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Understanding and reframing clinical errors through just culture: protocol for the DECIDE mixed-methods study in Spanish healthcare and community contexts

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ABSTRACT

Introduction Patient safety culture plays a crucial role in reducing clinical errors. By improving healthcare professionals' and patients' understanding of human fallibility and error attribution, patient care can be enhanced, fostering greater engagement from both groups. A Just Culture approach, which balances accountability and learning from errors, is a key factor in fostering this safety culture. The DECIDE Project aims to: (1) examine the conceptualisation of human fallibility within and beyond healthcare, (2) identify barriers and facilitators to Just Culture adoption, (3) assess the impact of psychoeducational interventions on professionals' and social leaders' attitudes toward clinical errors and (4) develop a roadmap for Just Culture implementation in healthcare.

Methods and analysis A 36-month mixed-methods study including qualitative research, a survey of 1255 healthcare professionals, an experimental study with 180 participants (60 per arm) testing interventions based on cognitive dissonance and reasoned action theories and a consensus conference to develop a Just Culture roadmap. Participants include professionals from hospitals, primary care, long-term care, nursing homes and social leaders in Spain. The qualitative data collected during stages 1 and 4 will be analysed using MAXQDA software. In identifying factors related to the implementation of Just Culture during stage 2, ANOVA, t-tests and multiple linear regression will be conducted. To examine the effects of the interventions in phase 3, a linear mixed-effects model for repeated measures will be employed.

Ethics and dissemination This study has received ethical approval from three institutional review boards. Findings will be disseminated through peer-reviewed publications, conference presentations and policy recommendations aimed at integrating Just Culture into national and international patient safety strategies. By promoting a constructive approach to errors, the project could enhance incident reporting, strengthen professional engagement in safety policies and foster a culture of learning and accountability. Its findings will guide policy recommendations for integrating Just Culture into national and international patient safety strategies, with potential applications beyond Spain.

ClinicalTrials.gov identifier NCT06835517.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The explicit categorisation of mistakes in this study strengthens a dimension still underdeveloped in international safety research.
⇒ By engaging extraintramural audiences, the study can challenge conventional thinking on individual and team fallibility, fostering transparency and accountability.
⇒ The study aligns with national and international patient safety strategies (eg, WHO strategy), addressing a timely and critical issue.
⇒ Despite independent group leadership and cross-coding, the interpretation of qualitative data may still be influenced by subjective perspectives.

INTRODUCTION

The analysis of the 1986 Chernobyl nuclear disaster highlighted how deficiencies in organisational safety culture can lead to adverse outcomes.[1] Since then, high-reliability sectors such as energy, chemical, transportation and healthcare have prioritised fostering a culture of safety.

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Safety culture encompasses the norms, values and attitudes that determine whether safety is considered essential in the daily activities of individuals, teams and organisations. It reflects efforts to implement safe practices and effectively manage incidents.[2] In healthcare, safety is a top priority and requires collective efforts from all stakeholders to ensure a secure environment.[3–5]

A 'Just Culture', which supports professionals following honest mistakes and encourages learning from these events, is a cornerstone of transitioning towards safer environments.[6 7] In contrast, complacency, fear of speaking out and the neglect of issues such as professional fatigue contribute to safety incidents, negatively impacting health outcomes. Therefore, fostering incident reporting, root cause analysis and support for the second victim is essential to ensuring safety.[8] However, after severe incidents, public and media perceptions often conflict with safety policies based on human fallibility. Instead, traditional blame and sanction models prevail.[4 5] For this reason, leaders and professionals need to embrace the principles of Just Culture,[9] which emphasise not holding individuals accountable for errors beyond their control while recognising that many errors stem from systemic working conditions. At the same time, reckless behaviour must not be tolerated.[10–14]

In 2016, the National Patient Safety Foundation and, later, the NHS (National Health Service) in 2018 introduced clear frameworks to differentiate honest mistakes from reckless or negligent behaviour, using substitution and intent tests.[15 16] A Just Culture requires honesty, accountability and transparency, upholding patient rights while aligning with the Safety II approach.[17 18] Promoting this culture requires a balanced approach to systemic and individual responsibilities, learning from errors and respecting users' rights.[19 20] Nonetheless, misconceptions about human fallibility and the pervasive culture of blame hinder the accurate identification of the root causes of honest mistakes. These misguided perceptions shape attitudes towards professionals involved in errors, delaying the development of a safety-oriented culture.[21] Reframing honest mistakes could benefit healthcare institutions in several ways: (1) improving the understanding of incident causes; (2) enhancing transparency in internal patient safety actions; (3) increasing professional engagement with safety policies; (4) strengthening the leadership role in implementing Just Culture principles.

The primary aim of this study is to promote the principles of Just Culture in hospitals, primary care, long-term care facilities and nursing homes, while offering new insights into key elements of human factor conceptualisation (fallibility) in safety incidents. The specific objectives of this project are: (1) to identify key elements in the social conceptualisation of human fallibility; (2) to identify barriers and facilitators to the implementation of Just Culture in healthcare institutions; (3) to evaluate the comparative effectiveness of two psychoeducational interventions, based on cognitive dissonance theory or the theory of reasoned action, in modifying attitudes, beliefs and behaviours regarding honest mistakes, risky behaviours and recklessness among professionals and social leaders and (4) to design a roadmap and criteria for implementing Just Culture in healthcare institutions.

METHODS AND ANALYSIS

This is a coordinated mixed-methods project that includes a qualitative phase for data collection, a survey to identify facilitators and barriers to implementing a Just Culture, an experimental study to evaluate the effectiveness of interventions in changing attitudes that diverge from the conceptualisation of honest mistakes and a consensus study to develop a roadmap. The DECIDE project started with its kick-off meeting in January 2025 and is expected to conclude in December 2027. This national project is structured into four main stages, with an initial pretest phase, over 36 months (figure 1). The first two stages focus on data collection, the third evaluates the effectiveness of interventions aimed at changing attitudes, and the fourth will emphasise the application of lessons learnt. The Standards for Reporting Qualitative Research guidelines (for qualitative studies) and Consolidated Standards of Reporting Trials standards for randomised trials from EQUATOR will be used to report the study.[22 23]

Research ethics approval: human participants

The study has been approved by the ethics committees of the following institutions: Hospital Universitario Ramón y Cajal (reference 203/24; 23 October 2024), Hospital Universitario Fundación Alcorcón (reference 24/96; 29 October 2024) and Hospital Universitari Sant Joan d'Alacant (reference 25/001; 28 January 2025). Additionally, the study has been registered in ClinicalTrials.gov (NCT06835517).

Definitions

Just Culture: An organisational environment that fosters transparency, respect and fairness. Staff feel safe expressing their opinions and learn from errors.[20 24]

Honest mistake: An error caused by intrinsic conditions of the task, system or communication failures, pressure, workload or equipment malfunction, among other factors.[25]

Risky behaviour: Engaging in an uncommon practice with an unknown risk.[26]

Reckless behaviour: Performing a practice that does not align with standard procedures.[26]

Social leaders: Individuals with influence in their communities or professional networks, such as consumer associations, patient advocacy groups, journalists, social media influencers, local health leaders from political parties, healthcare institutions or scientific societies. These leaders help shape public opinion and could act as key figures in fostering cultural change.[27 28]

Just Culture is a component of patient safety culture that promotes learning and fairness by differentiating between human error, at-risk behaviour and reckless

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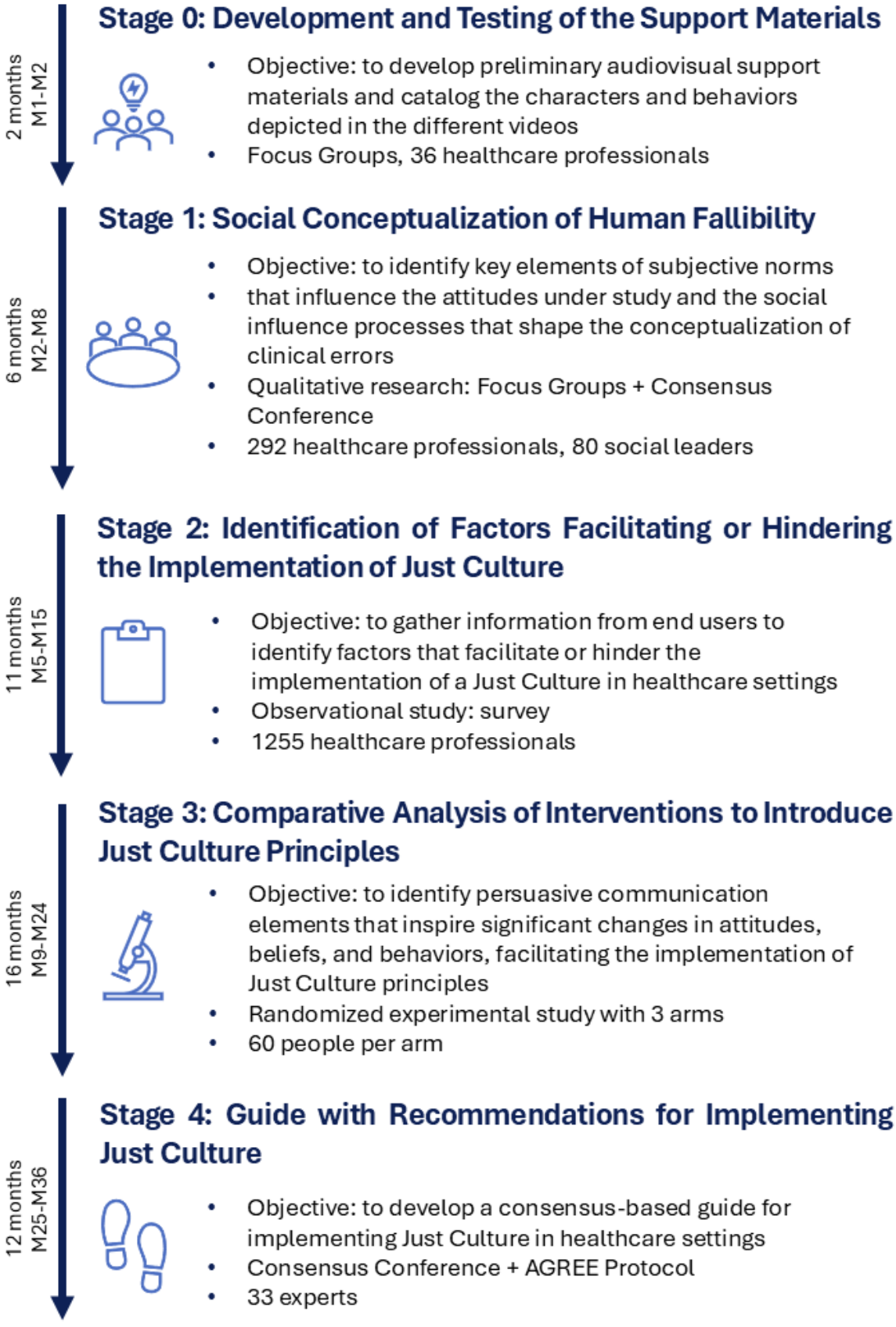

Figure 1 Project flowchart, with the objectives of each stage and the estimated execution time. AGREE, Appraisal of Guidelines for Research and Evaluation ; M, month.

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conduct. It encourages incident reporting, supports staff involved in adverse events and ensures accountability is proportionate to the behaviour and context, thereby fostering trust and continuous improvement.[17]

Spain has had a national patient safety strategy since 2005, which has been recently revised and strengthened for the 2025–2035 period.[29] The strategy sets out strategic objectives, lines of action and indicators to monitor progress and achievements and is aligned with the WHO Global Patient Safety Action Plan 2021–2030 and with the European Union's 2009 Council Recommendation on patient safety.

Theoretical assumptions

A safety-generating culture enhances health outcomes. 18 years after the launch of the National Strategy in Spain,[30] a broad social commitment is essential to solidify progress in patient safety and promote a safety culture across all sectors. Understanding human fallibility is crucial, as is challenging the belief that removing the 'bad apple' solves systemic problems.[25] Evidence supports the principles of Just Culture as a cornerstone for achieving deep and sustainable transformations in safety culture, addressing human fallibility in complex environments.[31]

Stage 0: development and testing of the support materials

Objective

To develop preliminary audiovisual support materials for the project and catalogue the characters and behaviours depicted in the different videos.

Design

12 short videos will be developed, each depicting different scenarios where characters exhibit different behaviours. The number of videos was determined through a prior call for narratives in which healthcare professionals were invited to describe situations representing adverse events of different causes and considerations. From these submissions, the research team selected the cases that best illustrated characteristic examples of honest mistakes, risky behaviours and reckless conduct. The scripts for these videos will be created by professionals with a minimum of 10 years of experience and reviewed by the project's principal investigators before production. The videos will follow a comic-style format. A total of six sessions will take place in four different locations, during which healthcare professionals will watch two videos per session. They will be asked to identify the characters and classify their behaviour into one of three categories: honest mistake, risky behaviour or reckless behaviour. Each session will include a discussion phase to refine and finalise the classifications. Additionally, participants will complete a validation questionnaire assessing the realism of the scenarios. Using a 5-point Likert scale, they will rate whether the depicted situation is realistic, whether it poses a risk of an adverse event for the patient and whether it presents a legal risk for the involved healthcare professional.

Participants

A minimum of 36 healthcare professionals from various backgrounds and specialities will be recruited. The number of participants reflects the research team's previous experience with these techniques and was considered sufficient to ensure data adequacy in line with qualitative research standards, where information saturation rather than statistical criteria is the key determinant. Selection will be conducted based on the criteria established by the centre's coordinator to ensure a heterogeneous and diverse group, thereby fostering a wide range of perspectives.

Data analysis

A triangulation process will be conducted across groups to consolidate the results from each video, producing a final list of characters and behaviours. This triangulation will consist of comparing participants' classifications of the behaviours depicted in the videos across groups to assess whether professionals from different centres or levels of care interpret the scenarios consistently and to identify potential sources of discrepancy if present.

Stage 1: social conceptualisation of human fallibility

Objective

To identify key elements of subjective norms (perceived as acceptable by the social reference group) that influence the attitudes under study as well as the social influence processes that shape the conceptualisation of clinical errors. This information will be used in stages 3 and 4 of this project.

Design

Qualitative research will be conducted. First, using the focus group technique (in person), participants' perceptions of human fallibility will be explored through videos of real-life scenarios depicting behaviours categorised by participants as honest mistakes, reckless behaviours or risky behaviours. Eight group sessions will be conducted with social leaders and another 31 with healthcare professionals, involving a minimum of 80 social leaders and 292 healthcare professionals. For the groups with social leaders, sessions will be facilitated by laypersons applying a citizen science approach.[32 33] Second, the results will be used to develop core ideas through a Consensus Conference (conducted remotely) to convey the meaning of the principles of Just Culture (honest mistake, risky behaviour and reckless behaviour) to various audiences.

Recruitment

A convenience sample will be recruited. A snowball sampling method will be used, targeting associations or unions of consumers, patients, journalists, social ambassadors, representatives of communication companies, local health leaders from political parties, healthcare institutions and scientific societies. Gender balance will be ensured to address stereotypes surrounding clinical errors. Inclusion criteria will consist of individuals aged 18 years or older with social leadership roles in associations,

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media, blogs, etc; professionals with more than 5 years of experience and participants who voluntarily consent to participate, commit to dedicating 5 hours and provide signed informed consent. Exclusion criteria will consist of individuals with ongoing legal claims or disputes with institutions, those who have experienced a severe adverse event and professionals with prior experience in patient safety groups or committees.

Materials

Short videos illustrating examples of clinical errors will be used to facilitate discussion (examples are included in https://decideculturajusta.com/videos/).

Data analysis

Data will be collected using a booklet designed for the sessions. This notebook will include a sociodemographic data section (workplace, gender, professional profile and years of experience). For the classification of behaviours, there will be a table for each character, which will include the behaviours identified during stage 0 and blanks in case other behaviours are identified. For each behaviour, they will have to describe what happened or what was wrong, classify it according to honest mistake, risky behaviour or reckless behaviour and justify why the classification was made. After completing the booklets, a brief discussion will be held and, finally, a behavioural verdict should be issued for each character. The MAXQDA tool will be used for discourse analysis, following Babchuk's 10-step process.[34]

Stage 2: identification of factors facilitating or hindering the implementation of just culture

Objective

To gather information from end users to identify factors that facilitate or hinder the implementation of a Just Culture in primary care settings, which will be used in stage 4 of the project.

Design

An observational study based on a survey will be conducted.

Participants

A stratified random sample of 1255 healthcare professionals will be selected, balanced by gender. The sample size has been estimated using p=q=0.50, with a 3% margin of error, a 95% confidence level and an estimated 15% attrition rate. Strata will include professional profile, region (named in Spain autonomous community) and setting (hospital, primary care and nursing home). Inclusion criteria will consist of professionals with a minimum of 7 years of experience, individuals who voluntarily agree to participate. Exclusion criteria include individuals involved in legal disputes or claims within the past 15 years. Participants will be recruited through invitations sent to healthcare professionals in a randomly selected sample of healthcare institutions.

Materials

A survey will be designed based on a cultural adaptation of the Just Culture Assessment Tool[35] and the Safety Culture Stack Approach.[36]

Procedure

First, the appropriateness of the selected instruments will be confirmed using the COSMIN (Consensus-based Standards for the selection of health Measurement INstruments) guidelines (translation-back translation, readability confirmation, reliability and validity testing with a representative sample of 120 subjects). Invitations will include a link to a secure online survey platform, ensuring complete anonymity for respondents. Up to three reminders will be sent to encourage participation.

Data analysis

Relationships between care levels and professional profiles will be analysed using ANOVA. Differences between genders will be assessed with a t-test. Multiple linear regression will be used to analyse the relationship between dependent variables (eg, survey scores) and factors such as years of experience, gender, professional profile and region.

Stage 3: comparative analysis of interventions to introduce just culture principles

Design

A randomised experimental design with three arms will be used to compare the effectiveness and acceptability of two interventions aimed at modifying attitudes, beliefs and behaviours related to honest mistakes, reckless behaviours and risky behaviours. Intervention A is based on the theory of cognitive dissonance,[37 38] and intervention B is based on the theory of reasoned action.[39 40] A control group will also be included.

Objective

To identify persuasive communication elements that inspire significant changes in attitudes, beliefs and behaviours, facilitating the implementation of Just Culture principles.

Null hypothesis

There will be no differences in outcome measures between the two interventions (intervention A based on cognitive dissonance theory and intervention B based on the theory of reasoned action) or the control group.

Interventions

(1) Theory of cognitive dissonance (intervention A): this intervention will target the psychological discomfort individuals experience when their actions conflict with their beliefs or values. Participants will be exposed to information that creates dissonance, encouraging adjustments in their beliefs, attitudes and behaviours. The intervention will include experiential activities, such as simulations, that provide compelling evidence supporting the acceptance of honest mistakes as opportunities for

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learning within a Just Culture framework. (2) Theory of reasoned action (intervention B): this intervention will focus on how social norms influence intentions and behaviour. It will involve testimonials, narratives and analyses of everyday clinical practices presented by opinion leaders and primary care professionals. These elements will encourage changes in subjective norms (individuals' beliefs about whether significant others approve or disapprove of specific behaviours), fostering the acceptance of honest mistakes and promoting learning and improvement in healthcare.

Participants

Social leaders and healthcare professionals, equivalent to those involved in stage 1.

Sample size

Each arm will include 60 participants, balanced by gender and proportionally distributed across four autonomous communities. The sample size was adjusted to maintain statistical robustness while optimising feasibility. It was calculated to detect a 5% difference in scores on the error-oriented and safety attitudes instruments, assuming an estimated mean score of 70, a SD of 16, a 90% confidence level and a statistical power of approximately 80–85%. Participants will be randomly assigned to one of the three groups after providing informed consent. Inclusion criteria are the same as stage 1. Participants must voluntarily agree to participate and commit to 90 min of involvement. Exclusion criteria include social leaders who have experienced a severe adverse event, initiated legal claims or disputes or healthcare professionals with prior experience in patient safety or participation in stage 1.

Materials

The interventions will use information gathered in stage 1. Both interventions will include audiovisual resources such as videos, podcasts and digital and traditional formats (eg, small group discussions). Participants in the control group will attend a 40 min lecture (followed by a 15 min discussion) on patient safety, causes of clinical errors and measures to reduce them in healthcare settings.

Measures

Attitudes and behavioural intentions: measured using a tailored instrument based on the Error-Oriented Motivation Scale[41] and the Safety Attitudes Questionnaire,[42] ensuring cross-cultural validity and robust psychometric properties. Cognitive dissonance indicators: assessed through linguistic markers of cognitive conflict, such as indecision, ambiguity or contradictions in discourse, increased use of first-person pronouns, shifts in perspective and abrupt content transitions. Participants will complete assessments at three time points: before the intervention (pre), immediately after the intervention (post) and 6 months later (follow-up).

Data analysis

The effects of the interventions will be evaluated independently for social leaders and professionals using a linear mixed-effects model for repeated measures, accounting for paired data. Data will be stratified by gender, age, participant profile and intervention group. Comparisons with coordinated subproject results will also be made. Statistical significance will be set at p value <0.05, and analyses will be conducted using the R software.

Stage 4: guide with recommendations for implementing just culture

Design

Consensus among professionals using the consensus conference technique. The Appraisal of Guidelines for Research and Evaluation (AGREE II) framework will be applied.

Objective

To develop a consensus-based guide for implementing Just Culture in healthcare settings.

Participants

A total convenience sample of 33 participants will be recruited, balanced by gender, with a minimum of 10 years of experience. Recruitment will be conducted among members of professional societies of health managers, physicians, nurses and other health professions and other relevant Spanish scientific associations.

Procedure

1. Define the scope of the guide and the specific situations to which it will apply. 2. Conduct an exhaustive review of the available scientific evidence. 3. Identify areas where discrepancies in opinion or gaps in evidence exist.

Data analysis

Transcripts from consensus conference sessions will undergo thematic analysis to identify recurring themes, consensus points and areas of disagreement among professionals. Qualitative findings will be synthesised to develop comprehensive recommendations aligned with AGREE II domains. Iterative rounds of analysis and stakeholder feedback will refine the guide, ensuring it reflects consensus and addresses gaps identified. Results will be documented in a detailed report outlining the development process, key qualitative findings and how AGREE II criteria informed the final recommendations.

Limitations and potential biases will be addressed through several measures. Subjectivity will be mitigated by ensuring the independence of group facilitators in coding ideas, while cross-group triangulation and independent coding will help minimise interpretation, replication and generalisation biases. Participant selection will aim for an appropriate balance to reduce potential biases related to gender or inclusivity concerns. Additional measures include addressing selection bias through snowball sampling or randomisation, mitigating interpretation bias using a dedicated app for discourse analysis

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and engaging citizen scientists and preventing low participation by incorporating motivational elements. Gender bias will be managed by ensuring gender balance among participants, and limited generalisation will be addressed by achieving statistical power and ensuring participant diversity. Follow-up reminders and a call centre will also be implemented to ensure an adequate response rate, particularly during stages 2 and 4, to support the development of the project.

Patient and public involvement

The DECIDE Project adheres to the principles of Citizen Science established by the European Citizen Science Association and the *Estrategia Nacional de Ciencia Abierta*. Voluntary participation of social leaders—including active members of patient associations, civic groups, non-governmental organisations and media representatives—will be sought for data collection, processing, interpretation and dissemination of results to diverse audiences, acting as Citizen Scientist Stakeholders (CSS).

Three webinars involving CSS will be organised to engage the general public, present findings and compare evaluations and perspectives, facilitating a more nuanced interpretation guided by CSS. During stages 1 and 4, CSS will lead discussion groups and contribute to the development of key messages aimed at enhancing public understanding of human fallibility and relevant guidelines, using illustrative examples provided by CSS. They will be acknowledged as coauthors.

All data and metadata will be made publicly accessible in a comprehensible format for the general public. The project will be registered on eu-citizen.science to ensure its dissemination within the European network of projects incorporating Citizen Science principles.

DISCUSSION

This project represents a groundbreaking approach that goes beyond intramural actions to promote patient safety. It introduces a unique and innovative initiative that has not been previously attempted. The proposed solution engages diverse extramural audiences by addressing a central issue in patient safety policies. The results are designed to challenge established conventions and provide compelling arguments for transforming traditional perceptions of individual and team fallibility. This outcome aims to enhance transparency and accountability. Furthermore, the project has the potential to foster trust in efforts to create increasingly safe environments. It actively promotes honesty, transparency and fairness in response to safety incidents, ultimately strengthening the culture of safety within healthcare.

Promoting a safety culture is a challenge in highly reliable organisations. Engaging individuals is crucial to achieving better outcomes and increasingly safer environments. In healthcare, professionals often hesitate to report errors due to fears of disciplinary actions, damage to their professional credibility and potential legal consequences.[43] These barriers limit transparency and hinder efforts to learn from mistakes. Effective implementation requires strong leadership engagement. Evidence suggests that leaders play a crucial role in shaping professionals' willingness to report incidents by reinforcing a non-punitive environment.[43 44] Our project could benefit from learning from the legal framework existing in different countries in the event of systemic errors produced in the health sphere. In this sense, the efficiency of the systems for the reporting and recording of adverse events and incidents in the health sector requires a normative context which guarantees that systemic errors produced in healthcare institutions will not give rise to sanctioning measures for the professionals involved in the patient's safety.[45]

The impact of errors on professionals has also been addressed in other industries,[46] finding practical solutions in the principles of Just Culture to address the issue of human fallibility. The regulatory framework in highly reliable organisations, such as aviation, incorporates the principles of Just Culture and establishes clear guidelines for actions to be taken in the case of honest mistakes, distinguishing them from incidents involving intentional wrongdoing or negligence. This framework is outlined in the State Operational Safety Program for Civil Aviation, supported by Law 21/2003 (7 July), subsequent amendments in Law 1/2011 (4 March) and Royal Decree 995/2013 (13 December). It aligns with European regulations, particularly Regulation (EU) No 376/2014 of the European Parliament and the Council (3 April 2014), concerning the reporting of occurrences in civil aviation. Additionally, there are recommendations on anonymisation and data handling by committees responsible for analysing the root causes of safety incidents, ensuring confidentiality and fostering a culture of learning and improvement. In the healthcare sector, there has been progress in promoting a safety culture in recent years. However, the consideration given to professionals involved in adverse events does not always contribute to learning from mistakes and creating safer environments. Just Culture could transform the culture of healthcare organisations, and this project aims to achieve this goal for the benefit of patients.

The European Commission's patient safety strategies, particularly the 2009 Council Recommendation, advocate for a strong safety culture, non-punitive incident reporting and systematic learning from errors. The DECIDE Project aligns with key initiatives and recommendations from leading international organisations and health agencies that promote patient safety by introducing Just Culture principles and formally recognising that professional support in healthcare settings is a fundamental requirement for quality and patient safety. In this regard, DECIDE embraces the agreements and recommendations of globally recognised patient safety organisations, including the Institute for Healthcare Improvement (IHI), the WHO, the Organisation for Economic Co-operation and Development (OECD), and the European Agency for Safety and Health at Work (EU-OSHA).

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The IHI has been a pioneer in advancing patient safety strategies and has emphasised Just Culture as a fundamental pillar for reducing medical errors and fostering learning environments. The IHI's Framework for Safe, Reliable and Effective Care[47] supports a learning-based approach to error management. DECIDE aims align closely with the goals of the IHI, reframing the perception of clinical errors and integrating Just Culture into healthcare organisations. Similarly, the OECD and others have highlighted the importance of creating non-punitive environments to promote continuous improvement in healthcare quality.[48] The DECIDE Project addresses these recommendations by developing policy guidelines and interventions to help institutions implement Just Culture principles, ensuring that errors are used as learning opportunities rather than grounds for punishment. The EU-OSHA has also recognised psychosocial risks and workplace safety as key factors influencing healthcare professionals. It has emphasised the need for initiatives aimed at strengthening professionals' resilience.[49] The DECIDE Project aligns with this focus by addressing gaps in resilience, a major issue affecting healthcare professionals involved in adverse events. By integrating with global patient safety strategies, the DECIDE Project reinforces international best practices in Just Culture, patient safety and professional support. Its primary emphasis is on Just Culture tools that can be adapted and implemented across different healthcare systems worldwide.

Potential practical implications

Integrating Just Culture into the organisational culture of healthcare institutions can significantly improve the quality and frequency of patient safety incident reporting. A non-punitive approach encourages professionals to report errors without fear of reprisal, leading to better data collection, improved root cause analysis and enhanced safety interventions, seeking the involvement of both healthcare professionals and patients across different settings.

One of the challenges is that these approaches, along with the use and conceptualisation of the term 'honest mistake', are not widely known among healthcare professionals, which limits their implementation.[50] This project can help shift the perspective away from the traditional blame-based conceptualisations of error that still persist.

Since healthcare leaders and managers play a crucial role in fostering a culture of safety, training in Just Culture principles is essential for ensuring consistent handling of adverse events. The DECIDE Project can support these efforts by providing empirical data and evidence-based recommendations to guide the implementation of Just Culture policies at various levels of the healthcare system. The study encompasses primary care, hospitals, nursing homes and long-term care facilities, allowing for a broad range of healthcare settings, professional profiles and experiences with a diverse array of patient safety incidents. While cultural and social factors shape the conceptualisation of error, data from the Spanish healthcare system could serve as a reference for future research in other countries pursuing a similar approach.

A decision-making tool designed to distinguish honest mistakes from reckless behaviours could offer a clear framework for healthcare executives, middle managers and frontline professionals. Such a tool set would enhance the conceptualisation of clinical errors, facilitate conflict resolution and establish clear criteria to determine when to initiate legal or financial accountability procedures, ultimately reducing unnecessary litigation and promoting a fairer approach to incident management. This would help address the existing mistrust among healthcare professionals regarding the handling of adverse events and ensure that affected professionals receive the needed emotional and psychological support to continue providing safe, high-quality care. Studies indicate that lack of institutional support exacerbates emotional distress, contributing to burnout and decreased engagement in safety policies.[43 51] This approach could improve the management of the aftermath of a severe adverse event. Although initially designed for the Spanish context, these tools could be generalised and applied in other countries.

The project's intervention strategies, focused on attitude change, will provide valuable insights into how tailored patient safety training can be designed for new healthcare professionals. These strategies will help instil a proactive mindset towards safety, learning and continuous improvement from the early stages of professional development. Several strategies have been described to promote Just Culture,[52] but changing attitudes is essential. Fostering open communication with leaders is also essential for the successful implementation of Just Culture in healthcare institutions.[20] Engaging social leaders, policymakers and media representatives is key to driving a cultural shift that recognises human fallibility as an inherent part of complex systems rather than an individual failure.[43] These results could be generalised to other contexts, particularly for healthcare professionals. However, the applicability of findings may be more limited for social leaders, as cultural differences in the perception of errors could shape their responses and attitudes.

In sum, applying Just Culture principles in healthcare has the potential to fundamentally transform how medical errors are perceived, reported and managed. The findings of this project will inform policy recommendations for integrating Just Culture into national healthcare frameworks, fostering a more transparent, accountable and learning-oriented system.

Beyond its impact on Spanish healthcare institutions, the DECIDE Project aims to transform societal perceptions of medical errors. By engaging social leaders, policymakers and media representatives, it seeks to reshape public narratives, reducing stigma and blame while fostering a more balanced understanding of human fallibility in complex systems. The project's findings will extend beyond healthcare institutions, influencing society and opinion leaders and paving the way for a cultural

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shift towards a blame-free, learning-focused approach to errors in healthcare.

Overall, the DECIDE Project offers a structured, evidence-based model to enhance patient safety by driving a cultural shift that promotes learning from errors, supports healthcare professionals and develops sustainable policies, fully aligned with patient safety objectives.

DISSEMINATION

DECIDE will prioritise Open Access publication of the protocol and the study results in journals indexed in Clarivate's Journal Citation Reports. Each output will be accompanied by a graphical abstract, a plain-language visual summary and a global results video under 60 s with open subtitles and on-screen sign-language interpretation. A coordinated social network strategy will deliver concise, audience-specific messages at key milestones; all visuals will include alt-text and clear calls to action. Also, a specific website contributes to disseminating key information (https://decideculturajusta.com).

Peer researchers—patients and/or social leaders—will play a visible role in dissemination: codesigning and reviewing messages and lay summaries, appearing in the video and selected social posts and acting as ambassadors through their associations to convene information sessions with citizen and patient groups. Healthcare workers will also support media briefings and help tailor content for healthcare managers and professionals (webinars, invited talks, conference contributions), ensuring accessible materials that promote uptake into practice and policy.

ETHICS

The study has been approved by the ethics committees of the following institutions: Hospital Universitario Ramón y Cajal (reference 203/24; 23 October 2024), Hospital Universitario Fundación Alcorcón (reference 24/96; 29 October 2024) and Hospital Universitari Sant Joan d'Alacant (reference 25/001; 28 January 2025,). Additionally, the study has been registered in ClinicalTrials.gov (NCT06835517).

The anticipated impact over a 3-year period is defined by the achievement of five publications in scientific journals indexed in the *Journal Citation Reports*, with a cumulative impact factor exceeding 19 and more than 975 visits on Open Access platforms.

Data curation and management will adhere to institutional and international standards to ensure integrity, confidentiality and long-term accessibility. Quality control procedures will be applied during data entry and analysis to minimise errors. All data will be pseudonymised and stored on secure servers with restricted access, in compliance with Spanish legislation and the European General Data Protection Regulation. Metadata will be documented following the Findable, Accessible, Interoperable, Reusable principles to facilitate reuse by the research community. The data will be made accessible by depositing them in an institutional repository for the research community and other stakeholders, except for those that must remain restricted due to intellectual property protection. As a general rule, the data will be available at the time of dissemination of results through publication or report issuance. Any data that are restricted due to their nature (pending intellectual property protection or patent application) will be clearly identified. A data management plan will be developed within the first 3 months of the project and regularly updated throughout its duration to ensure consistent procedures for data collection, storage, sharing and preservation.

The translation of the study protocol into English was supported by artificial intelligence (AI). Specifically, we used ChatGPT-4o (OpenAI, San Francisco, California, USA; https://openai.com) to assist in the translation process. ChatGPT-4o was employed to enhance the accuracy, fluency and clarity of the English text, particularly to improve academic readability and to avoid errors associated with literal translation. All AI-generated output was carefully reviewed, verified and edited by the authors to ensure accuracy, appropriateness and consistency with the intended meaning of the Spanish original. No content generated by AI was accepted without critical author oversight and revision. The Spanish version of the study protocol is available from the authors on reasonable request.

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drafted the first version of the manuscript. All authors critically revised the paper for important intellectual content and approved the final version. The guarantor is JJM. AI was used to improve the English translation. Diego San Jose Saras, Eva Gil-Hernández and Irene Carrillo are joint last authors.

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