2.4: Promote the implementation of safe practices in patient care

Safe practices entail drawing up **patient-specific care plans** for inpatient and at-home care. Such plans must be based on proper assessment and include, among other measures, those to prevent pressure ulcers and injuries from falls and, in certain cases, the use of physical restraints.

Efforts must be made to foster adoption of practices of proven effectiveness. All matters concerning a patient's safety must be reflected in their **health records and in the hospital discharge report**.

This objective was **monitored** by reference to indicators regarding the definition of care plans for inpatients, the appearance of pressure ulcers in patients admitted for more than 48 hours, the number of falls suffered by inpatients and an indicator on hospitals that use physical restraints.

Most Autonomous Communities stated that they used **care plans for inpatients**; however, not all such plans are mentioned in hospital discharge reports. Multiple sources and diverse modes of evaluation led to variability in the data. Moreover, five Autonomous Communities provided no data for this indicator. Consequently, caution should be exercised in extrapolating the results to the National Health System as a whole.

Similarly, data regarding pressure ulcers and fall-related injuries is potentially skewed by possible underreporting, the different sources of data and measurement methods used, as well as by possible differences in the evaluation of different types of patient.

Only 61% of the Autonomous Communities reported that they had implemented a **protocol on the safe use of physical restraints**.

On the basis of these data, the *Evaluation Report* included a number of recommendations for the Ministry of Health, the pertinent authorities of the Autonomous Communities and healthcare facilities (*Table 5*).

Table 5. Recommendations Strategic line of action 2, General objective 2.4. Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period	
Ministry of Health	Review the indicators evaluated with the Autonomous Communities to identify and select those that may have standardized data sources
	Foster training in the use of and development of evidence-based products to improve patient care, both at hospitals and at primary care centres
	Promote the creation and use of patient care records
Autonomous Communities	Establish actions to improve the recording of healthcare-associated AEs
	Establish a multidisciplinary coordination group to promote actions to improve patient care at all levels, with particular emphasis on preventing pressure ulcers and falls
	Establish mechanisms to prevent use of physical restraints on patients with mental health conditions
Healthcare facilities	Ensure that hospital and primary care centre managers establish the necessary measures for preparation of patient-specific care plans that include clinical practices of proven effectiveness in preventing pressure ulcers and falls
	Identify senior nurses that promote the preparation, use and evaluation of care plans
	Include care plans in patients' health records and hospital discharge reports and evaluate them and update them periodically

General objective 2.5: Promote the correct identification of patients

Introducing measures to ensure **correct patient identification** is recommended to prevent errors that could have serious consequences during the use of medicines, surgical procedures, diagnostic tests and invasive tests, among others. Identification errors could have major repercussions such as misdiagnosis or administration of medication to the wrong patient.

It is important to guarantee patients are correctly identified when a procedure of any kind is to be performed on them, especially if it is invasive.

To evaluate this objective, the Autonomous Communities reported data for indicators of implementation of **protocols for** correct identification of **inpatients** and patients requiring **high-risk procedures** and for identification and traceability of **biological samples**.

According to the findings of the *Evaluation Report*, most hospitals have a protocol for correct patient identification (*Figure 11*). However, the rate

of implementation for protocols to **correctly identify patients undergoing high-risk procedures is low**, with only five Autonomous Communities reporting such a protocol in place at 100% of their hospitals (*Figure 12*).

The data on **identification and traceability of biological samples** revealed the lowest implementation rates in this subgroup of indicators (*Figure 13*).

The evaluated indicators measure structural aspects; however, they do not enable assessment of whether the specific recommendations of the different protocols are applied. Other specific indicators or audits would be required to perform such an assessment.

Based on the above findings, the *Evaluation Report* includes recommendations for achieving this objective (*Table 6*).

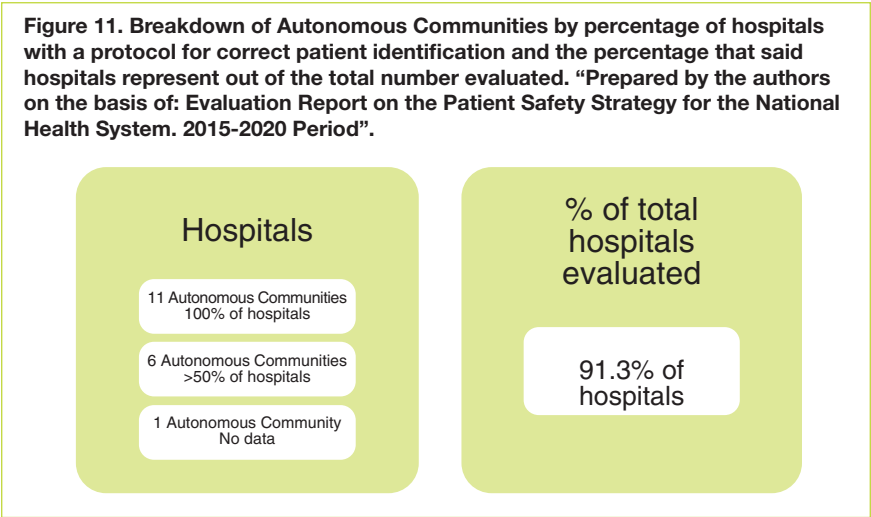


Figure 12. Breakdown of Autonomous Communities by percentage of hospitals with protocols for correct patient identification for high-risk procedures and the percentage that said hospitals represent out of the total number evaluated.
“Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.

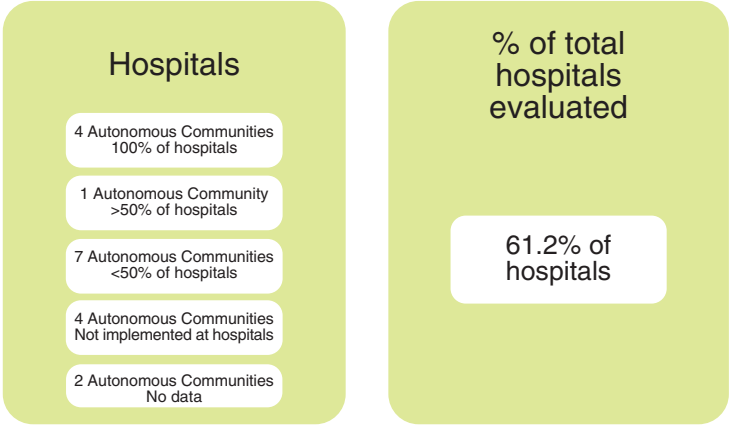
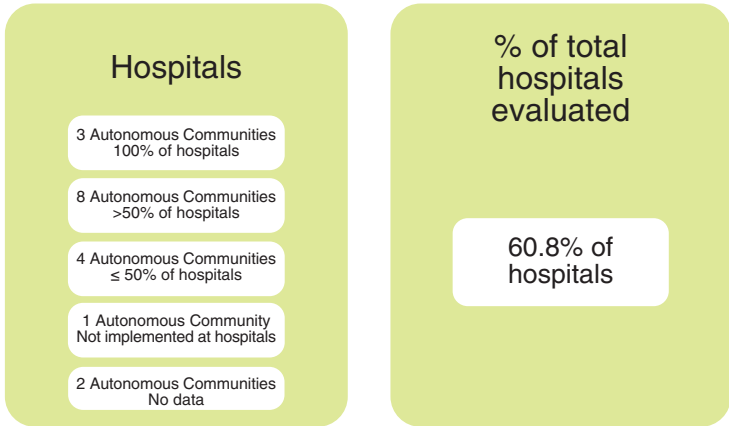


Figure 13. Breakdown of Autonomous Communities by percentage of hospitals with a protocol for identification and traceability of biological samples and the percentage that said hospitals represent out of the total number evaluated.
“Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.



**Table 6. Recommendations, Strategic line of action 2, General objective 2.5.
Evaluation Report on the Patient Safety Strategy for the National Health System.
2015-2020 Period**

Ministry of Health	Share results for these indicators with Autonomous Communities and identify those that are the most useable and useful
	Through the Network of Health Schools for Citizens, foster the sharing of information to involve patients in their identification
Autonomous Communities	Implement standardized systems for the correct identification of patients and biological samples at all hospitals in all the Autonomous Communities
	Foster evaluation of the protocols applied
Healthcare facilities	Organize specific training for professionals on the importance of the correct identification of patients and samples
	Carry out periodic evaluations of the process for correct patient identification and identify errors in order to adopt future improvements
	Incorporate correct patient identification measures into quality plans and patient safety plans

General objective 2.6: Promote communication among professionals

Measures must be in place to ensure that **information** shared by professionals on a patient's clinical status while they are receiving care is **correct, sufficient and addressed to the right person**.

Communication, especially during transitions of care, is a key element in the transfer of clinical information. Breakdowns in communication between professionals are a common factor in sentinel events, i.e. unforeseen events that cause serious physical or psychological harm or even death, or that present a risk of causing such harm.

Standardizing the communication process during transitions of care minimizes the variability of messages and contributes to the effectiveness of the process, helping to ensure that all the professionals involved are aware of the patient's clinical status, thereby reducing the risk of error.

The *Evaluation Report* does not include data for indicators specifically monitoring this aspect.

General objective 2.7: Promote the design and development of strategies for dealing with serious adverse events at healthcare facilities

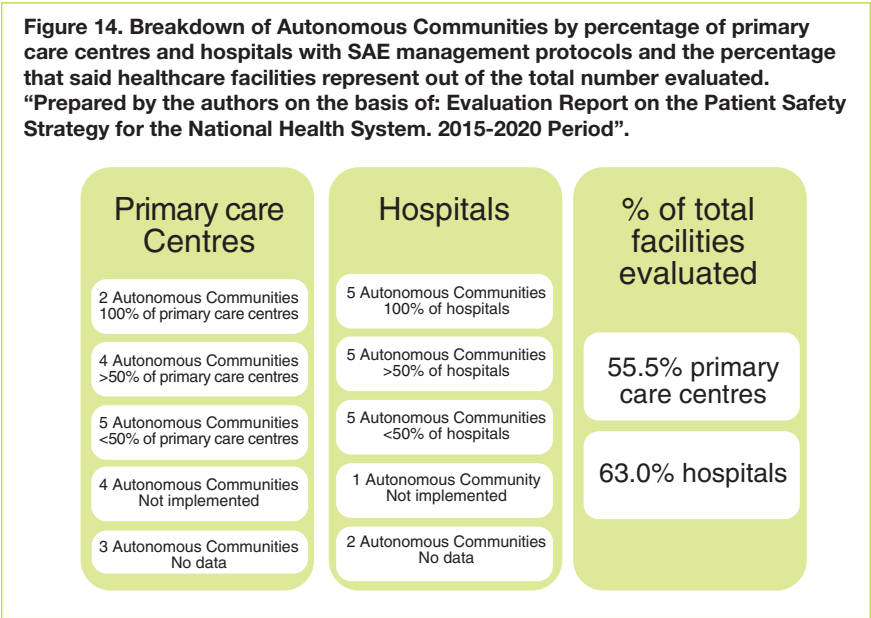
When AEs—and especially SAEs—occur, **patients and family members** (first victims) must be **supported** by healthcare organizations and receive **all the information they need** to understand the consequences. Moreover, the **right steps** must be taken to meet their needs.

Similarly, **health professionals** (second victims) involved in AEs must receive **institutional support** to be able to properly report the circumstances of such events and must also be supported to ensure a return to work without after-effects.

Healthcare organizations (third victims) must attempt to maintain or restore their **reputations** and the **trust** of the people who use their services. They must adopt a **proactive attitude** in order to anticipate and prevent conflict, implementing protocols and procedures to respond appropriately to patients and professionals when SAEs occur.

The *Evaluation Report* included a consensus reached with the Autonomous Communities on the need to **promote and analyse protocols** for proper management of SAEs, which would enable the needs of patients, health professionals and institutions to be met. Therefore, the report measured indicators of implementation of such protocols by hospitals and primary care centres, finding low implementation levels and ample room for improvement (*Figure 14*).

A number of different recommendations were issued on the basis of these findings at the national, Autonomous Community and healthcare facility levels (*Table 7*).



**Table 7. Recommendations - Strategic line of action 2, General objective 2.7.
Evaluation Report on the Patient Safety Strategy for the National Health System.
2015-2020 Period**

Ministry of Health	Develop a framework with clear instructions and indications for management of SAEs across the National Health System
	Share recommendations with healthcare facilities
	Improve handbooks on how to support patients that have suffered an AE and on supporting second victims
	Design an action plan for the short, medium and long term to foster proposals for legislative reform on patient safety in Spain
	Share details of the SAEs analysed to facilitate learning and reduce their occurrence
Autonomous Communities	Promote plans for the proper management of SAEs, both at primary care centres and at hospitals
	Establish training on aspects of caring for and supporting patients and professionals involved in SAEs
Healthcare facilities	Establish a plan for managing SAEs that actively engages management teams and professionals, is adapted to the circumstances of the healthcare facility and includes actions relating to the patients/family members affected by SAEs and the professionals involved

General objective 2.8: Promote the safe use of ionizing radiation in medical-radiological procedures

Advances in medical **radiation** technology (diagnostic radiology, radiotherapy and nuclear medicine) have improved the diagnosis and treatment of disease, greatly benefitting patients. Owing to the increased use of this technology, over recent years **medical exposure** has become the most common form of human exposure to artificial radioactivity.

Despite the beneficial applications of ionizing radiation, as its use increases, so do the possible health hazards if it is misused or not used at the appropriate dose. Exposure to high doses of ionizing radiation can have acute adverse effects such as burns, while long-term exposure at low doses can increase the likelihood of developing certain kinds of cancer.

At the international level, organizations such as WHO and the International Atomic Energy Agency (IAEA) have promoted the **International Action Plan for the Radiological Protection of Patients** in the healthcare sector. Minimum basic, harmonized criteria for patient safety in this area were agreed at the latest International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy.

At the national level, the *Framework Agreement between the Ministry of Health and the Nuclear Safety Council (CSN)* lays the foundations for

collaborative promotion of the **safe and controlled use of ionizing radiation in the National Health System**. The patient safety guidelines concerning ionizing radiation implement the provisions of Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

Spain's legal framework includes specific legislation on this matter such as Royal Decree 601/2019 of 18 October, on the grounds for and optimization of the use of ionizing radiation for the radiological protection of persons subject to medical exposure and Royal Decree 673/2023 of 18 July, laying down quality and safety criteria for nuclear medicine units.

This legislation lays the foundations for patient protection and for awareness-raising about ionizing radiation and its proper usage.

The *Evaluation Report* **examined** the safe use of this radiation through indicators to gather information from the hospitals of the Autonomous Communities on training for paediatric professionals on optimizing the ordering of tests using radiation, on risk mapping of radiotherapy and nuclear medicine unit processes and on drafting annual reports describing safety incidents at such units.

As regards **continuous training for paediatric professionals** at hospitals, only 25% of the 16 Autonomous Communities that reported data provided such training at more than 50% of their hospitals with paediatrics services (*Figure 15*).

The number of radiotherapy and nuclear medicine units that reported **mapping risks and preparing annual incident reports** was low. Four Autonomous Communities reported risk mapping at 100% of their hospitals (*Figure 16*), while six reported that 100% of their hospitals issued annual incident reports (*Figure 17*).

In response to these findings, the Evaluation Report made a number of recommendations to further progress towards this objective (*Table 18*).

Figure 15. Breakdown of Autonomous Communities by percentage of hospitals that provide training to paediatric professionals on optimizing the ordering of tests using ionizing radiation and the percentage that said hospitals represent out of the total number evaluated. “Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.



Figure 16. Breakdown of Autonomous Communities by percentage of hospitals that map risks in radiotherapy and/or nuclear medicine unit processes and the percentage that said hospitals represent out of the total number evaluated. “Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.

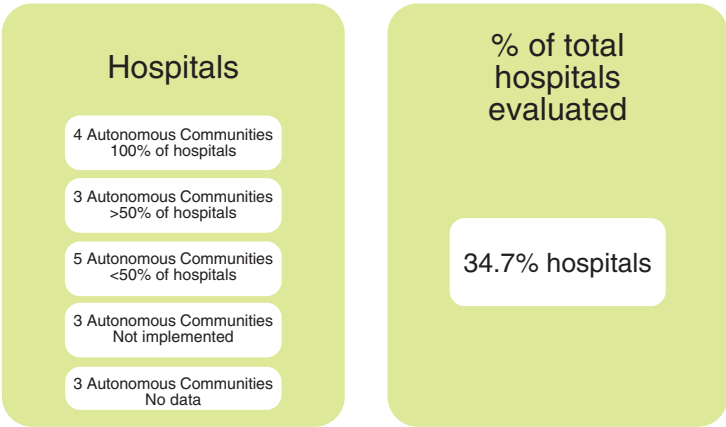


Figure 17. Breakdown of Autonomous Communities by percentage of hospitals whose radiotherapy and/or nuclear medicine units issue annual incident reports and the percentage that said hospitals represent out of total number evaluated. “Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.



Table 8. Recommendations - Strategic line of action 2, General objective 2.8. Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period

Ministry of Health	Strengthen collaboration between the Ministry of Health and the Nuclear Safety Council on the protection of persons in the use of ionizing radiation for medical purposes
	Share with the Autonomous Communities details of the incidents caused by ionizing radiation recorded in the safety incident reporting systems of the National Health System as well as recommendations for preventing their recurrence
	Conclude the transposition of the Directive into Spanish law
	Implement quality assurance programmes at all services working with ionizing radiation
	Establish a coordination group at National Health System level to formulate and adopt recommendations and report on quality assurance and safety programmes relating to the use of ionizing radiation for medical purposes
	Identify and share good practices
	Facilitate Spanish participation in international initiatives
Autonomous Communities	Ensure that healthcare facilities implement quality assurance and safety programmes in relation to the use of ionizing radiation
	Establish a coordination group to ensure monitoring of established standards
	Provide training to doctors who order tests and prescribe treatments on the use of ionizing radiation procedures

**Table 8. Recommendations - Strategic line of action 2, General objective 2.8.
Evaluation Report on the Patient Safety Strategy for the National Health System.
2015-2020 Period**

Autonomous Communities	Promote the internal and external evaluation of quality assurance and safety programmes at healthcare facilities, including clinical audits
	Adopt measures to improve the information provided to doctors who order tests and prescribe treatments on the effective doses received by patients
	Identify and share good practices
	Foster the inclusion of radiation doses administered in patients' health records
Healthcare facilities	Adopt a quality assurance and safety programme in relation to the medical use of ionizing radiation that meets the criteria set forth in national or international protocols
	Establish a committee to ensure adoption of the programme and monitor its implementation
	Guarantee training for the relevant professionals and the evaluation of mandatory courses for Health Science residents
	Establish mechanisms for proper reporting and management of incidents and related communications

3. Strategic line of action 3: Risk management and systems for reporting and learning from incidents

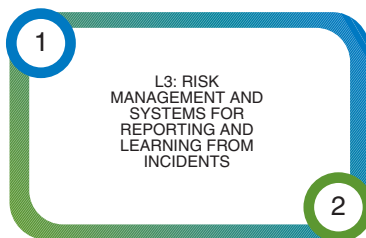
Managing healthcare-related risks entails studying patient safety-related incidents, taking steps to prevent their recurrence, and updating professionals on the progress made.

Healthcare facilities must develop **specific strategies** for the proper management of healthcare-related risks, including their identification and analysis. They must also develop **reporting systems** that enable the sharing of information and of lessons learned—not only at a local level but also between different facilities—to prevent errors and find solutions to problems, thus improving the safety of the care provided.

These actions shall be focused on achieving the two general objectives of this strategic line of action (*Figure 18*).

Figure 18. General objectives of Strategic line of action 3. Patient Safety Strategy for the National Health System. 2015-2020 Period

01: Promote risk management at healthcare facilities



02: Promote the implementation and development of systems for reporting and learning from healthcare-related incidents

It should be noted that health professionals have been found to be somewhat reluctant to report incidents for fear of possible punishment. This affects the quality of reporting systems and the optimization of the information recorded.

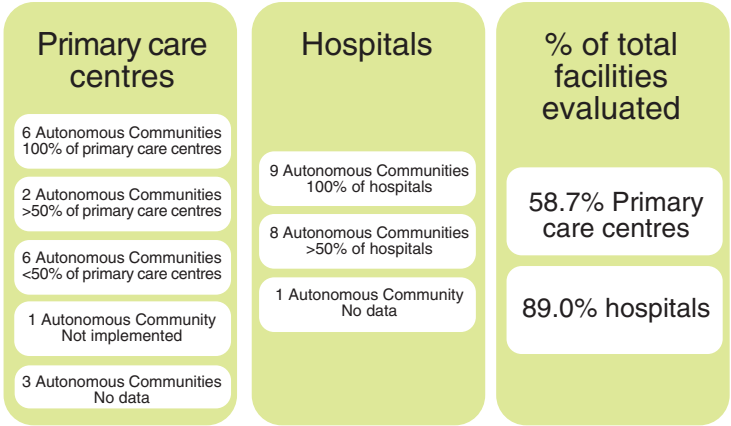
General objective 3.1: Promote risk management at healthcare facilities

Risk management at healthcare facilities aims to **improve the quality and safety of the services provided** through tools that enable better detection of errors, reduce their probability and mitigate their consequences.

To achieve the above-stated objectives, the creation of **risk management units (RMUs)** is recommended. The evaluation of this objective was based on indicators identifying hospitals and primary care centres with RMUs.

The findings showed that many hospitals had RMUs; 17 Autonomous Communities reported having operational RMUs at more than 50% of their hospitals. However, uptake in primary care was lower, with only eight Autonomous Communities reporting that they had RMUs at more than 50% of their primary care centres (*Figure 19*).

Figure 19. Breakdown of Autonomous Communities by percentage of hospitals and primary care centres that have RMUs and the percentage that said healthcare facilities represent out of the total number evaluated. “Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.



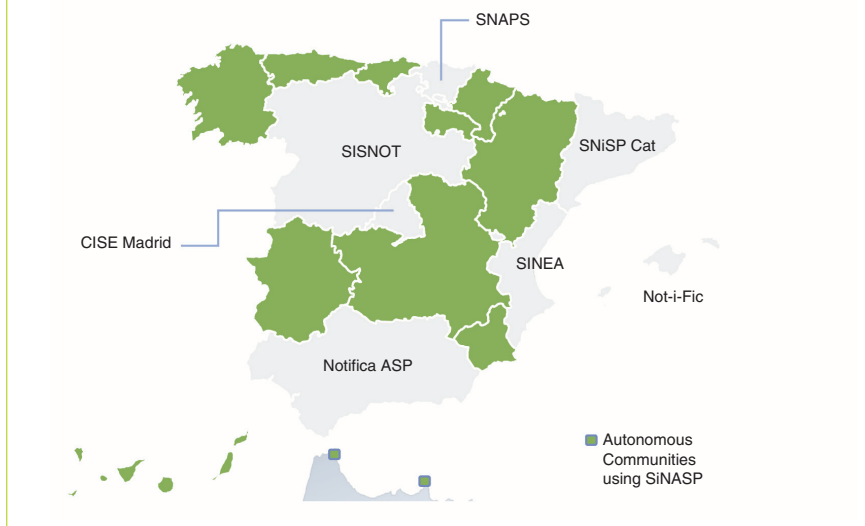
General objective 3.2: Promote the implementation and development of systems for reporting and learning from healthcare-related incidents

The Ministry of Health is promoting the implementation of safety incident **voluntary reporting systems**. The aim of these systems is to improve patient safety by enabling analysis of situations, events or problems that caused, or could have caused, avoidable harm to patients. These systems are tools for **preventing errors**.

Such systems follow a structured process which begins with the professional’s detection of the incident and ends with the communication of information on corrective measures to all relevant members of staff at the organization. This process has six stages: detection, reporting, classification, analysis and management, implementation of improvements, and feedback.

Currently, 11 Autonomous Communities have adopted **SiNASP**, a system spearheaded by the Ministry of Health as part of the Patient Safety Strategy, and the remaining Autonomous Communities have developed their **own reporting systems** (*Figure 20*).

Figure 20. Map of Autonomous Communities in which SiNASP or another incident reporting system has been implemented. “Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.



SiNASP is available for hospitals and primary care centres and is particularly focused on **learning** for improvement.

Incidents logged in reporting systems are primarily **analysed** locally, meaning that the analysis is conducted internally at the facility at which the incident occurred. Healthcare facilities prepare **periodic reports** on incidents logged, analyses conducted and improvements implemented and share these reports internally. **Reports presenting aggregated data** on the incidents reported by all healthcare facilities using **SiNASP** in each Autonomous Community are also prepared and distributed at Autonomous Community level.

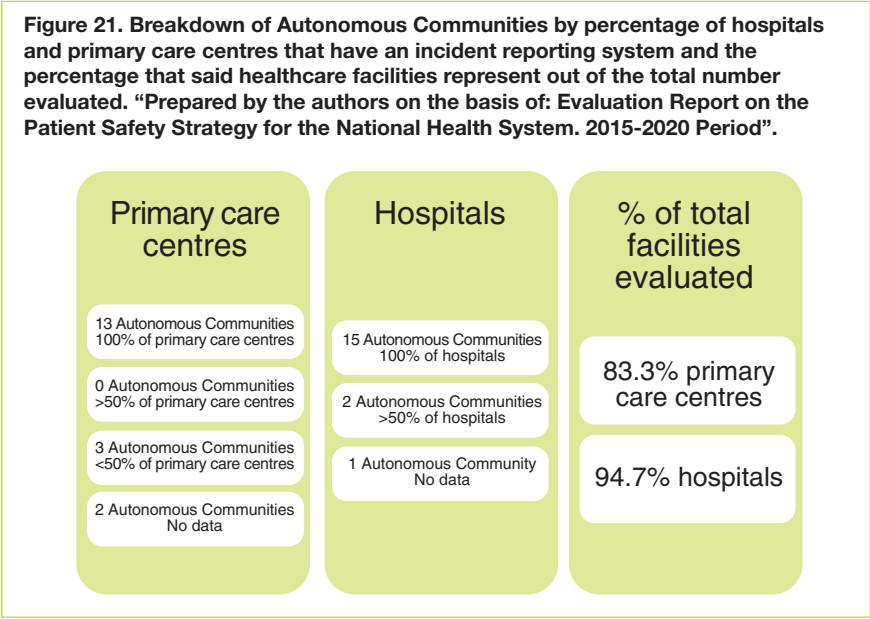
The aim of this general objective is to achieve **effective implementation** of incident reporting systems at all hospitals and primary care centres, and to encourage their use, to provide feedback to professionals and to publish/share information on safety incidents.

The *Evaluation Report* **examined progress on this objective** using 25 indicators that gather information from Autonomous Communities on adoption of incident reporting systems at hospitals and primary care centres, reporting of incidents, and classification of incidents according to whether they caused harm to the patient and whether they related to medication or the use of ionizing radiation. Additional indicators were taken into account that were obtained using SiNASP data on the number of incidents reported and the communication of subsequent actions carried out.

Based on that data, the *Evaluation Report* found that all Autonomous Communities have a safety incident reporting system. Fifteen Autonomous Communities reported having implemented a safety incident reporting system at 100% of their hospitals and 13 Autonomous Communities at 100% of their primary care centres (*Figure 21*).

The number of **incidents reported** across the National Health System was low and varied from one Autonomous Community to another; incidents **related to medication** were the most frequently reported. The considerable differences among Autonomous Communities may be because some report incidents related to medication through their drug safety monitoring systems.

A number of recommendations were proposed the basis of these data (*Table 9*).



**Table 9. Recommendations Strategic line of action 3, General objective 3.2.
“Evaluation Report on the Patient Safety Strategy for the National Health System.
2015-2020 Period”.**

Ministry of Health	Promote the use of incident reporting systems in the National Health System and the standardization of the data recorded
	Promote the training of medical residents on incident reporting systems
	Review incident reporting indicators with the Autonomous Communities to improve the definition and gathering of data
	Encourage the application of root cause analysis to any incidents that the reporting system management group select for such processing
	Strengthen the development and proper use of SiNASP in the Autonomous Communities that have adopted the system
	Put forward recommendations for analysis of AEs taking methodological and legal questions into account
	Promote national legislation to protect professionals that report and/or analyse AEs
	Involve senior management staff at primary care centres and hospitals in incident reporting
	Promote the sharing of good practices in incident reporting and management
Autonomous Communities	Establish a coordination group to monitor and evaluate risk management and reporting system actions
	Adopt actions to improve the training provided to health professionals on incident reporting
	Identify and encourage the sharing of good practices on incident reporting and management at healthcare facilities
	Inform health professionals of developments in this area on a periodic basis
	Maintain confidentiality
	Encourage the use of root cause analysis and the proposal of recommendations for safe management, taking potential legal action into account
Healthcare facilities	Foster senior management engagement with incident reporting at primary care centres and hospitals
	Ensure that the commitment of management and senior management staff to the incident reporting system is clearly reflected through feedback and through the inclusion of indicators in management agreements with teams/services
	Designate a professional to coordinate management of reported incidents
	Provide relevant training to professionals at healthcare facilities
	Maintain confidentiality
	Inform health professionals of developments in this area on a periodic basis
	Hold periodic sessions to examine the incidents reported and any associated factors and to draw up improvement plans

4. Strategic line of action 4: Participation of patients and the broader public for their safety

Participation is based on the right of each individual to have a say in the **decisions** that affect them, as well as on their **freedom of choice** within the healthcare system. This entails, among other aspects, providing patients and/or caregivers with the necessary information about their disease or condition to facilitate decision-making, as well as using admission plans, fostering training activities and establishing protocols for supporting inpatients.

However, healthcare facility managers and health professionals continue to show a certain degree of reticence that hampers both patient involvement in decisions made about their own care as well as collective public participation in healthcare decisions. Similarly, for cultural reasons, some patients remain hesitant to change their own role and profile within the healthcare system. Despite this, the **patient's role is changing**, with patients becoming increasingly well-informed and more interested in being actively involved in their treatment process. This calls for a significant cultural shift in the **health professional-patient relationship**, which must be based on **shared decision-making**.

In recent years, **empowerment of patients and their participation** in healthcare and in their own safety have become very important.

The specific actions referred to above relate to the single general objective of **promoting the participation of patients and their caregivers in patient safety**.

The indicators used in the *Evaluation Report* monitor, through data received from the Autonomous Communities, the adoption of inpatient admission plans and patient support protocols and the provision of training to patients regarding their own safety at healthcare facilities.

As regards **inpatient admission plans**, of the 16 Autonomous Communities that contributed data, only six had implemented such plans at 100% of their hospitals (*Figure 22*).

Training actions for patients are carried out in most Autonomous Communities both at hospitals and at primary care centres. However, only three Autonomous Communities carried them out at 100% of their hospitals and only two Autonomous Communities carried them out at all their primary care centres (*Figure 23*).

Fifteen Autonomous Communities contributed data on the implementation of *patient support protocols*, although only two had implemented these protocols at all of their hospitals (*Figure 24*).

On the basis of these data, the *Evaluation Report* proposes a number of recommendations at the levels of the Ministry of Health, the Autonomous

Communities and healthcare facilities to improve the individual and collective participation of patients and the broader public in healthcare and patient safety (*Table 10*).

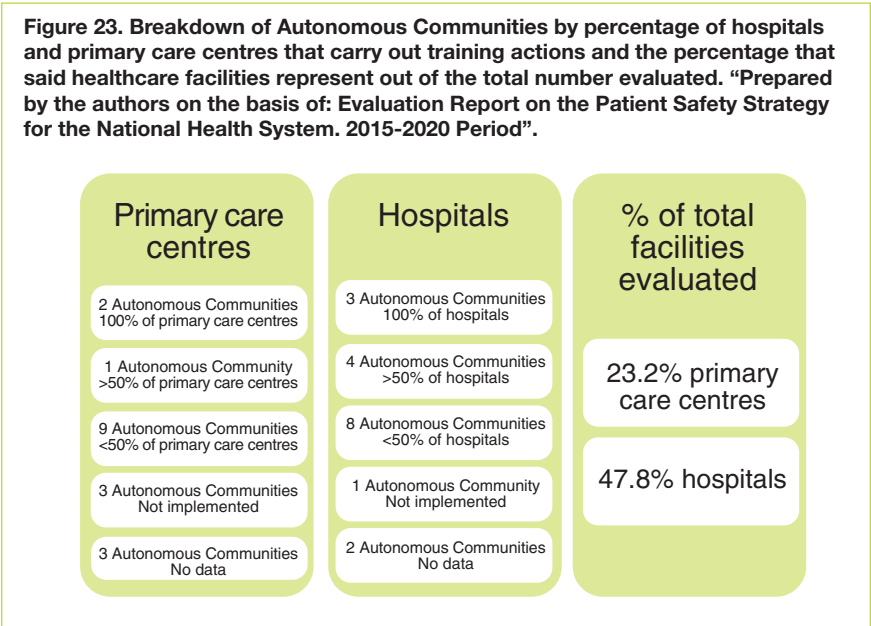
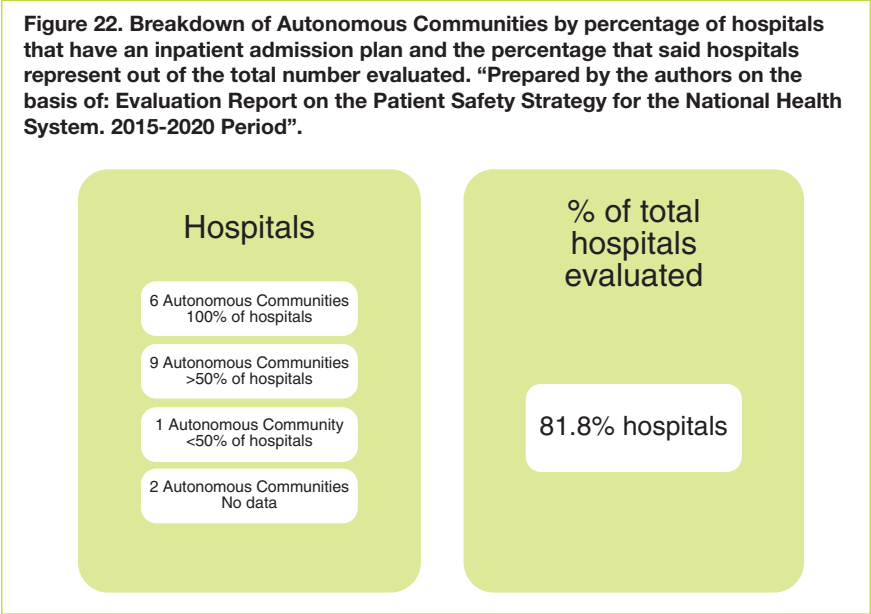


Figure 24. Breakdown of the 15 Autonomous Communities that provided the pertinent data by percentage of hospitals that have adopted patient support protocols and percentage that said hospitals represent out of the total number evaluated. “Prepared by the authors on the basis of: Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period”.

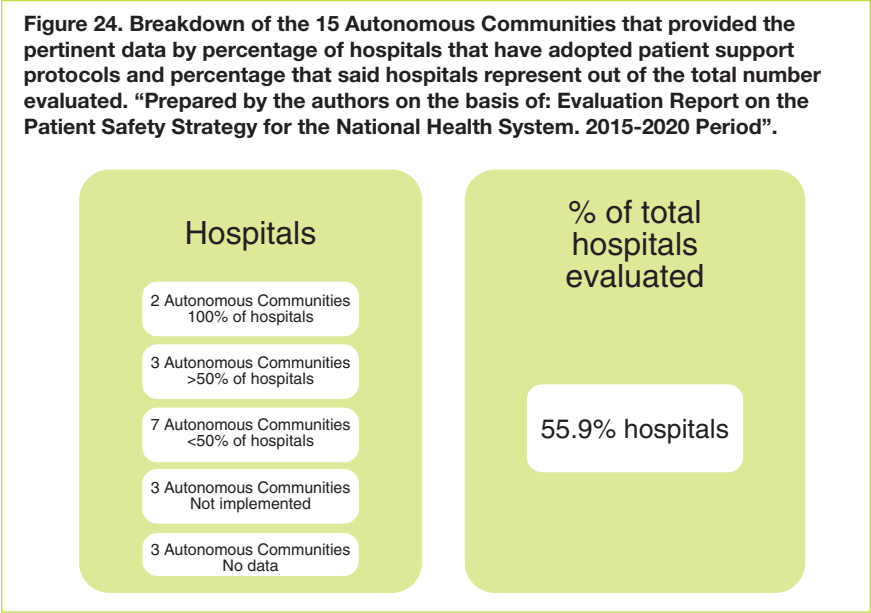


Table 10. Recommendations Strategic line of action 4, General objective 4.1. Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period

Ministry of Health	Promote the training of patients and family members on patient safety through the Network of Health Schools for Citizens
	Include the active participation of the main patients' associations in the Strategy
Autonomous Communities	Establish, implement and monitor inpatient admission plans at all hospitals in each Autonomous Community
	Establish, implement and monitor inpatient support plans at all hospitals in each Autonomous Community
	Promote the adoption of the Programme by all hospitals in each Autonomous Community
	Strengthen the Network of Health Schools for Citizens to promote the empowerment of patients and family members and facilitate their active participation in their own care
	Foster mechanisms of participation for patients' associations at the regional, provincial and local levels for the design, monitoring, measurement and communication of training activities and information to patients and caregivers
Healthcare facilities	Guarantee the active participation of patients in the patients' committees of healthcare facilities and/or healthcare districts, as well as that of family members, to improve the quality and safety of healthcare
	Establish mechanisms to implement and monitor an inpatient support plan
	Establish support mechanisms for the most vulnerable outpatients

5. Strategic line of action 5: Research into patient safety

Research into patient safety should aim to further knowledge about the scale and characteristics of clinical risks, to improve understanding of the factors that contribute to the occurrence of incidents and of the impact of AEs on the health system, and to identify cost-effective, feasible and sustainable solutions for providing safer care.

These aims are reflected in the general objective of **fostering greater knowledge about preventing healthcare-associated harm**.

Research projects on this matter, promoted by the Ministry of Health, can be found on the Patient Safety web page.

(<https://seguridaddelpaciente.sanidad.gob.es/proyectos/financiacionEstudios>)

In the framework of an agreement between the Ministry of Health and the Spanish Foundation for Science and Technology (FECYT), the *Evaluation Report* analysed the data on projects funded through **calls for applications** for national and European grants, as well as the **findings of research projects**. To this end, indicators were established with respect to patient safety projects funded with national and EU grants, the funding awarded, and the related patents applied for and granted.

The selection of data was validated manually by experts.

At the national level, grants were awarded for 27 patient safety projects during the period evaluated, with total funding of 3,848,011.50 euros.

At EU level, 13 projects were identified, 7 coordinated by Spain, with a total budget of 49,601,807.17 euros.

6. Strategic line of action 6: International participation

The Ministry of Health participates actively in activities carried out by WHO, the Pan American Health Organization (PAHO), the Organisation for Economic Co-operation and Development (OECD), the Council of Europe and the European Commission (EC) through programmes and groups focused on policymaking and technical aspects related to patient safety.

The sole general objective of this strategic line of action is **to foster international collaboration on patient safety**.

The most significant collaborations are listed below. Further information can be found on the **patient safety web page** (<https://seguridaddelpaciente.sanidad.gob.es/proyectos/participacionInternacional>):

- Patient Safety and Quality of Care Working Group: This is a working group of the High Level Group on health services and medical care of the European Commission. Operational from 2005 to 2016, this working group was established to coordinate strategies on patient

safety and quality of healthcare among Member States, creating a European network for collaboration. This working group proposed and collaborated actively in the preparation of the *“Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections”*.

- **EUNetPaS (European Union Network for Patient Safety):** This project, carried out from 2008 to 2010, was coordinated by the French National Authority for Health and funded in the framework of the European Commission Public Health Programme for 2007. Its objectives were to promote coherence at the EU level through sharing of knowledge, lessons and good practices, to promote a patient safety culture based on no-blame reporting and to promote education and information on patient safety.
- **European Union Network for Patient Safety and Quality of Care Joint Action (PaSQ-JA):** This project was co-funded by the European Commission as part of the Public Health programme for 2013 to 2016. Its aim was to support the implementation of the Council Recommendation on Patient Safety by strengthening cooperation between EU Member States, international organizations and EU stakeholders on issues related to quality of healthcare, including patient safety and patient involvement.
- **Methodology development and impact Assessment in Patient safety education for improving Effectiveness (MAP4E):** This project, which ran from 2016 to 2018, was funded under the EU Erasmus+ programme as part of Key Action 2 *“Cooperation for Innovation and the Exchange of Good Practices”* and aimed to develop and disseminate more effective educational courses for health professionals, enabling them to offer safer care based on good practices.
- **WHO patient safety programme:** the Ministry of Health collaborates in several different areas, primarily:
 - Clean care is safer care: supporting hand hygiene campaigns at several Spanish hospitals, following the WHO strategy. In addition, it has published a document providing guidance on how to apply the WHO Multimodal Hand Hygiene Improvement Strategy at primary care and outpatient care facilities.
 - Safe surgery saves lives: through the commitment of various Spanish professional societies to using the WHO **Surgical Safety Checklist**, which forms part of this specific patient safety challenge.
 - Research into Patient Safety
 - Linguistic validation of the Spanish version of the International Classification for Patient Safety: co-funding and co-managing this process.

- Global Patient Safety Action Plan 2021-2030. (<https://www.who.int/teams/integrated-health-services/patient-safety/policy/global-patient-safety-action-plan>)
- **Latin American Study of Adverse Events (IBEAS):** This 2010 study on the prevalence of hospital care-related adverse effects is the result of the collaborative efforts of Spain's Ministry of Health, WHO and the health authorities of Mexico, Peru, Argentina, Costa Rica and Colombia.
- **OECD:** Spain participates in the OECD Healthcare quality and outcomes programme, (formerly, the "Health Care Quality Indicators" (HCQI) programme) by providing data for healthcare quality indicators. An ad hoc sub-group has been created to assess the comparability of the indicators used in different OECD countries. This group also fosters indicator validity studies in each participant country. Other OECD publications on patient safety are available on the patient safety web page. (<https://seguridaddelpaciente.sanidad.gob.es/proyectos/participacionInternacional/ocde>).

In addition to the conclusions already shared with respect to the current strategic lines of action, we must also consider the Evaluation Report's conclusions, set out below, regarding the findings of the audits conducted at reference centres, services and units (hereinafter, reference facilities) and of various ad hoc questionnaires.

Evaluation of audits conducted at reference centres, services and units and ad hoc questionnaires

7. Reference facilities audit outcomes

The evaluation of **patient safety at reference facilities** commenced in 2018. This evaluation is based not only on the obligation of all professionals to **do no harm**, but also on the requirement for these facilities to roll out initiatives and strategies that **identify and minimize those risks** for patients that are inherent to the care they receive.

All reference facilities must undertake actions aimed at guaranteeing patient safety, applying the recommendations made with respect to the previous *Patient Safety Strategy for the National Health System*, to the initiatives adopted at their own hospitals, and to those of their Autonomous Communities, ensuring better management of healthcare quality.

The *Evaluation Report* considered the **ten patient safety criteria** defined by the Inter-territorial Council of the National Health System (CISNS) and which reference facilities must fulfil to be accredited. These criteria relate to

correct patient identification, hand hygiene, incident reporting and critical patient safety, among other issues.

The findings showed room for improvement as regards self-assessment and submission of documents, as well as regards knowledge of areas for improvement to advance in patient safety.

The most positive findings of the evaluation concerned the adoption of patient identification recommendations, while the most negative findings concerned recommendations regarding HRM.

The *Evaluation Report* highlighted variability in the findings concerning reporting systems and hand hygiene, attributing it both to different levels of quality and to differences in the evaluation processes used at that time.

The findings of the *Evaluation Report* **cannot be extrapolated**, owing to the low number of reference facilities evaluated (29) and to the lack of substantial historical data, as the evaluation was only begun recently (2018). However, it is hoped that they will help to **consolidate and strengthen safety programmes and the implementation of safe practices** at National Health System hospitals.

8. Questionnaire outcomes

Questionnaire submitted to the members of the Institutional Committee on Patient Safety Strategy

1. Questionnaire to determine participants' perception of the implementation of the Safe Surgery programme

The Safety in Surgery Programme includes two multimodal projects—the **Zero Surgical Site Infection Project** and the **Safe Surgery Project**—which seek to improve the quality and safety of scheduled surgeries (especially through use of the Surgical Safety Checklist and of thromboprophylaxis).

An ad hoc **online questionnaire** was sent to the members of the **Institutional Committee** on Patient Safety to identify the main barriers to and facilitators of this programme in the Autonomous Communities.

The **main obstacles** identified were the lack of specific resources and the insufficient observance of the steps and processes stipulated in the programme by surgical unit professionals.

The **facilitators** identified were the training provided under the programme and the participation of professionals in this training.

A number of recommendations were made on the basis of the findings (*Table 11*).

Table 11. Recommendations for implementing the Safety in Surgery Programme. Evaluation Report on the Patient Safety Strategy for the National Health System. 2015-2020 Period

Recommendations	Foster the involvement of managers and middle management as key to the success of the programme
	Hold periodic coordination team meetings
	Dedicate human resources to the programme at Autonomous Community level
	Present the Safety in Surgery Programme to the Inter-Territorial Council of the National Health System (CISNS)
	Involve scientific societies in informing and engaging the commitment of professionals
	Train new professionals joining surgical units
	Consider the possibility of offering incentives to units that foster safe surgery through this or another programme
	Review platforms for facilitating access to and use of data

2. Questionnaire to determine participants' perception of the implementation of the Critical Patient Safety Programme

This programme includes the aforementioned **Zero Bloodstream Infections, Zero Pneumonia and Zero Resistance Projects** (the Zero UTIs Project was being implemented at the time the survey was being conducted). These projects are aimed at reducing infection rates in ICUs from bacteria in catheters and ventilators and from multidrug-resistant organisms, respectively.

To determine the degree of implementation of the programme and its projects and the barriers to and facilitators thereof, **the members of the Institutional Committee on Patient Safety** were asked to complete an **online questionnaire**.

Most of the ICUs that contributed data stated that they had met the objectives set out in the Zero Bloodstream Infections, Zero Pneumonia and Zero Resistance Projects (75%, 76% and 80% of ICUs, respectively).

The **main barriers** identified were a lack of support from senior management, a lack of human resources and a lack of time, high staff turnover and resistance on the part of certain professionals. Other factors identified as hampering achievement of the objectives were the relaxation over time of observance of the measures adopted and the imprecision of certain records.

By contrast, efforts to foster the participation of professionals, the involvement of the administration and recognition were identified as **factors that facilitated successful implementation**.

Questionnaire completed by managers of the Patient Safety Reporting and Learning System

This **online questionnaire**, designed ad hoc and sent to local managers of hospitals, healthcare districts and primary care centres that had already been included in SiNASP when the survey was conducted, seeks to determine their opinion of the system, their level of satisfaction with the support received and their ideas for possible improvements.

The **low response rate** revealed a lack of interest and/or a lack of time to dedicate specifically to SiNASP.

The **barriers** to a broader implementation of the system identified were the doubts experienced by health professionals regarding its usefulness, the fear of negative consequences at a personal level, and the perception that reporting incidents takes up an excessive amount of time considering their workload, which is already high.

The **facilitators** identified were the system's guarantee of confidentiality and anonymity and the ease of access thereto from the workplace.

The areas for **improvement** identified were training, methodology and analysis of incidents; training in planning; implementation and evaluation, with support materials, of actions to improve results; analysis of serious cases and increased support for system managers to enable them to implement the measures they deem most necessary so that adhesion to SiNASP results in safer care.

Questionnaire to determine patients' perception of healthcare safety

In the last quarter of 2020, the participants were asked to complete a questionnaire that was validated in 2010 by the Ministry of Health and is published in the study *Evaluation of patients' perception of the safety of healthcare services: design and preliminary validation*, available on the patient safety web page (Spanish only): https://seguridaddelpaciente.sanidad.gob.es/informacion/publicaciones/2010/docs/informe_validacion_cuestionario.pdf).

Approximately **10 patients** were selected **per Autonomous Community**. These patients were aged 18 or over and met certain pre-defined criteria. Their verbal consent was obtained prior to completion of the questionnaire. While not sufficiently representative, this survey was considered a pilot programme and revealed the need for such surveys in the evaluation of programmes aimed at incident detection and for the *Patient Safety Strategy* itself.

The aims of this survey included that of determining **patients' opinion** of their own safety during hospital care, their perception of the safety of the healthcare received during hospitalization and, in the case of those patients affected by a clinical error during their hospital stay, their opinion of how well the situation was handled.

The results showed that the patients had had positive healthcare experiences and had faith in the national health system. In general, they considered that they had received enough information and felt that the care they had received had been safe.

As regards the questions addressed specifically to patients who had been affected by an incident, the highest scores were awarded for how the health professionals concerned had handled the incident, and the lowest scores related to whether the patient had received an apology and whether they had been informed that measures would be taken to prevent the occurrence of similar incidents in the future.

The findings show the extensive work that must be done to better **educate patients and the broader public** on patient safety.

Conclusions

According to the *Evaluation Report*, **significant progress** has been made in recent years within the framework of the Strategy in terms of improving the **safety culture**, creating a **working network** to improve patient safety in the National Health System, disseminating **the Strategy** across all Autonomous Communities, developing **patient safety infrastructure** at most healthcare facilities, providing **training** and establishing incident **reporting systems** and safety programmes aimed at prevention and monitoring of HAIs, among other aspects.

However, it should be noted that other aspects such as the **safe use of medicines**, the Safety in Surgery Programme, **the management of SAEs** and **patient engagement** present **ample room for improvement**, according to available information.

As previously mentioned, the *Evaluation Report* was affected by the COVID-19 pandemic. However, with the pandemic behind us, the Autonomous Communities and scientific societies must strengthen their commitment to key programmes such as those for the prevention and monitoring of HAIs, the safe use of medicines, safe surgery and incident reporting.

Actions must be aimed at achieving a positive change in the safety culture of healthcare organizations that will enable **lessons to be learned from past errors and that will promote continuous training** of professionals, especially those who have recently begun working for the National Health System, as well as the application of safe practices and the engagement of front-line health professionals.

Additionally, **patient safety** must also be fostered **at primary care centres and at facilities providing social care and healthcare** by strengthening

human resources and by adopting innovative tools and initiatives that facilitate safe care and ensure that the professionals at such facilities receive proper training and have the necessary time to dedicate to this issue.

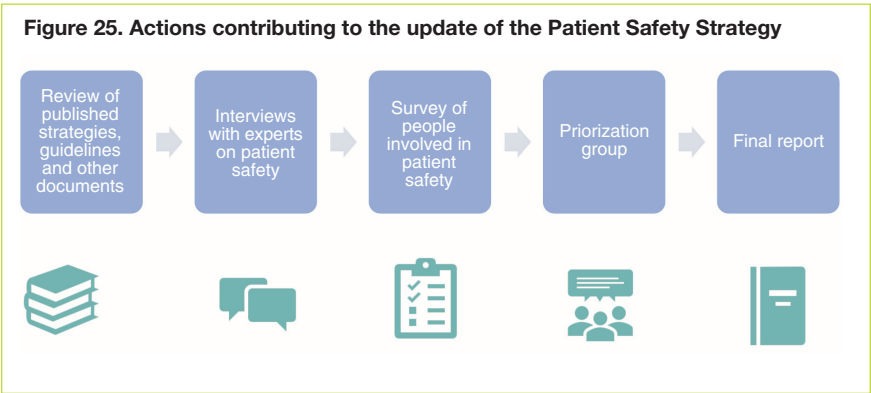
Work must also be done to **minimize the reporting biases** that may result from using both automated and manually inputted data and data recorded following differing criteria. Standardized methodologies must be applied.

These aspects must serve as pillars for the new period of the *National Health System Patient Safety Strategy*.

B. Methodology

To update the National Health System Patient Safety Strategy, a number of **different methodologies** were employed to conduct a quantitative and qualitative evaluation of the suitability and impact of the existing Strategy, as well as of the lessons learned therefrom. This enabled the **identification of priority strategic lines of action** for the period covered by the new Strategy, in line with international recommendations, the results of the *Evaluation Report*, the plans launched by Autonomous Communities and the opinions of experts and other persons involved in patient safety.

To achieve these aims, national and international safety strategies were reviewed, a survey and interviews were conducted, and a prioritization group of national experts on patient safety was convened (*Figure 25*). This process enabled the identification of a list of aspects which could potentially be added to or given greater importance in the new version of the Strategy.



Guides and strategies published internationally, as well as those published by Spain's Autonomous Communities, were reviewed, and a report was issued on aspects that might require modification or inclusion in the new Strategy.

The following international and national strategies were reviewed:

- World Health Organization (WHO)
- Agency for Healthcare Research and Quality (AHRQ)
- Institute for Healthcare Improvement (IHI)
- Health Service Executive (Ireland)
- Australian Commission on Safety and Quality in Health Care (Australia)
- Danish Patient Safety Authority (Denmark)
- The National Health Service (NHS) Patient Safety Strategy (England)
- Dutch Hospital Patient Safety Programme (Netherlands)

Patient safety plans and strategies recently implemented in six of Spain's Autonomous Communities (Andalusia, ⁽⁴⁾ the Basque Country, ⁽⁵⁾ Castilla-La Mancha, ⁽⁶⁾ Galicia, ⁽⁷⁾ La Rioja ⁽⁸⁾ and Madrid ⁽⁹⁾) were also reviewed.

An analysis of the differences and similarities between these strategies and Spain's Patient Safety Strategy concluded that the update of the Spanish Patient Safety Strategy should add and/or review certain actions and highlight specific aspects such as **reducing avoidable harm to patients to zero**, **improving the resilience** of health organizations and clinical practice, **learning from the experience** of patients and their families, and **strengthening collaboration** with centres of excellence for education and training in patient safety.

Based on this review, 14 **interviews were conducted with experts on patient safety** to gather their views on which approach the new Strategy should adopt, which helped identify several aspects which needed to be added or given greater importance.

This was a starting point for the drafting of **a questionnaire** which was sent to 122 **persons linked to patient safety**, in order to gather their views on the different strategic lines of action of the previous Strategy and areas for improvement.

This online questionnaire was answered by 56.6% of recipients. The main quantitative results were:

- The six current lines of action were considered suitable by most respondents, and no suggestions were made for additions or changes.
- Most respondents believed the degree of achievement of the general objectives was average, except for the objective of promoting the participation of patients and their caregivers in patient safety, where half of respondents considered the degree of achievement was low.
- The general objective of second strategic line of action which respondents believed had best been achieved was that relating to correct patient identification, while prevention of HAIs was

perceived to receive the most resources from the Ministry of Health. According to respondents, effective communication among and by professionals had the lowest degree of achievement and received the least amount of investment, and was the area where barriers to implementation were greatest.

- All programmes implemented to boost safe practices were perceived as very useful, especially the Hand Hygiene Programme.

At a qualitative level, several proposals were made to add or give greater importance to certain actions in the updated Strategy, in line with the findings of the interviews.

After the data obtained was analysed and the report on questionnaire responses completed, a **prioritization group** composed of 23 persons involved in patient safety was convened to assess the relevance and feasibility of incorporating new issues into the Strategy.

The prioritization group identified strengthening **leaders' commitment to patient safety as the most relevant issue and the incorporation of other areas of safe clinical practice** as the **most feasible action**.

The issues identified by the group as **both relevant and feasible** were the incorporation of **other areas of safe practice** into the new Strategy, the availability of protocols, guides, manuals and working groups to ensure **good communication**, and the strengthening of **do-not-do recommendations**.

The evaluation of all these aspects provided a comprehensive, far-reaching overview of the strengths and weaknesses of the existing Strategy.

In conclusion, the existing Strategy is a **useful and relevant** document which follows international recommendations. However, the issues identified by the evaluation detailed above will allow the update of the Strategy to incorporate suggested improvements and build on its strengths.

C. Purpose of the strategy: mission, vision, general aims and cross-cutting values

Mission

To define and establish objectives and recommendations based on available scientific evidence aiming to minimize healthcare risks and reduce the harm associated with healthcare, with the ultimate aims of achieving healthcare free from avoidable harm, promoting the establishment and development of systems to identify and manage risks optimally, taking into account the experience of all health system stakeholders (patients, family members, health workers and the health system).

Vision

To be the consensus-based reference and management framework for Spain, guiding healthcare provision towards a model that is proactive about patient safety, based on the value of safe health systems and building on a shared commitment to patient safety. To thus encourage the Ministry of Health, Spain's Autonomous Communities, health managers, health directors, scientific societies, health system professionals and patient organizations to adopt an active role in supporting patient safety, to ensure that every patient receives safe and respectful care at all times and in all situations and to minimize avoidable harm associated with healthcare.

General aims

To achieve the greatest possible reduction in avoidable harm due to unsafe healthcare in the National Health System.

To prioritize patient safety in all healthcare plans as the basic, crosscutting component of quality of care.

To improve, foster and consider patient safety at all levels and in all spheres of care within the National Health System.

Crosscutting values

Commitment to patients: promote patient autonomy to involve patients in their safety. Adapt care to care processes and needs.

Social responsibility: manage and reduce the impact on the community of adverse patient safety events by increasing transparency.

Promotion of gender equity in health: take gender-based inequities in patient safety into account as a socially determining factor.

Collaboration, participation, coordination: foster different professionals' cross-sector and interdisciplinary work, recognition and support for and between professionals, inter-institutional collaboration, participation by society, patients and their families, and the involvement of all stakeholders.

Non-punitive learning culture: encourage systems thinking, ongoing assessment and auditing, methodologies to improve quality, change management, and multidisciplinary teams working for patient safety.

D. Target population

The target population of this Strategy comprises all patients and members of the public who receive healthcare from the National Health System, all (clinical and management) professionals, healthcare organizations and suppliers, and all academic bodies and other stakeholders involved in the improvement of patient safety in Spain.

E. Guiding principles

1. Involve patients and families in safe healthcare

Safe healthcare must be understood as a basic right. Patients, families and caregivers have a growing interest in their own health and in that of their communities. The provision of safe healthcare requires that patients are informed, participate and are treated as full co-participants in their own care.

Patients and their relatives/caregivers must be involved in all levels of care, from planning to fully informed consent and shared decision making at the point of care, aspects which have already been considered in other regulatory documents such as Basic Act 41/2002 of 14 November, regulating patient autonomy and rights and obligations regarding clinical information and documents.

2. Adopt a collaborative approach to achieving results

A collaborative approach based on multidisciplinary work must be pursued, in which everyone contributes, shares and learns.

3. Create knowledge through analysis and the sharing of data

Strengthen systems for reporting AEs and incidents, as well as other reporting systems from other sources providing homogeneous and normalized data that contribute to a better understanding of safety incidents and problems and to finding solutions to prevent them. The obtention of reliable, high-quality data must be encouraged by means of a culture of trust among professionals.

4. Use scientific evidence to improve patient safety, calling for social commitment and leadership by political decision-makers

The creation of safe healthcare systems not only requires planning, designing and producing a strategy, but also social and political commitment and awareness-raising. To this end, it is important to foster excellence centres, learn from them, extend proven best practice and take patients' personal experiences into account with a view to improving care.

5. Promote a safety culture in the attitudes, beliefs, values, skills and practices of healthcare staff and managers

The importance of this principle is such that it has been adopted as a strategic line of action. Commitment, transparency, communication, learning from mistakes and best practices, and striking a sensible balance between a no-blame policy and accountability are all essential components of the safety culture.

A robust safety culture is fundamental to reducing harm to patients, but also to providing a safe working environment for healthcare staff where they can speak openly about patient safety and other matters without fearing negative consequences.

4. Strategic lines of action

Line of action 1: Safety culture, human and organizational factors and training

Establishing a positive patient safety culture at healthcare institutions is indispensable to preventing and minimizing patient safety incidents and to learning from mistakes in order to reduce the probability of reoccurrence.

One of the most widely accepted definitions of safety culture refers to the integrated individual and organizational behaviour model, which is based on shared beliefs and values and on maintaining a constant focus on preventing and minimizing the harm associated with healthcare.⁽¹⁰⁾

Safety culture seeks to create an environment which supports safe healthcare. Institutions, organizations and healthcare facilities must be capable of appropriately responding to and managing risks. The active participation and experience of staff, managers and the general public will help them achieve this goal. It is a shared responsibility of health professionals to contribute to safety in different, ever-more complex spheres of care encompassed within primary care, continuity of care and hospital care.

Given their central role in this matter, it is important that staff's environment, training and working conditions are optimal for the performance of their tasks. This will reduce the likelihood of mistakes being made.⁽¹¹⁾

Promoting a safety culture entails changing ways of working and the manner in which errors—and unintended harm resulting from ever-more complex care—are addressed. Such changes are crucial, as patient safety is an essential component of healthcare, and they must be led by health professionals. An eminently proactive approach must be adopted, fostering teamwork and the standardization of safe practices based on scientific evidence, seeking open, patient-centred communication, engaging patients as partners in safe care.

It is because of the importance of this aspect that instilling a safety culture is one of the guiding principles of the WHO *Global Patient Safety Action Plan 2021-2030*. This plan stresses the essential balance to be struck between a no-blame policy leading to learning without punitive outcomes and appropriate accountability in relation to the healthcare provided.

To improve safety culture we must continue to carry out actions to assess and improve the safety environment, inform and train all National Health System professionals in safety matters, foster training in effective care

through clinical simulations, train teams in risk management, foster leadership in safety, report and learn from incidents and keep professionals informed of assessment data on their healthcare facilities, stimulating their active participation in proposed improvements.⁽¹²⁾

The Evaluation Report (3) examined the implementation of patient safety plans in primary care and in hospital care, and concluded that plans are more often available in primary care, although in both cases availability is above 70%.

Leadership is critical to the success of patient safety programmes. Leaders in safety play a key role in improving the patient safety culture of an organization and in managing risks. They must believe in their role and in what they do, and they must also be respected by their team and by their managers. Support for the safety officer by the rest of the team, as well as the visible and active involvement of competent authorities guarantees risk management, implementation, monitoring, the assessment of goals and the implementation of actions that promote safety in all areas of care, care services and care facilities.

It is also essential that professionals with management and clinical duties receive training in patient safety, as a fundamental element to improve safety culture in healthcare organizations.

A recent study on patient safety culture, published in 2024, reveals that in primary care 80% of professionals rate patient safety good to excellent overall, down from 93% in 2011. However, the overall rating for patient safety in hospitals is similar to the 2009 rating, while 8 out of 12 aspects analysed received a more positive assessment.⁽¹³⁾

Based on the findings of the literature review, the surveys and the prioritization teams, this update of the Strategy will include the following general objectives, specific objectives, and specific recommendations.

General objective 1.1: Improve the National Health System safety culture in all areas and at all levels

- Specific objectives:
 - Establish institutional or centre-specific safety plans for National Health System healthcare facilities—with annual targets, built-in evaluation and plans for sharing findings—that involve all professionals, are shared by the organization, and include care for professionals involved in AEs.⁽¹⁴⁾
 - Periodically assess the safety climate at National Health System healthcare institutions through validated Spanish versions of questionnaires, and offer recommendations to improve patient safety.
 - Share, through the different media available, national and

international knowledge and lessons learned regarding patient safety and safe practices with all spheres and levels of care.

- Implement initiatives, such as training programmes, to strengthen the safety culture among management and mid-management staff at National Health System healthcare institutions.
- Promote patient safety culture among healthcare policy-makers, legislators, judges, non-health professionals at Autonomous Communities' health departments and non-health professionals at healthcare organizations.
- Favour a patient safety approach when allocating and adapting human and material resources for healthcare facilities, taking into account the characteristics of the care environment.
- Strengthen the existing patient safety network within the National Health System, bringing in patient safety officers from different National Health System healthcare facilities, as well as other national organizations interested.
- Renew the public commitment to health professionals and patients to promote a patient safety culture in all healthcare organizations.
- Periodically assess the degree to which the objectives of the Patient Safety Strategy have been achieved, including recommendations for ongoing improvements.
- Undertake a joint commitment with healthcare administrations to allocate specific resources that make it easier to implement the National Health System Patient Safety Strategy.
- Develop national legislation (or strengthen existing legislation) to facilitate the implementation of safety policies aiming to prevent and minimize healthcare-associated harm, following the recommendations made by WHO in the Patient safety rights charter.⁽¹⁵⁾

General objective 1.2: Encourage health professionals to take the lead on patient safety

- Specific objectives:
 - Establish institutional governance and organizational elements for patient safety within Autonomous Community administrations, health services and other organizations.
 - Identify clinical and management leaders at healthcare facilities to facilitate the implementation, monitoring and evaluation of the safety plan.
 - Identify a clinical leader for each programme/practice implemented at healthcare facilities.

- Foster the creation of inter-disciplinary working groups to promote a patient safety culture.
- Ensure patient safety officers at healthcare facilities are members of management teams.
- Ensure patient safety officers at healthcare facilities have the necessary training and commitment to properly address patient safety at said facilities.
- Engage management teams in initiatives and activities to improve safety.
- Combine safety teams with quality teams and ensure that they work together on common issues based on a cross-cutting approach.
- Give due recognition to healthcare facilities that meet patient safety standards, in coordination with Autonomous Communities.

General objective 1.3: Training

- Specific objectives:
 - Implement initiatives to train all health professionals within the National Health System in patient safety, in all areas and levels of care.
 - Establish a roadmap to foster, alongside the institutions involved, training in patient safety during university degrees or other training modules relating to healthcare, as well as in specialized healthcare programmes in line with the multi-professional edition of the WHO Patient Safety Curriculum Guide. ^{(16) (17)}
 - Reach an agreement on the minimum requirements for basic training in patient safety for National Health System professionals in collaboration with healthcare administrations and other organizations interested. ^{(18) (19)}

Line of action 2: Safe clinical practice

When patients receive care from the National Health System, they take part in a process in which different clinical practices are intertwined to offer them the best possible service in all aspects of prevention, diagnosis, treatment, monitoring and care.

Different international organizations have issued recommendations on how to conduct these clinical practices safely based on the frequency of the most common AEs and on existing evidence on handling said events.

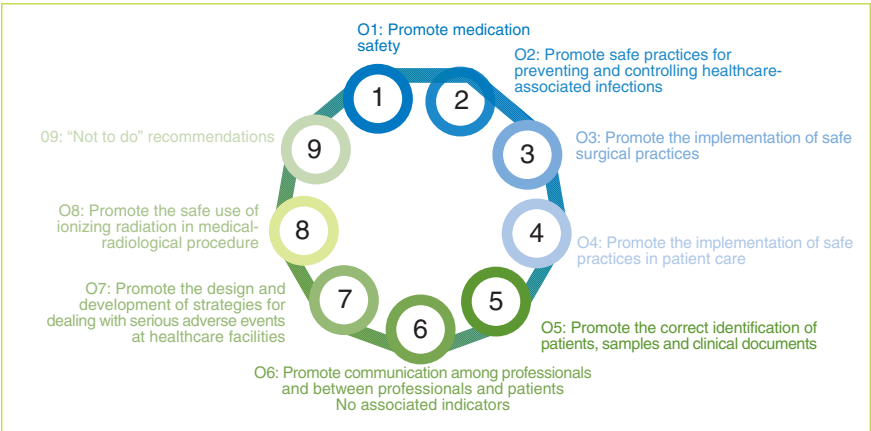
The Ministry of Health has promoted a number of safe practices in line with international recommendations within the framework of the Patient Safety Strategy and in collaboration with the Autonomous Communities.

This strategic line of action includes internationally recommended safe clinical practices of proven efficacy. These practices are aimed at the safe use of medicines and prevention and control of HAIs, avoidance of harm associated with surgery or patient care, correct identification of patients, effective communication, design and implementation of protocols or strategies aimed at preventing the use of measures which limit patient autonomy and patients' rights, design of strategies to address SAEs at health centres, and the safe use of ionizing radiation in clinical procedures.

In addition to promoting, guaranteeing and fostering safe clinical practices, it is essential to implement a system that enables assessment of their adoption in different health environments, as well as internal and external auditing thereof.

Do-not-do recommendations are also paramount to patient safety, as they inform National Health System professionals and users of those clinical practices of little value which should be abandoned. All these practices will improve the quality and safety of care provided by the National Health System.

To this end, this strategic line of action has nine general objectives:



General objective 2.1: Promote medication safety

According to WHO, unsafe medication practices and medication errors are a leading cause of injury and avoidable harm in health systems across the world.^{(20) (30)} In fact, AEs caused by medication errors may represent up to 50% of avoidable harm associated with healthcare.⁽²¹⁾ These errors occur when medication systems are unsafe or because of human factors such as fatigue, deficient environmental conditions or staff shortages. They affect medication circuits and can result in severe harm, disability and even death.⁽²⁰⁾⁽²²⁾ Medication errors can be reduced by implementing safe practices and incorporating technologies of proven effectiveness into medication system processes. This requires a multi-disciplinary approach and engagement and sustained support from all stakeholders.

In March 2017, WHO launched the third Global Patient Safety Challenge: **Medication Without Harm**, aware of the high impact of avoidable medication-related harm.⁽²⁰⁾ It later adopted the **Global Patient Safety Action Plan 2021-2030**, whose strategy 3.2 focuses on the need to implement a programme to transform the safety of medication management and use based on this challenge.⁽²³⁾ The “Medication Without Harm” challenge established a strategic framework comprising three key action areas for improving patient safety: high-risk situations, polypharmacy and transitions of care.⁽²⁰⁾

High-risk situations can refer to medication, patients and environments.⁽²²⁾⁽²⁴⁾ **High-risk medications** are those that are more likely to cause severe or even life-threatening harm to patients when used incorrectly. This does not mean that errors with these medications are more frequent; rather, that the potential consequences for patients when errors do occur are often more severe. Healthcare facilities must adopt programmes aimed at avoiding the most common errors with these medications, which must include the implementation of safe practices in all stages of the medication circuit.⁽²⁵⁾ Healthcare facilities must also focus their efforts on initiatives to improve care for **high-risk patients**, who are the most vulnerable to medication errors. These include older patients, paediatric patients and cancer patients. Healthcare facilities must also pay special attention to **high-risk environments**, such as geriatric units, intensive care units, surgical units and emergency care units, where avoidable medication-related AEs are more frequent.^{(21) (22)}

Polypharmacy is a growing problem due to population ageing and the increasing number of persons with multiple chronic conditions, entailing a heightened risk of interactions, lack of adherence and other medication-related incidents.⁽²⁶⁾ According to WHO, **polypharmacy**, which occurs when a patient is prescribed more medication than clinically necessary, is another key action area. To reduce mistakes, WHO proposes periodic medication reviews, better communication and collaboration between health care

professionals, the use of technology to help clinical decision-making, and greater engagement of patients and caregivers in decision-making about care.

Transitions of care and patient transfers between areas of care or services constitute critical points with a high risk of mistakes or discrepancies in the information about the courses of treatment that patients are receiving.⁽²⁷⁾

Medication reconciliation seeks to improve communication and ensure the information transmitted regarding medication at transition points is accurate, complete and safe. It is a structured and multi-disciplinary process that involves health professionals, patients and their families or caregivers. It requires obtaining a complete and accurate list of all the medication that the patient is actually taking; comparing it with new medication prescribed at every transition of care to resolve discrepancies, and thus avoid duplication, omissions and possible interactions; ensuring that this process is completed at each transition of care; and ensuring that the complete, accurate and updated list of medication is available at all times to all professionals providing care to the patient, as well as to the patient themselves and their caregivers.^{(28) (29)}

The strategic framework for action defined in the WHO third Global Patient Safety Challenge also specifies that to achieve improvements in these three key action areas, the relevant programmes and initiatives must be adopted across four domains: medicines, systems and practices of medication, health care professionals, and patients and the public.^{(20) (22)}

- Systems and practices of medication: it is essential to implement practices and incorporate technologies of proven effectiveness, such as electronic prescription and barcodes in hospitals, across all stages of the medication system, in order to make it less vulnerable to error. Moreover, the designation of medication safety officers is advised at all facilities working towards the full adoption of these practices. The officers' role is to assess the impact of practices in terms of harm reduction.
- Medicines: the pharmaceutical industry and regulatory agencies must work to improve the safety of naming, labelling and packaging to guarantee the correct identification, differentiation and administration of medicines. In addition, WHO recommends that healthcare facilities implement safe practices to avoid errors caused by similarities in the naming, labelling and packaging of medication.
- Health care professionals: training on safe practices, especially in priority areas, and on communication techniques and teamwork skills is essential. It is also necessary to foster an institutional safety culture at healthcare facilities and to encourage professionals to report and learn from medication errors.
- Patients and the public: active participation is crucial for medication to be used safely. Therefore, it is fundamental that patients and caregivers are properly informed about the medication they use,

understand how they should use it and are actively engaged in the care process.

Although many safe practices have been recommended to reduce medication errors in the areas and domains defined in this third challenge, the findings of the *Evaluation Report* ⁽³⁾ and the results of studies conducted on the implementation of safe practices in Spanish hospitals, critical care units and emergency services, ⁽³⁰⁾ ⁽³¹⁾ ⁽³²⁾ reflect that many facilities have either not implemented them at all or only implemented them partially, despite the efforts made by administrations and health facilities over the last two decades. ⁽³³⁾ Moreover, the analysis of medication incidents reported to SiNASP and to ISMP-España show that some mistakes that could be avoided through implementation of the basic medication safety practices published in the latter's medication error prevention bulletins continue to occur repeatedly. ⁽³⁴⁾ ⁽³⁵⁾ ⁽³⁶⁾ Therefore, work remains to be done on the implementation of safe practices to reduce avoidable harm associated with medicine, in line with WHO recommendations.

- Specific objectives:
 - Maintain a single health record for each patient listing all medication prescribed to them throughout transitions of care, thereby allowing health professionals easy access to the patient's complete medication history.
 - Maintain and optimize the set-up of electronic prescription programmes, integrating them into each healthcare facility's information systems.
 - Maintain clinical decision-making support systems which, at minimum, issue alerts regarding possible interactions, suspected or diagnosed allergies, ⁽³⁷⁾ out-of-range doses, therapeutic duplication, etc.
 - Encourage every healthcare facility to establish a programme to reduce errors with high-risk medication which includes the creation of a list of the high-risk medication it administers and the implementation of effective safe practices in all processes and in all domains for, at minimum, anticoagulants, insulin, opiates, antineoplastics, and methotrexate (non-oncological use). In hospitals, neuro-muscular blocking agents and intravenous potassium should be added to this list.
 - Standardize preparation and administration procedures for injectable medication and parenteral nutrition.
 - Ensure that healthcare facilities use smart infusion pumps with dose-error reduction software, at least when administering high-risk medications.

- Implement barcode technology at hospitals to verify medication and guarantee appropriate selection in the medication circuit.
- Implement safe practices at healthcare facilities to avoid errors caused by similarities in the naming, labelling and packaging of medication.
- Strengthen initiatives to improve medication safety in high-risk patients, especially in chronic, polymedicated patients, paediatric patients and oncology patients.
- Develop initiatives to improve medication safety in high-risk units, particularly in geriatric units, intensive care units, surgery units, and emergency units.
- Develop and promote the implementation of guidelines and tools to conduct frequent, structured medication reviews for chronic, polymedicated patients, assessing the necessity, effectiveness and safety of every medication in each case, de-prescribing if necessary.
- Expand do-not-do recommendations regarding medication, including the identification of do-not-do recommendations based on scientific evidence, and launch mechanisms to ensure their implementation and monitoring.
- Establish monitoring programmes for chronic patients, review their use of medication and improve adherence to treatment.
- Establish and improve programmes for medication reconciliation during transitions of care, especially when discharging patients and in primary care, prioritizing chronic, polymedicated patients and/or patients undergoing treatment with high-risk medications.
- Engage patients and families or caregivers in the medication reconciliation process and provide them with a complete and updated list of their medication.
- Involve pharmacies in the safe use of medicines.
- Designate medication safety officers or teams at healthcare facilities, responsible for drafting action plans to reduce errors, lead implementation of patient safety projects and practices, and assess results periodically.
- Develop ongoing training programmes for health professionals regarding safe practices, and especially those focusing on the safe handling of high-risk medications, the review and reconciliation of medication, and on providing information and explaining the reasoning for prescriptions to patients and caregivers.
- Train health professionals in electronic prescription systems and other technologies used in dispensing, preparing and administering medication.

- Encourage the reporting of medication-related incidents by health professionals through existing reporting systems; assess said systems and propose improvements at local level, ensuring that learning is prioritized.
- Monitor the advances made in reducing harm related to medication, using the existing drug safety monitoring system when necessary.
- Ensure that healthcare facilities conduct periodic self-evaluations of their medication safety procedures, to ensure the prioritization and implementation of safe practices that minimize the risk of error.
- Ensure that patients and caregivers receive understandable and appropriate information on medication, favouring open communication with the professionals providing care, especially in the case of higher-risk patients, ensuring that medication is handled safely.
- Foster patient engagement in medication processes and encourage patients to ask questions and check their treatments, facilitating access to tools such as 5 Moments for Medication Safety.⁽³⁸⁾
- Provide each patient with a list of their prescribed medication and insist that they keep it up to date and bring it with them any time they request healthcare.

General objective 2.2: Promote safe practices for preventing and controlling healthcare-associated infections

Prevention and control of infections and antimicrobial resistance is a global priority. This is reflected in strategy 3.3 of the *WHO Global Patient Safety Action Plan*,⁽³⁹⁾ and WHO has stressed the need for specific programmes focused on this task. The Seventy-Fifth World Health Assembly⁽⁴⁰⁾ adopted a resolution which led to the **Global strategy on infection prevention and control**⁽⁴¹⁾ (GSIPC), which includes a global action plan with a framework for consultation and monitoring.

The guiding principles underpinning the GSIPC include a people-centred approach that emphasizes the protection of health workers and of visitors to healthcare facilities as well as patient safety. **Infection prevention and control** also play a key role in combating antimicrobial resistance and in outbreak preparedness, readiness and response. This global strategy also provides WHO Member States with guidelines to reduce HAIs, including those caused by multidrug-resistant organisms (MDROs), and to limit infectious disease outbreaks by 2030.

According to the latest available data, in 2024 the total percentage of inpatients in Spain who suffered an HAI was 8.19% (95% confidence interval (CI): 7.97%-8.41%). In the case of inpatients at acute care centres, the percentage was 7.17% (95% CI: 6.96%-7.38%), while in the case of inpatients in long-term care centres or hospitals, it was 1.05% (95% CI: 0.97%-1.13%). HAIs cause high morbidity and mortality rates and an increase in direct and indirect care costs. ⁽⁴²⁾

The prevention and control of HAIs is based on robust, versatile, efficient and appropriate surveillance systems, allowing proper data analysis and guiding the application and assessment of evidence-based safe practices.

Similarly, experience has revealed the need for interdisciplinary work involving management and senior management and professionals working in all health areas.

It is therefore necessary to combat these infections and antimicrobial resistance through an effective, multifaceted approach that involves different sectors and professionals from different areas.

The Ministry of Health, in collaboration with Spain's Autonomous Communities and several scientific societies, has been working on multimodal, interdisciplinary programmes and strategies, such as the **Hand Hygiene Programme**, the **Critical Patient Safety Programme** and the **Safety in Surgery Programme**, which have proven their effectiveness in the prevention of these infections.

Hand hygiene is considered the main measure needed to reduce HAIs and the transmission of MDROs, ⁽⁴³⁾ which is why professionals' correct hand hygiene is essential. For monitoring purposes, it is necessary to assess a number of indicators related to compliance, infrastructure and ABHRs. The Ministry of Health publishes an annual report on hand hygiene indicators, as part of the National Health System Hand Hygiene Programme, which is available on the Ministry's patient safety website. ⁽⁴⁴⁾

The main types of HAIs, such as surgical site infections, catheter-associated UTIs, catheter-related bloodstream infections and ventilator-associated pneumonia, are linked to invasive procedures. Prevention of HAIs is an important factor to be considered in the care of both immuno-depressed patients and critical patients.

Given the complexity of the care they receive, ICU patients are especially vulnerable to adverse events. As a result, the Ministry of Health has, in collaboration with scientific societies, launched the **Critical Patient Safety Programme**, which encompasses several projects (Zero Bloodstream Infections, Zero Pneumonia, Zero Urinary Tract Infections, and Zero Resistance).

Surgery is one of the pillars of healthcare, yet it also constitutes a key transmission point for HAIs. To address this situation, the Ministry of Health, in collaboration with scientific societies, has launched the Safety in Surgery

Programme, which includes the Safe Surgery and Zero Surgical Site Infection Projects. This section will focus on the Zero Surgical Site Infection Project, which includes the implementation of safe practices, grouped into a bundle of five measures of proven effectiveness: antibiotic prophylaxis, use of alcoholic chlorhexidine, hair removal, perioperative normothermia and perioperative normoglycaemia. The first three are compulsory, while the last two are optional. Compliance is assessed using a specific checklist. Between 2017 and 2021, the percentage of hospitals reporting that they had implemented a surgical site infection monitoring programme rose from 55.2% to 70.7%. ⁽⁴⁵⁾ According to a recent study assessing the effectiveness of these five measures, after adjusting for several factors, the preventive fraction stood at 32%, owing solely to partial observance of these measures. ⁽⁴⁶⁾

The use of the **Safe Surgery** Project Surgical Safety Checklist is crucial to guaranteeing safety during surgery. By ensuring safe practice guidelines are followed, it makes their implementation easier to assess.

The main barriers to implementation of these programmes, projects and practices are the high pressure placed on healthcare services, lack of training and poor communication between professionals.

A number of other projects launched—such as **Zero Phlebitis**—are in line with those of the Critical Patient Safety Programme, but are more specifically focused on inpatients. While not currently led by the Ministry of Health, these projects are nonetheless contributing to the decline in HAIs. ^{(47) (48) (49) (50) (51) (52)}

Despite the progress and good results obtained thanks to the aforementioned programmes and projects, work must continue to expand these practices to other environments and patient groups.

- Specific objectives:
 - Strengthen prevention measures in coordination with plans and results obtained through HAI surveillance systems.
 - Strengthen and encourage the creation of regional committees working on prevention, surveillance and control of infections for effective and structured coordination with those responsible for public health surveillance, for the Programme for the Optimization of the Use of Antibiotics, for the National Action Plan against Antimicrobial Resistance, and for the prevention and control of infections. Regional patient safety officers may take responsibility for the prevention and control of infection in their Autonomous Community, depending on its internal organization.
 - Emphasize the importance of hand hygiene in all patient safety programmes aimed at prevention and control of HAIs and actions to improve hand hygiene.

- Meet with the National Health System national coordination group for hand hygiene regularly to receive information on obstacles to implementation and to identify possible solutions.
- Publicize the outcomes of the Hand Hygiene programme.
- Continue and improve the National Health System Critical Patient Safety Programme, meeting with the Advisory Council regularly.
- Encourage the implementation of the National Health System Critical Patient Safety Programme by Autonomous Communities.
- Publicize the results of and obstacles encountered in the correct implementation of the National Health System Critical Patient Safety Programme.
- Continue and extend measures for the prevention of surgical site infection, for example through the Zero Surgical Site Infection Project.
- Build skills for the prevention and control of HAIs through specific professional training programmes.
- Encourage and extend HAI prevention and MDRO transmission programmes to other areas of hospital care, especially to high-risk areas, using the surveillance and control systems available at health centres.
- Develop specific infection control and prevention programmes at nursing homes for older people.⁽⁵³⁾
- Coordinate transitions of care and monitoring of patients colonized and infected by MDRO when they return home or to a nursing home for older people following hospital care.
- Reduce resistance to antibiotics and optimize their use by addressing the issue from a multi-disciplinary approach, in line with the action included in the National Action Plan against Antimicrobial Resistance.

General objective 2.3: Promote the implementation of safe surgical practices

As stated above, surgery represents a pillar of healthcare. However, it is not free from complications. The complexity of most surgical procedures requires a coordinated team to prevent complications, insofar as possible.

The Ministry of Health, in collaboration with scientific societies, has developed the **Safety in Surgery Programme**, which includes the Safe Surgery and Zero Surgical Site Infection Projects. The aim of the **Safe Surgery Project**⁽⁵⁴⁾ is to create a collaborative network of surgeons from different specialities who apply safe practices of proven effectiveness and to enable them to share tools to foster surgical safety.

The use of **surgical safety checklists** has proven its effectiveness and efficiency in improving patient safety in surgical procedures, facilitating compliance with the universal protocol (correct patient, procedure and site) and prevention of surgical site infection.⁽⁵⁵⁾ Surgical checklists have a positive impact on team relations and communication, cut rates of secondary morbidity and mortality after surgical procedures, and increase patient safety. What is needed is a multimodal, interdisciplinary strategy that allows the effective implementation of the Surgical Safety Checklist, including adequate completion and use in order to detect incidents in this area.

Respondents to an ad hoc survey on an update of the Strategy believed the main barriers to the implementation of the Safe Surgery Project were the lack of communication between professionals, the lack of leadership, and the high pressure placed on healthcare services. Nevertheless, it was considered a highly useful programme.

- Specific objectives:
 - Strengthen the recommendations of the Safe Surgery Project, paying special attention to implementation and correct use of the Surgical Safety Checklist.
 - Facilitate the implementation, adaptation, correct use, and quantitative and qualitative assessment of the Surgical Safety Checklist, including through professional training.
 - Build surgical professionals' cross-cutting soft skills, such as communication and teamwork
 - Align the Programme with other National Health System initiatives to improve the quality and safety of surgical procedures.
 - Coordinate Programme actions for prevention with epidemiological surveillance and other infection prevention programmes.
 - Implement structured tools to ensure safe handovers from surgery to reanimation or the ICU, paying special attention to patients with serious systemic diseases.^{(56) (57) (58) (59)}
 - Standardize and adapt safety in surgery indicators to ensure their usefulness in clinical practice.
 - Reduce the occurrence of post-operative embolism by improving prophylactic measures.

General objective 2.4: Promote the implementation of safe practices in patient care

The implementation of safe practices of proven effectiveness in patient care must be systematically pursued.

Safe care is a care team mission, mainly involving nurses and healthcare assistants, but also doctors and other health and non-health professionals.⁽⁶⁰⁾

Strategic Objective 5 of the WHO *Global Patient Safety Action Plan 2021-2030* ⁽²³⁾ is to inspire, educate, skill and protect health workers to contribute to the design and delivery of safe care systems.

These practices address the need to establish strategies to prevent AEs related to patient care in the three levels of healthcare. Said strategies must lead to the development of individual care plans which include prevention and pain control measures for adults and children, as well as safe care for vulnerable older people, ⁽⁶¹⁾ ⁽⁶²⁾ taking account of the needs and preferences of patients and their caregivers. After the patient's ability to swallow, continence, mobility, cognitive status and caregiver have been fully assessed by nurses, personalized care plans will be drawn up which include measures to prevent pressure wounds, ⁽⁶³⁾ ⁽⁶⁴⁾ other kinds of injuries and falls, as well as patient safety measures.

Safe patient care must include informing patients and caregivers of their plans, which must be added to their health records and discharge reports; and the creation of specific plans for comprehensive assessment of patients receiving home care.

To date, the extent to which these goals have been achieved varies considerably across the country. This could be a result of different data sources and assessment methods. ⁽³⁾

- Specific objectives:
 - Maintain and strengthen the implementation, quality and updating of personalized care plans (for inpatients and outpatients) as the main tool for continuity of care and transitional care. Plans must include at least the following aspects relating to patient safety in the relevant care environment:
 - Prevention of falls and associated injuries (paying particular attention to hip fractures) through assessment scales and stratification of risk. ⁽⁶⁵⁾ ⁽⁶⁶⁾
 - Prevention of pressure wounds for patients who are bedbound or are found to have suffered severe or total functional impairment, after risk assessment using validated scales. ⁽⁶⁷⁾ ⁽⁶⁸⁾ ⁽⁶⁹⁾ ⁽⁷⁰⁾ ⁽⁷¹⁾ ⁽⁷²⁾
 - Prevention of functional impairment in long-term inpatients.
 - Prevention of HAIs.
 - Implement an action protocol in the most relevant services. To reduce the use of physical restraints and other coercive measures, this protocol must include the creation and maintenance of a record of their use, as well as the monitoring thereof and of the impact on all the persons involved (patients with mental health conditions, family members and

professionals), in line with the recommendations of the Mental Health Strategy of the National Health System. ⁽⁷³⁾

- Prevention of malnutrition and dehydration in inpatients and primary care patients, especially in older patients.
- Prevention of aspiration.
- Prevention of hyper- and hypoglycaemia in patients with diabetes mellitus during hospitalization.
- Prevention of adrenal crisis and/or diabetes insipidus in patients with acute intercurrent diseases.
- Safe care for fragile patients (identification, assessment, monitoring, communication) in all care settings.
- Prevention and pain control in adults and children, depending on the needs of patients and caregivers.
- Prevention of delirium (also known as acute confusional state) in inpatients.
- Use of validated scales for early warning of clinical deterioration.
- Supplement plans with information campaigns aimed at patients and caregivers.
- Foster improvements to patient care records, incorporating them into health records and discharge reports.
- Identify leaders among nursing professionals to promote care plans and their proper implementation and evaluation.
- Establish information/training mechanisms for health professionals and informal caregivers.

General objective 2.5: Promote the correct identification of patients, samples and clinical documents

Patient identification is the process of correctly matching a patient with their planned intervention and relaying information on patient identity in a reliable and accurate manner based on uninterrupted care. ⁽⁷⁴⁾

Shortcomings in patient identification entail the risk of misdiagnosis, of unnecessary or mistaken interventions, or of medicines being administered to the wrong patient, among other errors.

Cases of mistaken identity can occur at any time in the care process, from intake (registration) to clinical encounter (diagnosis, treatment, monitoring, discharge), as well as at points outside the healthcare facility's circuit, such as during referrals or the electronic prescription of medicines. ⁽⁷⁴⁾ The lack of integration of the information systems used for electronic health records (EHRs) means several platforms need to be accessed when providing care, which could lead to the health records of different patients being opened

simultaneously. This could lead to mistakes in the EHR, and in the prescription of medicines and other procedures.

Correct identification is required to avoid such errors, which could have serious consequences. It is achieved by means of suitable methods and protocols, which ensure a patient is correctly identified throughout the process of care.

US non-profit ECRI has published a report analysing over 7,000 cases of patient identification errors. It found that:⁽⁷⁴⁾

- The majority of the failures (72.3%) occurred during patient encounters; another 12.6% occurred during the intake process.
- More than half of the failures involved either diagnostic procedures (2,824 or 36.5%) or treatment (1,710 or 22.1%). Diagnostic procedures cover laboratory medicine, pathology, and diagnostic imaging. Treatment covers medications, procedures, and transfusions.
- The majority of the events for which a harm score was provided were caught before they caused any harm (1,601 of 1,752 events, or 91.4%).
- Wrong-patient events involving physical identification of patients constituted about 15% of all the failures identified; most of these events fell into three categories: wristband missing, patient identity not verified, or wristband identifiers incorrect.
- Almost 15% of events (1,148) were associated with technology contributing to patient identification errors.

It was also observed that certain factors can contribute to wrong-patient errors:

- Using a room number or bed assignment to identify a patient who has been moved to a different room or bed.
- Asking a patient to confirm his or her name (“Are you Mr. X?”) instead of asking the patient to state his or her name (“Tell me your name”).
- Pulling the medical record of a patient with a name similar to that of the intended patient.
- Administering a patient’s medications before confirming the patient’s identity with bar-code scanning.

At national level, the *Evaluation Report* ⁽³⁾ concluded that most Autonomous Communities had established protocols to ensure patients are identified correctly. However, the implementation of protocols for patients undergoing risky procedures and of protocols for the identification and traceability of biological samples was poor.

- Specific objectives:
 - Continue to promote the correct identification of patient, procedure and site.
 - Implement standardized, assessable and—preferably—automated systems for the correct identification of patients and

biological samples at all healthcare facilities in all Autonomous Communities.

- Adopt measures to avoid confusion when two patients have similar identifiers (such as the same name).
- Confirm patient identity when labelling samples, label them with at least two patient identifiers, avoiding interruptions or distractions throughout the identification process. Preferably use automated identification methods.
- Identify newborns before they leave the maternity ward and before any possible separation from the mother, in the presence of the mother or a family member if possible.
- Provide training to health professionals regarding the importance of correct identification of patients, samples and clinical documents throughout the process of care.
- Actively involve the patient/caregiver in the identification process.
- Promote the correct identification of patients with specific risks.
 - Through the Network of Health Schools for Citizens, provide information to involve inpatients in their correct identification, especially when undergoing high risk procedures or treatments.
- Ensure correct identification of biological samples that are decisive for diagnosis.
 - Establish actions which ensure the traceability of biological samples from collection to delivery of results, such as labelling biological samples upon collection and imaging tests upon realization.
- Foster correct identification of patients' clinical documents.
 - Check that clinical documents correspond to the correct patient, involving the patient/caregiver in this process.
 - Develop EHR and e-Prescription systems which facilitate correct patient identification.

General objective 2.6: Promote communication among professionals and between professionals and patients

Clinical information must be reported accurately to the correct health professional, using the correct channel. Measures must be taken to ensure the accurate reporting of information throughout the process, especially during transitions of care, as these are a critical moment for patient safety.⁽⁷⁵⁾

It is essential to foster training in communication as a crucial element of care and interprofessional relations, especially taking into account the

beliefs and attitudes of health professionals with regard to health system users, patients, colleagues, superiors and subordinates.⁽⁷⁶⁾

Effective communication requires the use of standardized methods through the application of structured tools that facilitate the reduction of errors.⁽⁷⁷⁾

Moreover, WHO calls on health professionals to engage with patients, not only to identify their expectations, needs and preferences and to ensure joint decision-making, but also to promote transparency, by ensuring that patients are informed of their rights and responsibilities, and by disclosing safety incident to patients, families and caregivers.⁽⁷⁸⁾

Interoperable and shared health information systems are key contributing factors to better communication between professionals, patients and family members. The sharing of EHRs between hospitals, primary care centres and out-of-hospital emergency services makes it easier to record information during the process of care. The patient's care journey will thus be safer, allowing all professionals to be properly informed of the patient's health status and the care provided at each stage. In parallel, the patient's access to their own health records gives them an active role in improving the process of care and self-care.

- Specific objectives:

Communication between professionals

- Foster the use of National Health System interoperable EHRs by the different health services, ensuring patient safety.
- Establish standardized procedures and/or channels for communication within units (information transfer during shift handovers) and for transitions of care, ensuring uninterrupted safe care for patients. (79) (80)
- Foster the implementation of structured and validated communication techniques.⁽⁸¹⁾
- Boost staff training in interprofessional communication.
- Create working groups to improve effective and consistent communication between professionals.
- Publish guides, protocols and manuals on good communication.
- Implement standardized communication channels that enable the timely and effective escalation of issues to leaders and managers.

Communication with patients

- Use plain language to communicate with patients, taking their individual characteristics into account to determine the most appropriate means and style of communication, facilitating transparency and comprehension.
- Implement actions to ensure that diagnoses of potentially life-threatening conditions are communicated effectively.

- Foster active and empathetic listening at health centres, providing training and disseminating protocols on the use of clear language and empathetic communication techniques when delivering news and information.

General objective 2.7: Promote the design and development of strategies for dealing with serious adverse events at healthcare facilities

When an AE occurs, especially if it has caused serious harm, one of the organization's priority lines of action is to provide adequate support and information to the patient and their family (main victims).⁽⁸²⁾ These must be provided with adequate information regarding the circumstances of the event, as well as its consequences and the action that will be taken to address their needs, ensuring that this information has been fully understood.

Managing SAEs from a patient-safety perspective requires a paradigm shift from a blame-based approach to handling errors to one that focuses on the system as a whole. This systemic approach is based on the premise that people make mistakes and mistakes can occur even in the best organizations. That is why mistakes must be understood as a result of the system, therefore requiring not changes in staff, but changes to the conditions in which staff do their work.

To manage SAEs effectively, the safety culture must be strengthened, encouraging professionals to report incidents, understanding the learning opportunities that mistakes represent. Reporting incidents must be made easier and must be fostered as the main tool for raising awareness of safety and ongoing improvement.

Health professionals involved in AEs are secondary victims, and as such they must be supported by institutions and feel protected when openly reporting these events. They must receive the necessary support without punishment.⁽⁸³⁾

Healthcare organizations must adopt a proactive attitude to forestall conflict, using protocols and procedures to respond adequately to patients and professionals when an SAE occurs.

The reputation of an organization at which an SAE occurs (tertiary victim) can suffer, and the organization may have to implement action to recover users' trust.

The *Evaluation Report* highlights the scarcity of plans and protocols for managing SAEs that respond to the needs of patients, professionals and healthcare institutions. Improvement is therefore required.⁽³⁾

- Specific objectives:
 - Develop and implement recommendations for managing SAEs in the National Health System.

- Continue and strengthen strategies to support primary victims (patients and their relatives) and secondary victims (professionals involved).
- Implement measurable plans for managing SAEs that are adapted to the healthcare facility's specific circumstances and include actions focused on the patients/relatives affected and the professionals involved.
- Offer support to health professionals involved in SAEs through protocols adopted by management teams at healthcare facilities.
- Strengthen channels used by professionals to report to the organization and to managers, ensuring early management of SAEs.
- Reduce the impact of SAEs on tertiary victims and help to restore trust in the organizations involved through transparency and communication of accurate information to the media and other organizations and institutions.
- Increase the dissemination of best practices regarding SAEs.
- Facilitate appropriate communication of lessons learnt from the analysis of SAEs through anonymized reports in order to reduce the probability of future occurrence.
- Provide training to improve the skills of healthcare facility staff and management in relation to quality of care, patient safety, and the reporting, evaluation and management of SAEs.
- Foster proactive analysis of SAEs (failure mode and effects analysis).
- Foster reactive analysis of SAEs (root cause analysis).
- Study the possibility of establishing guidelines and/or regulations for the management of SAEs in the National Health System.

General objective 2.8. Promote the safe use of ionizing radiation in medical-radiological procedures and ensure that comprehensive quality assurance programmes are implemented pursuant to legislation

The use of ionizing radiation in medicine has significantly improved diagnosis and treatment. Diagnostic and interventional radiology, radiotherapy and nuclear medicine are undoubtedly its most extended uses.

Given its importance and the need to guarantee its safe use to avoid possible AEs, the application of ionizing radiation is highly regulated.^{(84) (85)}
^{(86) (87)} Legislation on the medical use of ionizing radiation started to be adopted in the 1990s and has since been amended and adapted. A significant milestone in this legislative journey was Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing

Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. This Directive was partially transposed into Spanish law by means of Royal Decree 601/2019 of 18 October, on the justification and optimization of the use of ionizing radiation to ensure radiation protection for all individuals subject to medical exposure, and Royal Decree 673/2023 of 18 July, establishing quality and safety criteria for nuclear medicine care units. ^{(88) (89) (90) (91)}

In this context, in 2012, WHO and IAEA published a joint position statement entitled the Bonn Call for Action, ⁽⁹²⁾ whose aims are to: strengthen the radiation protection of patients and health workers overall; attain the highest benefit with the least possible risk to all patients by the safe and appropriate use of ionizing radiation in medicine; aid the full integration of radiation protection into healthcare systems; help improve the benefit/risk-dialogue with patients and the public; and enhance the safety and quality of radiological procedures in medicine.

With backing from the European Commission, the Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA) was adopted in 2021. This initiative established three priority areas for EU action: securing the supply of medical radioisotopes, improving radiation quality and safety in medicine, and facilitating innovation and the technological development of medical ionizing radiation applications. It also seeks to strengthen safety culture and increase knowledge about the risks associated with these technologies, especially in paediatrics, in line with the aforementioned legislation. ^{(93) (94) (95) (96) (97)}

Spain, as an EU Member State, is involved in the application of SAMIRA. This strategic agenda constitutes the EU's first comprehensive action plan to support the safe, high quality and reliable use of radiological and nuclear technology in healthcare. It is supported by previous advances and lays the foundations for future coordinated action at EU level. The plan focuses on improving the safety and quality of medical procedures used in ionizing radiation, with the aim of ensuring that its use in diagnosis and treatment in EU countries meets with the highest standards of quality and safety, always in the patients' best interests.

To achieve the coordination and complementarity required in this field, the Commission created the Steering Group on Quality and Safety of medical applications of ionising radiation (SGQS). ⁽⁹⁷⁾ This group is composed of representatives from both the health and the radiation protection authorities of EU countries. SGQS offers a common platform to support the implementation of European requirements for radiation protection and other quality and safety standards into the EU national health systems. In particular, it develops high-quality evidence, clinical guidelines and practical tools, and supports their implementation in clinical practice across Europe.

Another key aspect of SAMIRA is the education and training of researchers and professionals in radiology, radiotherapy and nuclear medicine, which will be supported by EU programmes in these areas. The initiative also seeks to reduce inequalities within and between EU countries by supporting access to modern technology and interventions.

Commission Recommendation (Euratom) 2024/1112 of 18 April 2024 on clinical audits of medical radiological practices carried out pursuant to Council Directive 2013/59/Euratom builds upon the Position Paper adopted by SGQS in June 2023. ⁽⁹⁸⁾ The recommendations for Member States include that of establishing a national framework and infrastructure, including legal and administrative provisions, for the effective implementation of clinical audits carried out pursuant to Article 58, point (e) of Directive 2013/59/Euratom in all medical practices using ionizing radiation, commensurate with the level of radiological risk. This recommendation is reflected in the Royal Decrees transposing the aforementioned Council Directive.

The *Evaluation Report* ⁽³⁾ highlighted the scarcity of ongoing training for hospital paediatricians on the optimization of the application of diagnostic tests using radiation, and on risk mapping in nuclear medicine and radiotherapy units. The *Evaluation Report* also identified the need for greater reporting of safety incidents in radiotherapy units.

- Specific objective:
 - Facilitate Spanish participation in international and European projects aimed at improving the safety and quality of radiological procedures using ionizing radiation and sources of radiation in medicine.
 - Implement prospective risk analysis methods to enhance safety in clinical practice, in line with the Bonn Call for Action. ⁽⁹²⁾ These include risk mapping of processes in all radiotherapy, nuclear medicine and diagnostic radiography units.
 - Have services that use ionizing radiation prepare risk maps for processes in radiotherapy and nuclear medicine units.
 - Continue and strengthen the detection and prevention of incidents and accidents in the medical use of ionizing radiation, especially in radiotherapy and in interventional radiology and nuclear medicine.
 - Maximize the reporting of incidents and accidents in the medical use of ionizing radiation and, in general, of SAEs, by entering them in incident reporting systems, and encourage communication of lessons learned and recommendations resulting from the analysis of incidents and accidents to avoid their recurrence.
 - Enforce compulsory reporting to the competent health authority of any significant event related to accidental or unintentional exposure, in line with regulations. ⁽⁹⁰⁾

- Identify and share good practices regarding the medical use of ionizing radiation.
- Implement training and skill-building in radiation protection for doctors prescribing clinical practices using ionizing radiation, especially in patients under the age of 18 and pregnant women.
- Adapt and implement the recommendations of the European Commission on clinical audits of medical radiological practices carried out pursuant to Council Directive 2013/59/Euratom.
- Undertake activities to update diagnostic reference levels (DRLs) in line with the SAMIRA Action Plan and the guidelines of Royal Decree 601/2019.
- Establish clinical audit programmes, harmonized by the Ministry of Health, in all Autonomous Communities.
- Increase awareness among health professionals, patients and the public of the benefits and risks related to procedures using ionizing radiation.
- Implement standardized criteria for the discharge of patients undergoing radionuclide therapy.
- Foster monitoring of patients receiving high doses in diagnostic and interventional radiology procedures to monitor the deterministic effects caused by radiation.⁽⁹⁹⁾
- Include information on all procedures undergone using ionizing radiation in patients' health records. It will be necessary to implement dose management systems and ensure that the interoperability of health records extends to imaging tests.
- Periodically review the suitability of equipment to guarantee the lowest possible dose in clinical procedures using ionizing radiation.

General Objective 2.9. Promote the abandonment of low-value practices through the implementation of do-not-do recommendations

Under General Healthcare Act 14/1986 and Act 16/2003 on the Cohesion and Quality of the National Health System, the health system must guarantee high-quality, efficient and high-value care. However, owing to a variety of factors—such as uncertainty⁽¹⁰⁰⁾—healthcare services often apply lower-value, inefficient practices, or practices with little scientific basis. Nonetheless, scientific progress can enable adoption of new approaches and treatments, which must be integrated into care services to replace others that have proven less effective, and which should be discontinued.

A do-not-do recommendation is an instruction to discontinue a low-value clinical practice. A practice is considered low-value if it has no known

benefits for patients or puts them at risk of harm and may also waste healthcare or social security resources.

Identifying, reducing and discontinuing such practices has become a priority, both nationally and internationally.^{(101) (102) (103) (104)}

In 2013, the Ministry of Health, in response to a proposal from the Spanish Society of Internal Medicine, launched a project entitled “Commitment to quality of the Spanish scientific societies”, with the primary goal of reducing the number of unnecessary operations, i.e., those that have not proven effective, whose effectiveness is limited or doubtful, which are not cost-effective, or are not priority operations.

The work of this project has continued under the **Do-not-do Initiative**. The new phase, spearheaded by the Ministry of Health, with the support of GuíaSalud, aims to bolster the do-not-do culture in the National Health System and is focused on improving the quality and safety of care, minimizing the application of low-value healthcare practices. The aim of the initiative, in which more than 50 scientific societies are participating, is to raise awareness of do-not-do recommendations among National Health System staff and users, making them more easily accessible by offering a catalogue of recommendations (<https://portal.guiasalud.es/no-hacer/>),⁽¹⁰⁵⁾ and supporting the drafting of new recommendations based on the most recent scientific evidence, adding them to the catalogue, which will be a living document that is constantly updated.

- Specific objectives:
 - Support identification of low-value practices.
 - Encourage participation by professionals, through their scientific societies, in identifying low-value practices.
 - Step up publicity of do-not-do recommendations.
 - Organize training and awareness-raising activities for health professionals, to improve knowledge regarding low-value practices and their impact.
 - Hold scientific seminars to raise awareness of the initiative.
 - Publicize the initiative through patients’ associations.
 - Promote gradual implementation of the recommendations at healthcare facilities.
 - Roll out support systems and tools for clinical decision-making, to assist health professionals in identifying practices that are unnecessary or low-value and determining whether an operation would actually benefit a specific patient.
 - Implement, at the Autonomous Community level, strategies for ensuring clinical practice is fit for purpose and for bolstering the Do-not-do Programme and evidence-based medicine.

- Maximize good practices, focusing on incorporating patient safety standards into process management.
- Institute monitoring of the initiative's impact and provide feedback on outcomes to health professionals.
- Incorporate do-not-do recommendations into management plans and quality assurance plans for healthcare facilities, in the form of good practice indicators.

Line of action 3: Risk management and systems for reporting and learning from incidents

Risk management is crucial to patient safety, as its purpose is to identify and analyse healthcare-related risks and to draft action plans to prevent or minimize negative impacts on patients, professionals and institutions, as well as to inform professionals of successes.

Healthcare facilities must establish mechanisms for identifying healthcare risks, implementing targeted strategies to adequately manage those risks, and strengthening their commitment to enable reporting systems to operate correctly and in a standardized way, taking into account training, information and feedback for professionals, to reduce the likelihood of avoidable harm to patients during care.

Incident reporting systems enable useful information to be gathered on sequences of events that have led to incidents, thus allowing lessons to be learned to prevent recurrence, and improvements to be made to mitigate contributing factors. That is why such systems are recommended by different international bodies, such as WHO and the Council of the European Union. In Spain, Act 16/2003 of 28 May, on the Cohesion and Quality of the National Health System, states that practices that have given rise to potential safety problems for patients must be recorded, and the necessary infrastructure must be available both to the Ministry of Health and Consumer Affairs and to the Autonomous Communities.⁽¹⁰⁶⁾

Such reporting systems enable facilities to not only learn from their own experiences to prevent mistakes, but also from the experiences of other facilities. Despite this, because there is a lack of information about the practicality of these systems and sparse feedback on the analyses performed and the measures adopted as a result, and because of a fear of punishment and a shortage of time, some professionals are rather averse to reporting incidents.

Management and analysis of incidents relating to patient safety, especially in the case of sentinel events (those that may result in death or serious physical or psychological injury to a patient), and establishment and implementation of measures adopted as a result of such analysis, enable repeat incidents to be prevented, minimize harm, and ensure that the public receive safe healthcare.

The 2022 report by the Ministry of Health to support updates to the safety strategy for the National Health System (*Informe de resultados: apoyo en la actualización de la Estrategia de Seguridad del Sistema Nacional de*

Salud) recommends maintaining this strategic approach and does not propose any major changes. The report also states that various professionals who were interviewed or surveyed indicated that efforts needed to be made to strengthen support for professionals in legislation. However, although the *Evaluation Report* recommends that the Ministry of Health spearhead national law to protect professionals who report or analyse AEs, the view was that this was not a feasible change in the short term. The recommendation is, therefore, to seek partnerships with patients' associations and professional associations, and give consideration to strategies for publicizing the alternatives that have been proposed in meetings and forums on the subject, while continuing to actively work to identify and overcome the barriers that hinder such changes in law. Lastly, the *Evaluation Report* recommends reviewing and analysing regulatory developments in other European countries that could be drawn on to achieve this goal, which is vital to strengthening the culture of patient safety.

As mentioned in this Strategy's situation analysis, the *Evaluation Report* notes that Risk Management Functional Units (Unidades Funcionales de Gestión de Riesgo or UFGR in Spanish) are commonplace in Spanish hospitals but are slightly less common in primary care.

The *Evaluation Report* also states that all the Autonomous Communities have systems for reporting healthcare-related incidents, and that 11 of the Communities have opted to use SiNASP (the Patient Safety Reporting and Learning System developed by the Ministry of Health). Reporting systems are also well-established at the hospital and primary care levels; in this regard, the main area that requires work is encouraging professionals to participate voluntarily.

The general objectives, specific objectives and recommendations for this strategic line of action are based on all the above considerations.

General objective 3.1: Promote risk management at healthcare facilities

- Specific objectives:
 - Establish healthcare risk management units or similar bodies to perform these functions (at the facility level or the management level).
 - Encourage preparation and updating of risk maps for key areas of the different levels of care.
 - Promote other methods for identifying risks relating to safety (analysis of complaints and suggestions, safety patrols, reviews of health records, sessions to learn from mistakes, epidemiological studies, etc).

- Plan training for healthcare facility staff on risk management and use of related tools aimed at professionals.
- Foster proactive management of risks through methodologies to identify problems, analyse causes and develop measures to prevent incidents or reduce their frequency.
- Systematically conduct reactive analyses of incidents which caused no harm and AEs as necessary, including measures for improvement in organizations' quality assurance plans based on the findings.
- Organize specific training based on the lessons learned from management of incidents.
- Review, on a periodic basis, the systems for reporting patient safety warnings, with a view to making any necessary improvements.
- Bring the time spent analysing incidents into line with the officially required time-frames, regularly including measures to address the areas for improvement identified.

General objective 3.2: promote the implementation and development of systems for reporting and learning from healthcare-related incidents

Specific objectives:

- Analyse the characteristics of the process for patients and their families and caregivers to report incidents, adapting it to the specific requirements of the National Health System.
- Establish a reporting system for healthcare incidents, at those healthcare facilities and services that do not have one, that is voluntary, confidential, non-punitive and promotes learning and problem-solving at the local level.
- Facilitate use and appropriate management of systems for reporting healthcare-related incidents (for example, by improving the ease of access to the reporting system through EHRs), and ensure they are sustainable, standardized and have unified criteria for recording data, with a view to improving healthcare safety.
- Organize training, instructive events and publicity aimed at health professionals, to promote proper reporting of safety incidents.
- Hold instructive and training activities for board members, senior management, middle management, and persons in charge of reporting systems, to improve reporting, analysis and timely feedback for safety incidents and to draft improvement plans.
- Promote inclusion of the plan resulting from analysis of an SAE in the organization's patient safety plan, while ensuring respect for

the confidentiality of all documents containing in-depth analysis of SAEs.⁽¹⁰⁷⁾

- Inform professionals about the analysis of the identified incidents in a proper and timely manner, and provide them with information on the best way of preventing such incidents, as well as the steps taken following management of the known incidents reported through the system.
- Publish, periodically and at the national, regional and local levels, information on the most frequent safety incidents in the National Health System and the recommendations for preventing them.
- Work to identify and overcome barriers that hinder regulatory changes, and pursue development of national legislation (or reform existing legislation), to strengthen patient safety policies and policies to protect data gathered in reporting systems.
- Promote expansion of the practice of reporting patient safety incidents to all areas of care, especially primary care and social care.
- Promote research in the identified areas for improvement.

Line of action 4: Participation of patients, families and the broader public in patient safety

Participation by patients and their families or caregivers is covered by World Health Assembly resolution WHA72.6 (*Global action on patient safety*) and in the *Global Patient Safety Action Plan 2021-2030*, which are key to bringing an end to avoidable harm in healthcare.

Patient safety is a basic requisite, arising from the constitutional right to protection of health in Spain, as recognized by Spain's Bioethics Committee in its report on ethical aspects of safety.⁽¹⁰⁸⁾

In the healthcare field, patient participation is defined as **facilitation and strengthening of the role of patients** using health services, as co-contributors to the health policies and practices that affect **their health**. This **entails ensuring patients are actively involved** in their own care and in improving the health system.^{(109) (110)}

This strategic line of action is a cornerstone of improvements to patient safety. The lines of work established at the international level by WHO reflect this, as set out in the *Global Patient Safety Action Plan 2021-2030* and specifically in its *Engaging patients for patient safety* report,⁽¹¹⁰⁾ published in 2023, which identifies greater commitment to their own health among patients, and their families and caregivers, as a key means of minimizing avoidable harm that may result from unsafe healthcare.

Patient engagement and participation in health- and healthcare-related decision-making has a proven **beneficial effect**^{(110) (111)} on patients' relationship with the health system and their experiences within it, by improving health outcomes and health system performance, and by reducing incidents, thus also lowering healthcare costs.

Since 2005, WHO has been running a programme called Patients for Patient Safety (PFPS), which focuses on **patients' rights, transparency and collaboration with healthcare personnel to boost the engagement of patients in healthcare safety**. In 2006, PFPS issued the London Declaration, setting out four key areas for action:

- Devising and promoting programmes for patient safety and patient empowerment.
- Developing and driving a constructive dialogue with all partners concerned with patient safety.
- Establishing systems for reporting and dealing with healthcare harm on a worldwide basis.

- Defining best practices in dealing with healthcare harm of all kinds and promoting those practices throughout the world.

In this regard the WHO *Global Patient Safety Action Plan 2021-2030* ⁽³⁹⁾ proposes engaging and empowering patients and families or caregivers to help and support the journey to safer healthcare, through the following five strategies:

- Engage patients, families and civil society organizations in co-development of policies, plans, strategies, programmes and guidelines to make healthcare safer.
- Learn from the experience of patients and families exposed to unsafe care to improve understanding of the nature of harm and foster the development of more effective solutions.
- Build the capacity of patient advocates and champions in patient safety.
- Establish the principle and practice of openness and transparency throughout healthcare, including through patient safety incident disclosure to patients and families.
- Provide information and education to patients and families for their involvement in self-care and empower them for shared decision-making.

In addition, the intention is to approach these strategies at the different levels for action: global, national and local.

In the *Evaluation Report* on the Strategy, published by the Ministry of Health in 2022, measurement of the different indicators relating to the general objective of promoting participation in patient safety by patients and their caregivers revealed that such actions had been adopted in most of Spain's Autonomous Communities, with 80% to 100% having adopted measures of this kind. However, at healthcare facility level within these Autonomous Communities the level of implementation was considerably lower.

As indicated in the Evaluation Report prepared by the Ministry of Health for the purpose of updating this strategy, efforts should be made to highlight the need to **learn from the experiences** of patients, caregivers and families, and to promote expert **patient champions**, who are those health system users who have experienced an AE in healthcare—or whose loved ones have experienced such an incident—and are working from within health systems to improve safety.

This report also underscores the importance of establishing **transparency** principles for all areas and levels of healthcare, of making it possible for patients or caregivers to **easily report and advise of incidents**, and of promoting the correct use of **complaints, suggestions and requests** received, from which lessons can be drawn to improve safety.

General objective 4.1: Promote the participation of patients and their caregivers in patient safety

- Specific objectives:
 - Identify instruments to establish patient safety as a right of all members of the public, to ensure healthcare is safe and of good quality.
 - Establish mechanisms to include patients, caregivers and families in the governance of health policies, in order to improve patient safety within the National Health System.
 - Forge partnerships at the country level with national patient and user organizations on issues relating to patient safety.
 - Build a broad-based consensus among health professionals, scientific societies, healthcare decision-makers, patient associations and healthcare authorities (Autonomous Communities and Ministry of Health) on patient safety as a right of all members of the public, to ensure healthcare is safe.
 - Offer educational activities for patients, caregivers and family members on patient safety through the Network of Health Schools for Citizens.
 - Develop national publicity, awareness-raising and public information strategies aimed at patients and the wider population. Pursue specific official programmes and campaigns.
 - Raise the profile of expert patient champions. In addition, aim to promote partnerships between champions and patient associations, to improve safety and spread information.
 - Promote, within the National Health System, sharing of experiences by patients and families, from which lessons can be learned to improve patient safety.
 - Develop patient admission plans for National Health System healthcare facilities. The plan must include clear, accurate, accessible information on patients' rights and duties, the health services that will provide the care, the risks of the care, the patients' role in decision-making and patients' participation in improving clinical safety.
 - Perform periodic reviews of admission plans, especially as regards patient safety recommendations.
 - Provide patients and families, during healthcare, with full, easy to understand, tailored information on their healthcare process, enabling shared decision-making and strengthening patient-staff relations, while ensuring that the information provided has been understood.

- Organize training activities to improve healthcare staff's communication with patients.
- Promote active participation by patients, families and caregivers in activities relating to patient safety at the Autonomous Community level (promote joint patient-staff committees, patient councils, working groups, etc)
- Promote the use of Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs), through well-established tools, to gather information on patients' experiences in terms of safety in a structured manner.
- Establish, develop and monitor hospital inpatient support plans in Autonomous Communities, focusing on the most vulnerable patients (paediatric, cognitive impairments, end-of-life, etc).
- Contribute to informed consent being obtained correctly from patients, pursuant to Act 41/2002 of 14 November, regarding the basic regulation of patients' autonomy and of rights and obligations regarding clinical information and documentation.
- Facilitate registration of duly informed prior consent.
- Promote standardization and adaptation of information provided to patients, families and caregivers, to improve understanding and transparency.
- Develop the necessary resources to boost empowerment of patients, caregivers and families.
- Facilitate the lodging of complaints, suggestions and claims at healthcare facilities, from which lessons can be drawn to improve patient safety within healthcare organizations.
- Identify complaints and claims from patients relating to patient safety and enter them into the patient safety incident reporting system.

Line of action 5: Research and innovation in the field of patient safety

Research and innovation are **essential tools** that can be employed to ensure patient safety. Generation of robust scientific evidence and its effective application to clinical practice enable safer healthcare to be provided, reducing the likelihood of failures or mistakes.

Improved insight into patient safety is key to developing more reliable, efficient and resilient health systems.

In this respect, **strategic objective 6** of the WHO *Global Patient Safety Action Plan 2021-2030* is for patient safety research to ensure a constant flow of information and knowledge to drive mitigation of risk, a reduction in levels of avoidable harm, and improvements in the safety of care. The *Action Plan* highlights that one of the major strategic goals of patient safety research is to produce new knowledge that improves the capability of healthcare systems, as well as the health organizations and practitioners that comprise them, to **reduce the harm associated with healthcare**.

In this area, **standardization, consistency and consensus are particularly important as regards terminology and information**. To achieve this, there must be **harmonization** with the WHO International Classification for Patient Safety, which will enable data to be shared globally, with a view to setting priorities and sharing solutions, and increasing the value and quality of research work.

Technological progress and digitalization of health information can promote and facilitate interoperability and improved research output in this field.

Patient safety research areas should take into account aspects that can improve insight into: the extent and nature of clinical risk, preventive risk analysis, understanding of the factors that contribute to incidents relating to patient safety and their impact on the health system, identification of effective and efficient safe practices, viable and sustainable solutions that prevent use of low-value practices, and analysis of implementation and evaluation of such solutions.

Specific **areas** of research that have been recommended internationally must also be taken into account, such as formal evaluation of health policies to improve patient safety, risks arising from the use of artificial intelligence in healthcare, improvement of studies in areas such as primary care, mental health, socio-health care, and care for certain population groups that are at greater risk of being harmed during healthcare. ^{(1) (39)}

Spain has been highly active in patient safety research since the Strategy was first launched, as reflected by the numerous publications in the field and national and international research projects. ⁽¹¹²⁾

General objective 5.1: Foster greater knowledge about preventing healthcare-associated harm

- Specific objectives:
 - Prioritize, at the National Health System level, specific areas of research such as prevention of risks and harm related to healthcare, identification, implementation and evaluation of safe practices, and do-not-do recommendations.
 - Perform periodic studies of the incidence and prevalence of AEs and determining factors, in different healthcare settings.
 - Facilitate participation by the Autonomous Communities in research projects on patient safety, at the national and international levels.
 - Establish areas of research into patient safety within Autonomous Communities' research programmes.
 - Use available evidence to improve identification, dissemination and evaluation of safe practices in different healthcare settings.
 - Foster participation by patients and their families in setting research priorities and in conducting appropriate studies.
 - Perform activities to publicize the results of research studies into patient safety:
 - Publicize key projects, original publications, and meta-analyses in the area of patient safety research and innovation, in the different divisions of the National Health System.
 - Compile and disseminate the final results of European patient safety projects.
 - Foster dissemination and updating of websites on patient safety at the local and regional levels.
 - Publicize the Ministry of Health Patient Safety website (<https://seguridaddelpaciente.sanidad.gob.es/>).
 - Develop recommendations to promote safe use of digital tools within the National Health System—including telemedicine, artificial intelligence and remote care—addressing risks concerning continuity of care and accuracy of diagnosis.
 - Facilitate participation by health professionals in patient safety research projects.

Line of action 6: National and international participation

To improve and expand knowledge of patient safety, partnerships and working networks must be established with the different international organizations that have an interest in the subject. Such partnerships will also allow experiences to be shared as regards safe practices and their successful implementation.

Recently, the COVID-19 pandemic demonstrated the need for all countries to follow a standard for safe universal health coverage, in our increasingly globalized world beset with mounting crises among health workers.

In 2015, the world leaders of the Member States of the United Nations adopted a set of global goals, the Sustainable Development Goals (SDGs), with specific targets that the Member States including Spain must strive to **meet by 2030. Goal 3 of the SDGs is to “ensure healthy lives and promote well-being for all at all ages”**, including through access to health-care services based on **safe, high-quality care**.

WHO, through its patient safety programme, has implemented challenges, programmes and actions, as well as a working network in which Spain is an active participant. Spain's strategy is fully aligned with the *Global Patient Safety Action Plan 2021-2030* and shares its principles and goals.

In this respect, key activities are also being implemented under the WHO *Global strategy on infection prevention and control*, and Spain participates actively in them. Although this Strategy includes many new aspects, it is also based on several existing resolutions, global strategies and action plans relating to patient safety, such as World Health Assembly resolution WHA72.6 (*Global action on patient safety*) and strategy 3.3 of Strategic Objective 3 of the Global Patient Safety Action Plan.

Spain is also a member of the technical working groups and policymaking groups concerning patient safety within **OECD**, the **Council of Europe** and the **EU**, and is involved in the patient safety activities of **PAHO**.

The key areas of collaboration can be viewed on the patient safety web page (<https://seguridaddelpaciente.sanidad.gob.es/en/proyectos/participacionInternacional/>).

The 2022 report by the Ministry of Health to support updates to the safety strategy for the National Health System (*Informe de resultados: apoyo en la actualización de la Estrategia de Seguridad del Sistema Nacional de Salud*) highlights the need to refer not only to international participation but also national participation, bolstering collaboration among the Autonomous

Communities and between the Communities and the scientific societies, and sharing success stories.

General objective 6.1: Foster international collaboration on patient safety

- Specific objectives:
 - Continue and strengthen collaboration on patient safety, with WHO and PAHO.
 - Continue and strengthen collaboration with other Member States and the European Commission in working groups and joint actions, as part of EU activities concerning quality of care and patient safety.
 - Continue and strengthen collaboration with OECD working groups relating to patient safety.
 - Publicize collaboration at the international level among professionals and the public, through media such as the patient safety web page.
 - Identify and take advantage of opportunities for collaboration with international centres of excellence in patient safety education and training.

General objective 6.2: Promote national collaboration on patient safety

- Specific objectives:
 - Publicize the National Health System Patient Safety Strategy and the activities performed under it among the Autonomous Communities and other interested parties.
 - Develop collaboration initiatives and spaces for learning and sharing success stories among the Autonomous Communities.
 - Hold annual events including seminars on patient safety, with participation by scientific societies and representatives of the Autonomous Communities.

Line of action 7. Patient safety in all areas of care

In 2024, WHO published the *Patient safety rights charter*,⁽¹⁵⁾ a key resource that is intended to support implementation of the *Global Patient Safety Action Plan 2021-2030: Towards eliminating avoidable harm in health care*. The charter aims to set out the rights of patients in the context of their safety and to support the defence of those rights, as established by international human rights law, **for everyone, everywhere, at all times**, recognizing patient safety as a vital component of the right to health.

Even strategic objective 3 of the *Global Patient Safety Action Plan 2021-2030*⁽³⁹⁾ includes the strategy of assuring the safety of patients in all settings, including in mental health settings, care homes and other areas, with a focus on transitions of care.

Strategic line of action 2 of Spain's Strategy refers to clinical practices to ensure patient safety in the case of critical patients, in surgery and during anaesthesia, during care, and as regards safe use of ionizing radiation and medication, and prevention of HAIs.

The aim of this strategic line of action is to increase the reach of information and safe practices relating to safety in other areas.

General objective 7.1: Guarantee patient safety in all areas

- Specific objectives:
 - Address risks to patient safety, as a priority area for all strategic planning and roll-out of healthcare services.
 - Include patient safety infrastructure in all facilities, ensuring that the care environment is safe through proper management of equipment, infrastructure and buildings.
 - Establish and strengthen patient safety aspects when providing services, granting permits and authorizing facilities and services.
 - Strengthen measures that encourage proactive and responsible attitudes among professionals, in the interest of patient safety.
 - Support and promote adaptation of programmes and initiatives relating to patient safety in other settings, such as care homes for older persons.
 - Incorporate patient safety aspects that encompass risk management in emergency settings, disease outbreaks and extremely adverse environments.
 - Establish metrics with standardized indicators, to facilitate comparison across organizations.

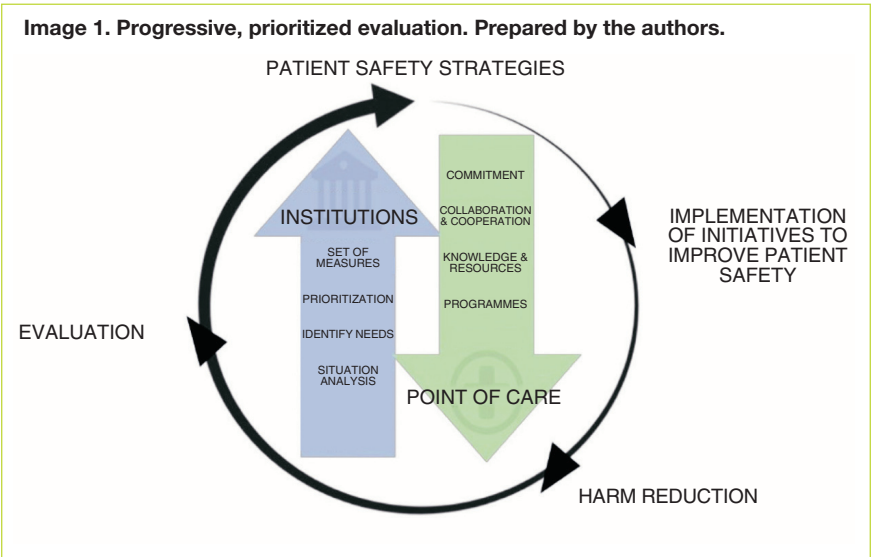
5. Evaluation

Evaluations of patient safety and of progress in implementing the lines of action and objectives of the Strategy will enable analysis of its effectiveness in preventing and reducing healthcare-associated harm and identifying potential areas for improvement, either by refocusing the best patient safety activities or by making ongoing improvements to healthcare management and clinical practice.

The current status, progress and implementation of initiatives and programmes must be evaluated and analysed. It is vital for this to be a collaborative and organized process, with a progressive approach that gradually involves the Autonomous Communities, local authorities and ultimately healthcare facilities and services themselves (*Image 1*).

Preparing patient safety strategies and implementing initiatives to improve the different areas of patient safety—such as safety culture, reporting and learning systems, teamwork and communication, identification and establishment of safe practices, and patient participation—and the subsequent evaluation of both will trigger a number of improvements and adaptations of the system that will contribute to the ultimate aim: reducing harm to patients at the point of care. (*Image 1*).

Therefore, since its inception, this Strategy has been evaluated using **multi-layered methodologies** that offer insight into the safety levels of the National Health System’s health services at the macro-management level.



The handbook for evaluating the Patient Safety Strategy for the period from 2015 to 2020 (*Manual para la Evaluación de la Estrategia de Seguridad del Paciente del Sistema Nacional de Salud. Periodo 2015-2020*) published by the Ministry of Health sets out the methodology used to determine a set of indicators that are reviewed, updated and agreed by the Autonomous Communities. The results of the evaluation for the 2015–2020 period were published in the *Evaluation Report (Informe de evaluación de la Estrategia de Seguridad del Paciente del Sistema Nacional de Salud. Periodo 2015-2020)*.

For the future evaluation of the next period covered by the Strategy, **indicators and evaluation criteria** must be reviewed, updated and agreed with the Autonomous Communities, to guarantee:

- **Transparency of information** on patient safety within the National Health System.
- **Promotion of patient safety** at the different points of care.
- **Identification of success stories** and non-successes, to foster collaborative **learning** that can lead to improvements.
- Highlighting of **opportunities for improvement** to focus new actions.

To achieve this, indicators will be identified and selected by the Institutional Committee on Patient Safety, taking into account the lessons learned from the prior evaluation.

Indicators defined as part of programmes and projects that fall within the framework of the National Health System Patient Safety Strategy will also be taken into account, including initiatives such as the **Hand Hygiene Programme**, the **Critical Patient Safety Programme**—covering the Zero Bloodstream Infections, Zero Pneumonia, Zero Resistance, and Zero Urinary Tract Infection projects—the **Safety in Surgery Programme**—covering the Safe Surgery and Zero Surgical Site Infection projects—and the patient safety reporting and learning systems. Other indicators from the rest of the National Health System reporting systems will also be taken into consideration.

6. Abbreviations and acronyms

ABHR	Alcohol-based hand rub.
AE	Adverse event.
CISNS	National Health System's Inter-Territorial Council.
EHR	electronic health records.
EU	European Union.
EUNetPaS	European Network for Patient Safety.
HAI	healthcare-associated infection.
HCQI	Health Care Quality Indicators.
HRM	high-risk medications.
IAEA	International Atomic Energy Agency.
IBEAS	Study of Patient Safety in Latin American Hospitals.
ICPS	International Classification for Patient Safety.
ICU	intensive care unit.
IHI	Institute for Healthcare Improvement.
ISMP	Institute for Safe Medication Practices.
MDROs	multidrug-resistant organisms.
NHS	United Kingdom National Health Service.
OECD	Organisation for Economic Co-operation and Development.
PAHO	Pan American Health Organization.
SAE	Serious Adverse Event.
SAMIRA	Strategic Agenda for Medical Ionising Radiation Applications.
SDGs	Sustainable Development Goals.
SGQS	Steering Group on Quality and Safety (of medical applications of ionising radiation).
SiNASP	Reporting and Learning System for Patient Safety.
SSC	Surgical Safety Checklist.
UTI	Urinary tract infection.
WHO	World Health Organization.

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Since 2005, the Ministry of Health has been promoting the National Health Service (NHS) Patient Safety Strategy.

Harm suffered by patients as a result of unsafe care is one of the leading causes of death and disability worldwide, representing a growing and significant challenge to global public health. The economic costs associated with safety failures are high, and most of these harms are preventable.

Patient safety is everyone's responsibility and requires the active involvement of many key stakeholders, ranging from patients and their families to governmental, non-governmental and professional organisations. In our country, this involvement has been essential to the development of the three Patient Safety Strategies published to date.

This new edition, in line with the WHO's global framework covering the period 2025-2035, aims to reduce harm associated with healthcare through coordinated, sustainable and evidence-based actions. It is structured around seven strategic areas: a culture of safety; human, organisational and training factors; safe clinical practices; risk management through reporting and learning systems; active involvement of patients and families; research and innovation to prevent harm; national and international engagement; and safety across all areas of care.

The 2025-2035 Strategy is a key tool for moving towards a safer, more efficient and people-centred model of care: a model that minimises risks, prevents avoidable harm and promotes collective learning.



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