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The Human Factor as Resource in Care and Risk Management

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Abstract

As a result of the automatization of care and time and staff rationing due to economic imperatives, the human aspects of clinical practice are too often undervalued or ignored, thus resulting in dehumanized care. On one hand, patients experience a lack of respect and autonomy which may negatively affect the patient-provider relationship. On the other hand, healthcare providers have to face a great performance accountability in the highly complex and increasingly fragmented healthcare environment. In this perspective, the human factor has been commonly considered as potential threat to patient safety and standardized healthcare. However, a new, alternative approach has recently reversed this trend, considering also the intrinsic characteristics of the human factor, such as flexibility, as essential resources for system resilience.

This thesis sheds new light on the question of how patients, patients' caregivers and healthcare providers may be strengthened and supported in care and risk management in order to be acknowledged and valued as resource for a resilient healthcare system. Divided into different chapters, it assesses the key elements of the concept of humanization of care, evaluates ways to empower two particularly vulnerable groups of patients (i.e., patients with mental health conditions, patients harmed by adverse events), examines the psychological responses and resources (i.e., psychological and psychosomatic symptoms, coping strategies) of healthcare providers involved in adverse events, and lastly outlines ways for promoting a new, blame-free patient safety culture for the next generation of healthcare providers, starting from early medical education and training.

In conclusion, our findings underline that establishing and strengthening respectful, trusting patient-provider relationships is the core element of humanized healthcare. Promoting these relationships also implies for healthcare institutions fostering the individual persons that are part of this connection. Empowering patients and their caregivers in care and risk management and adequately supporting healthcare providers, particularly after adverse events, represents a promising way to recognize and value these humans as beneficial resource for a flexible, resilient, and thus high-performing healthcare system based on a positive safety culture.

Sommario

La progressiva automatizzazione delle cure mediche, così come le ridotte risorse di tempo e di personale, imposte dalle ingravescenti restrizioni economiche, sono responsabili del fatto che sempre più spesso nella pratica clinica l'aspetto umano sia sottostimato o addirittura ignorato, determinando un approccio deumanizzato alla cura del paziente. Se da un lato i pazienti lamentano una minor soddisfazione nella relazione terapeutica, influenzata dalla loro percezione di una mancanza di rispetto e coinvolgimento nel percorso di cura, d'altro lato, gli operatori sanitari devono affrontare le continue richieste di efficientismo all'interno di un sistema sanitario caratterizzantesi per una crescente complessità e frammentazione. In quest'ottica il fattore umano è stato a lungo considerato un elemento di criticità per la sicurezza e la standardizzazione delle cure erogate ai pazienti; recentemente tuttavia una nuova prospettiva ha invertito questa tendenza, giungendo a considerare le caratteristiche intrinseche al fattore umano, come per esempio la flessibilità, risorse essenziali alla base della resilienza del sistema.

Questa tesi supporta l'attuazione di un modello organizzativo in cui i pazienti, i famigliari e gli operatori sanitari siano supportati nel percorso terapeutico e nella gestione del rischio in quanto riconosciuti come una risorsa essenziale su cui fonda un sistema sanitario resiliente. Nei diversi capitoli vengono affrontati gli elementi chiave del concetto di umanizzazione delle cure, valutate possibili strategie di *empowerment* di due categorie di pazienti particolarmente vulnerabili (i.e., pazienti con disturbi mentali, pazienti vittime di eventi avversi), esaminate le risposte e le risorse psicologiche (i.e., sintomi psicologici e psicosomatici, strategie di coping) di operatori sanitari coinvolti in eventi avversi, e infine delineati percorsi finalizzati a promuovere, per le nuove generazioni, a partire dal percorso formativo in ambito medico, una nuova cultura della sicurezza del paziente priva di carattere punitivo.

In conclusione, i nostri risultati sottolineano come una rispettosa ed onesta relazione medico-paziente sia l'elemento essenziale per una adeguata umanizzazione delle cure. La promozione di questo tipo di rapporto favorisce i singoli individui in esso coinvolti. L'*empowerment* dei pazienti e dei famigliari nel percorso terapeutico e nella gestione del rischio

clinico così come un adeguato supporto degli operatori sanitari, specie in caso di eventi avversi, sono fondamentali per riconoscere e valorizzare l'essere umano come risorsa per la creazione di un sistema sanitario flessibile, resiliente e quindi altamente performante.

1. Introduction

The last decades have been characterized by significant improvements and innovations in the medical field, also associated with the progressive increase in specialization and subspecialization¹ and the use of technology¹⁻³, with the overall aim to improve the quality, efficiency, effectiveness, and safety of care⁴. Nevertheless, due to these recent approaches, the human aspects of clinical practice are too often undervalued or even ignored, leading to a dehumanization and depersonalization of care². Indeed, it has been demonstrated that especially nowadays patients whose emotions and individual needs as human beings are often underestimated experience a lack of respect and autonomy^{5,6}. This may negatively affect the patient-provider relationship and impair patients' and caregivers trust in the healthcare system^{7,8}. Moreover, healthcare providers have to face a great performance accountability in highly complex settings^{9,10}. A medical approach, pointing towards perfection and the absence of accidents and incidents¹¹, as also promoted in the so-called Safety I approach¹², leads to stigmatization of medical errors and of human imprecisions. Such a negative perception of failures and mistakes may increase the psychological suffering of second victims (i.e., healthcare providers involved in medical adverse events)¹¹. Trying to address the challenges linked to the approach of *Safety I*, recently, a new perspective (i.e., *Safety II*) was introduced by Hollnagel et al.¹². From this perspective, the human factor, usually labeled as a potential threat to patient safety, is valued and considered as a beneficial resource for system flexibility and resilience¹².

Considering all the above-mentioned aspects, this thesis looks from different angles at the human factor in care and risk management by using a comprehensive, multi-methodological approach. It discusses how stakeholders involved in the healthcare process (patients, patients' caregivers, and healthcare providers) might be strengthened and supported in order to be recognized and valued as a resource for a resilient healthcare system. It aims to assess the main characteristics of a humanized, relationship-centered care, to evaluate ways to empower two particularly vulnerable groups of patients (i.e., patients with mental health conditions, patients harmed by adverse events), to examine the psychological responses and resources (i.e., psychological and psychosomatic symptoms, coping strategies) of healthcare providers involved in adverse events, and lastly to outline ways for promoting a new, blame-free patient safety culture among the next generation of

healthcare providers, starting from early medical education and training. The findings of this thesis are expected to inform policy, clinical practice, and medical education.

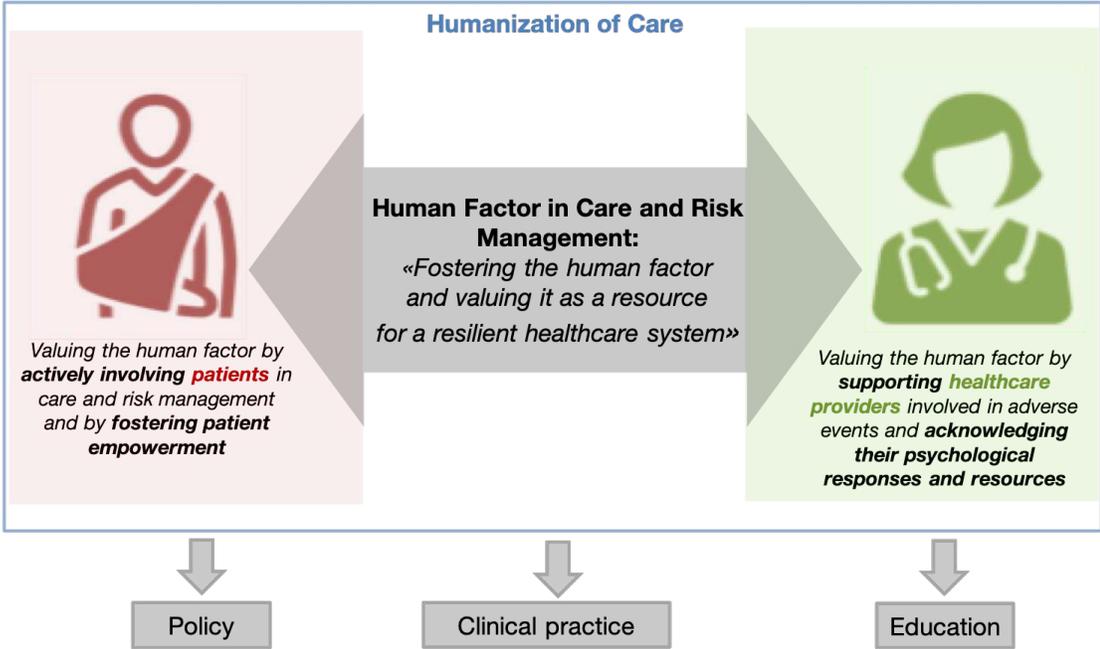


Figure 1. Graphic representation of the core features of this thesis

THEORETICAL BACKGROUND

Humanization of Care as Pathway for Delivering High-Quality Care

The past decades have seen rapid advances in the healthcare field, such as a greater use of technology and an increase in specialization and subspecialization in medical settings¹⁻³, with the overall aim of making healthcare safer, more efficient and effective⁴. However, these improvements have been accompanied by automatization and standardization of care, fragmented work and care pathways, thus often resulting in dehumanized and depersonalized care². Indeed, the patient is often not treated as a human being with a unique voice and individual needs, demands, and wishes but only as a “body piece, an illness” (p.201)¹³, as Santos et al. pointed out¹³. Such an attitude may erode patients’ and caregivers’ trust in healthcare providers and impede the patient-provider relationship^{7,8}, which, according to a wide-ranging agenda set out by the Institute of Medicine for the healthcare system of the 21st century, should be the basis for the delivery of care⁴. However, not only patients but also the healthcare workforce is often seen from a narrow, very pragmatic perspective. Considered a risk rather than a beneficial resource for a safe and high-quality healthcare system¹², healthcare providers are mostly judged by their job performance, potentially leading to stress, compassion fatigue, and burnout⁹.

This problematic trend has heightened the need for a more humane approach in healthcare, that is, humanization of care. Although humanized care has a prolific tradition in South American countries^{5,14-16}, it is nevertheless still an indistinct concept, missing clear dimensions and showing certain overlaps with other concepts, such as patient-centered care and person-focused care^{4,17,18}. In patient-centered care, which stands in contrast to the traditional, “illness-orientated medicine” (p.269)¹⁷, patients are met with compassion and empathy and their values, needs, and preferences regarding their medical conditions are respected⁴. Person-focused care goes even one step further by concentrating on the individual history of patients and by linking health promotion, prevention, and treatment of disease to the course of patients’ lives¹⁸. Lastly, humanization of care, taking into account both aspects (i.e., patient-centered and person-focused care), adopts the most holistic perspective. Indeed, using a system-wide approach, it takes into account all

stakeholders involved in healthcare (i.e., patients, patients' caregiver, healthcare providers, and policy makers), their individual background and history as well as their interactions and relations¹⁹⁻²¹. Further, medical tasks and interventions are also addressed²¹. By emphasizing the human aspects in the entire healthcare system and by fostering the therapeutic alliance between patient and healthcare provider, the concept of humanization of care may represent a pathway for delivering high-quality care.

While there is a great body of literature on patient-centered and person-focused care and their implementation in clinical practice, too little attention has been paid to humanization of care. Although some authors have tried to capture this concept²²⁻²⁴, a detailed review focusing on different settings of care and including the actual perspectives and opinions of different stakeholders, such as patients, patients' caregivers, and healthcare providers, was still missing.

Valuing the Human Factor in the Process of Care and Risk Management

Several studies have addressed the concept of humanization of care in different settings (e.g., primary care²⁵, anesthesia¹³), often linking it to the therapeutic alliance. However, it has been rarely considered²⁶ that humanizing care and valuing the humanness of patients, patients' caregivers and healthcare providers alike is also very important in the field of risk management.

Since the publication of the seminal article *To Err is Human* around twenty years ago²⁷, risk management and patient safety have been attracting a lot of interest. As recently highlighted by the World Health Organization (WHO)²⁸, patient safety is “a burning issue that no one can ignore” (p.7)²⁸. The importance of this statement becomes especially clear if we consider that one in 10 hospitalized patients is harmed by unsafe care²⁸ and that preventable harm ranks as the world's twentieth most common cause of overall morbidity and mortality²⁹. Adverse events (i.e., events that result “in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient”(p.201)³⁰) may harm patients and caregivers in multiple ways, affecting patients' physical and psychological well-being³¹⁻³⁴ and even leading to death in some cases³⁵. Further, medical errors frequently put heavy strains on relationships with family members

and on patients' financial resources as a survey by the Institute for Healthcare Improvement (IHI)/National Patient Safety Foundation (NPSF) Lucian Leape Institute and the NORC at the University of Chicago recently reported³⁴. Moreover, adverse events may profoundly impact healthcare providers' emotional well-being³⁶ and usually constitute a significant burden on the healthcare system, in terms of financial loss^{37,38}, loss of productivity, and impaired trust in healthcare institutions³⁸.

Concerted efforts (e.g., WHO Global Safety Challenge³⁹) have been undertaken to enhance safety and quality of care. While there is still a long way to go until "patients and those who care for them are free from harm" (p. ix)⁴⁰, and a *blame culture* still prevails in many workplaces⁴¹, understanding has grown in the healthcare community that a systemic approach^{42, 43} and a positive safety culture⁴⁴ are needed in order to tackle patient safety issues. Indeed, as Reason⁴² pointed out, patient safety incidents usually happen because of an interaction between healthcare providers' active mistakes or errors and latent conditions of the healthcare system (e.g., decisions taken by the top-level management). Thus, instead of blaming and judging exclusively the individual provider, a *just culture* concentrates on system failures and simultaneously acknowledges individual behaviors contributing to risk⁴⁵⁻⁴⁷. According to Carthey and Clarke⁴⁴, just culture is only one element of a positive safety culture, which is also characterized by transparency, openness, the willingness to report, and the commitment to learn from errors.

However, in patient safety investigations it is still often wrongly assumed that adverse events are due to few detectable causes, rather than to a complex interaction of factors⁴³. It is probably because of this narrow focus that standardized investigation methods, such as root-cause analyses, do not necessarily reduce future errors^{43,48,49}. Although in other work environments it has been demonstrated that changes targeting the system (e.g., improvement of the technological equipment, change in workplace culture) are the most successful, the recommended corrective actions in patient safety are still too focused on introducing changes at the individual level (e.g., disciplinary procedures, warnings, labels)^{48,50}.

While it is vital to react to errors and protect patient safety⁵¹ by introducing changes in the system and improving defense mechanisms^{42,48,50}, according to the group of Hollnagel,

Braithwaite and Wears, risk management should go beyond that^{12,51}. The human factor has been historically considered as problematic element and potential threat to patient safety and quality of care. In contrast to this traditional, so-called Safety I approach, recently, Hollnagel et al. introduced the Safety II approach¹². This innovative perspective calls for a different view of the human factor by considering its particular characteristics, such as human variability and adaptability, as precious resources needed for system flexibility and resilience¹². By acknowledging that the healthcare system, despite its complexity, is most of the time high-functioning because of human flexibility and adaptability¹², Safety II appreciates the great value of the human factor.

Valuing the Human Factor by Involving Patients and Fostering Patient Empowerment

As explained above, the concept of Safety II sees the human factor as a valuable resource driving system resilience rather than as a potential danger to healthcare and patient safety¹². It can be thus argued that patients and patients' caregivers who represent, together with healthcare providers, the sharp end of any healthcare process can and should play a key role in improving safety. One way the human factor might be then adequately valued is by actively involving patients in the process of care and risk management and by fostering patient empowerment.

Over the past years, patient empowerment has emerged as a key principle of patient-centered healthcare⁵², enhancing patient autonomy and self-determination^{53,54} and potentially leading to improved health outcomes (e.g., adherence to treatment, self-care)⁵⁵⁻⁵⁸. Moreover, already in 2004, the World Health Organization (WHO)³⁹ directed efforts towards the promotion of patient empowerment also in patient safety.

Despite growing prominence of patients' role in healthcare and safety^{39,40,52,59-61}, patients' perspective in risk management still remains undervalued^{40,62}. This might be partially due to several challenges associated with the implementation of patient empowerment in safety. On one hand, some healthcare providers have paternalistic attitudes towards patients, fear a loss of control, and even feel threatened by empowered patients who, more informed about healthcare processes, may even file malpractice claims^{61,63,64}. On the other

hand, some patients may experience anxiety over the prospect of being co-responsible for their safety^{65,66}. This might be especially the case if they belong to a particularly vulnerable group of patients⁶⁶. Thus, there is the need to tackle these challenges and further promote patient involvement and empowerment in risk management.

Several lines of evidence suggest that patients can significantly contribute to the improvement of their own safety⁶⁷⁻⁷². For example, Weingart et al.⁶⁸ found that patients who participated in their care to a great extent were less likely to experience an adverse event than those who were less involved. Further, a number of studies have demonstrated that patients and also their caregivers are able to detect and report unsafe conditions or patient safety incidents missed by the healthcare staff^{67,69,70}. Thus, including patients in incident investigations (e.g., in one-on-one interviews, meetings for events discussion and action planning)^{73,74} may not only represent a possibility to empower patients by appreciating their perspective and experience but also to increase the effectiveness of such error analyses. Although the importance of patients' role in care and safety has been increasingly acknowledged, there has been too little discussion so far about how to actually involve patients in incident investigations⁴³.

Another understudied question is how to empower patients with mental health conditions in safety and risk management. Safety in mental health care faces particular challenges (e.g., self-harm, suicidal behavior, use of restraint) which have not received enough attention up to now⁷⁵⁻⁷⁸. This is particularly critical since adverse events in mental health care occur often^{79,80} and represent a high socio-economic burden⁸¹. While healthcare agencies^{75,82} have called for the active involvement of patients with mental health conditions, ways to empower this group of patients in terms of safety have been rarely examined^{83,84}.

Valuing the Human Factor by Supporting Healthcare Providers Involved In Adverse Events

Medical errors are frequently considered as the most direct expression of the fallibility of the human factor and thus seen rather as the personal failure of the involved healthcare provider¹¹ than as the interaction of healthcare provider's active failures and latent systemic conditions⁴². However, the Safety II approach¹² has recently reversed this negative trend

to some extent, considering also the positive intrinsic characteristics of the human factor, such as the flexibility and adaptability of healthcare providers, as essential resources for system resilience. It can thus be suggested that the human factor can be valued in care and risk management not only by promoting patient empowerment, as described above, but also by adequately supporting healthcare providers involved in adverse events and by properly addressing and acknowledging their psychological responses and resources.

Indeed, adverse events affect not only patients as first victims but have also a strong impact on the involved healthcare providers, thus frequently referred to as second victims¹¹.

The use of the term second victim has recently sparked controversy in the healthcare community⁸⁵⁻⁸⁸. In fact, several authors believe that the term second victim may imply a lack of responsibility and accountability of the healthcare provider considering them passive and powerless^{85,86,88}. Moreover, there is the concern that such a term minimizes patients' suffering^{85,86,88}. By contrast, others, like Petersen⁸⁷, a first victim who has lost his son due to medical errors, still regard the term as fitting. Despite this active debate, a more suitable alternative has not been established up to now^{86,88}.

The psychological impact of the adverse event on the involved healthcare providers may manifest itself in different ways. For instance, second victims may question their professional ability and experience a range of psychological and psychosomatic symptoms, like anger towards themselves, embarrassment and guilt, fear of future errors, and difficulty sleeping^{89,90}. Some authors^{91,92} have argued that the experience of becoming a second victim may even generate a vicious cycle, increasing the risk of burnout and depression, worsening patient safety and quality of care, and enhancing the probability of being involved in future medical errors.

In response to these negative experiences, second victims may apply adaptive coping mechanisms⁹³, such as considering career changes, modifying their attitude to work or seeking social support^{94,95}. These strategies can be shaped by both individual (e.g., personality traits, regulatory control processes) and situational factors (e.g., stressor perceived as controllable or uncontrollable, workplace culture⁹⁶⁻⁹⁹). In the literature⁹⁹⁻¹⁰⁵, the different types of coping mechanisms have been subject to considerable discussion. Indeed, several authors have attempted to draw fine distinctions between problem-

focused, emotion-focused^{99,100}, and avoidance-oriented coping¹⁰²⁻¹⁰⁴ as well as between adaptive/functional and maladaptive/dysfunctional coping^{96, 106-108}.

Over the past two decades, there has been, along with the above-mentioned improvements in safety culture, an increasing scientific interest in the second victim phenomenon and a growing awareness of its impact not only on healthcare providers but also on patient care and the overall healthcare system^{91,92,95,109}. This trend has led to the successful implementation of second victim support programs, such as RISE (Resilience in Stressful Events, Johns Hopkins Hospital, Maryland, United States of America)^{110,111}, forYou (University of Missouri Health Care, Columbia, USA)¹⁰ and Medically Induced Trauma Support Services (Chestnut Hill, Massachusetts, USA)¹¹². For instance, at the Johns Hopkins Hospital, trained RISE peer responders provide confidential, timely psychological first aid and emotional support to health care workers who have experienced stressful, patient-related incidents or adverse events¹¹¹.

As underlined in the literature¹¹³, profound knowledge of second victims' reactions to adverse events is necessary to create effective support programs as well as to ensure high standards of patient safety and quality of care. Although there are already reviews on the different aspects of adverse events and their effects on second victims^{36,92-94,114,115}, a meta-analysis on the psychological impact of adverse events on second victims or on the type and frequency of coping strategies has not been published yet.

AIMS

As illustrated in Figure 1 (p.10), this thesis looks, by using a multi-methodological approach, from different perspectives at the human factor in care and risk management and discusses how patients and patients' caregivers might be empowered and healthcare providers supported in order to be recognized and valued as a resource for healthcare system resilience. Indeed, it aims to assess the main characteristics of a humanized, relationship-centered care, to evaluate ways to empower two particularly vulnerable groups of patients (i.e., patients with mental health conditions, patients harmed by adverse events), and to acknowledge the psychological responses and resources (i.e., psychological and psychosomatic symptoms, coping strategies) of healthcare providers involved in adverse events (i.e., second victims). Lastly, this thesis outlines ways for promoting a new, blame-free patient safety culture for the next generation of healthcare providers, starting from early medical education and training and serving as antidote to the prevalent culture of blame and shame and stigmatization of medical errors.

Aim 1

To clarify the concept of humanization of care and identify its key elements by a systematic review examining not only the main features of humanized care but also the associated challenges and the implementation strategies, taking into account the perspectives of different stakeholders (patients, caregivers, healthcare providers).

Aim 2

Aim 2.1

To assess, by applying a mixed-method design, how the empowerment of patients with mental health conditions may improve risk management according to the perspective of healthcare providers and to investigate critical issues and strategies linked to such empowerment.

Aim 2.2

To develop through a review of the literature a conceptual framework for involving patients in error investigations which outlines specific paths to disclose the error, identifies

barriers hampering patients' and caregivers' involvement, and proposes possible strategies to overcome such barriers.

Aim 3

Aim 3.1

To quantify and critically analyze by conducting a systematic review and a meta-analysis the type and the prevalence of psychological and psychosomatic symptoms affecting second victims in the aftermath of adverse events.

Aim 3.2

To quantify and critically analyze by performing a systematic review and a meta-analysis the type and the frequency of coping strategies applied by second victims in the aftermath of adverse events.

Aim 4

To explore strategies for promoting a new, blame-free patient safety culture for the next generation of healthcare providers, starting from early medical education and training, considering also the related challenges.

METHODOLOGICAL APPROACHES

The next section provides a short overview of the main methodological approaches applied in the projects of this thesis.

While literature reviews (see Chapter 4) seek to summarize the literature on a specific topic without using rigorous methods, thus being prone to subjectivity¹¹⁶, systematic reviews, on the contrary, have a strict methodological approach which can be replicated by other researchers¹¹⁷. Systematic reviews (see Chapter 2, 5, 6) aim to solve explicit research questions by analyzing empirical studies^{117,118}. Methodological steps include the systematic search of electronic databases with pre-defined search criteria (e.g., search strategy, restrictions to publication date or language) and, preferably, also the search of additional sources (e.g., gray literature, reference lists of key books), the selection process (identification and screening of studies, assessment of eligibility according to pre-defined criteria, inclusion or exclusion of studies), the detailed assessment of the quality of the included studies as well as the extraction, synthesis, and interpretation of study characteristics and findings¹¹⁷⁻¹¹⁹.

Meta-analyses (see Chapter 5, 6), often part of systematic reviews, are applied to combine data from different quantitative studies and to examine common effects as well as differences across these studies by performing statistical analyses^{117,120}. A meta-analysis can enhance the quality of a systematic review since it allows, for instance, to address research questions that could not be investigated by the primary studies and to statistically explore contradictory results from different articles^{117,120,121}. Further, statistical effects are more likely to be found and precisely estimated than in individual studies with smaller sample size¹²¹.

One way to systematically collect and combine data from various qualitative studies is the thematic synthesis (see Chapter 2), introduced by Thomas and Harden¹²². By using this approach, large amounts of text can be coded, underlying themes identified, and key elements produced¹²².

A mixed-method approach (see Chapter 3) combines quantitative and qualitative methods and allows to summarize and analyze a great deal of data collected in different ways¹²³. In this process, the limitations of quantitative and qualitative research can be reciprocally compensated^{124,125}. The qualitative content analysis of focus groups is one example of a mixed methods approach¹²⁶. It is a rigorous method for coding and interpreting qualitative data gathered, for example, in focus group discussions¹²⁶. The focus group produces data by investigating not only participants' understanding of a certain topic or research question but also by collecting their opinions about it¹²⁷. The answers of the individual participants, the interactions among the participants as well as the evolving group dynamics are of high interest for the researchers¹²⁷. Once the data are collected, deductive or inductive content analysis can be performed. The former, in order to code and analyze the data, uses pre-defined categories, informed by underlying theories. Applying the latter, the coding system and the related categories emerge from the material itself¹²⁶.

OUTLINE OF THE THESIS

The different projects developed during my PhD program led to six articles (all published in international, peer-reviewed journals) which are presented in the following chapters (Chapter 2-7).

Chapter 2 analyzes the key elements of the concept of humanization of care based on the perspectives of patients, patients' caregivers, and healthcare providers.

The two subsequent chapters look at patient involvement and empowerment in the field of risk management. While Chapter 3 deals with the question whether and how, according to healthcare providers, empowering patients with mental health conditions may enhance risk management, Chapter 4 proposes a conceptual framework for healthcare institutions which can be used in approaching patients about an active role in investigating a medical error made in their care.

Then, in Chapter 5 and 6, performing a comprehensive synthesis and critical analysis of second victims' emotional distress and coping strategies applied after adverse events, the diverse psychological responses and resources of healthcare providers involved in an adverse event are examined.

Chapter 7 makes a case for incorporating the topic of a positive patient safety culture into the curricula of professional medical schools and training programs.

Chapter 8 represents a comprehensive discussion of all projects of this thesis. It summarizes and discusses all main findings, sets out implications for policy, clinical practice, education, and training, then addresses the strengths and limitations of the thesis. In the last sections, future research directions are described before the overall conclusions are drawn.

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2. Humanization of Care: Key Elements Identified by Patients, Caregivers, and Healthcare Providers. A Systematic Review

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This chapter contains *Supplementary Material* which can be found in Appendix A.

¹ Acknowledgement of author contributions:

All authors jointly designed the study. IMB, GT, and FM were involved in the search and selection process. IMB and FM performed the quality assessment. IBM, FM, and MR were involved in data extraction and synthesis. IB, FM, and MR drafted the initial manuscript, which was critically revised by AW and then approved by all co-authors.

ABSTRACT

Background: Given the automatization of care and time and staff rationing due to economic imperatives, often resulting in dehumanized care, the concept of “humanization of care” has been increasingly discussed in the scientific literature. However, it is still an indistinct concept, lacking well-defined dimensions and no literature review has tried so far to capture it.

Objectives: To identify the key elements of humanization of care by investigating stakeholders’ (patients, patients’ caregivers, healthcare providers) perspectives and to assess barriers and strategies for its implementation.

Methods: We carried out a systematic search of five electronic databases up to December 2017 and examined also additional sources (e.g., grey literature). Search terms included “humanization/humanisation of care” and “dehumanization/dehumanisation of care”. We conducted a thematic synthesis of the extracted study findings to identify descriptive themes and to produce key elements.

Results: Of 1,327 records retrieved, 14 full-text articles were included in the review. Three main areas (relational, organizational, structural) and 30 key elements (e.g., relationship bonding, holistic approach, adequate working conditions) emerged. Several barriers to implementation of humanization of care exist in all areas.

Conclusion:

Our systematic review and synthesis contributes to a deeper understanding of the concept of humanization of care. The proposed key elements are expected to serve as preliminary guidance for healthcare institutions aiming to overcome challenges in various forms and to achieve humanized and efficient care. Future studies need to fully examine specific practices of humanized care and to test quantitatively their effectiveness by examining psychosocial and health outcomes.

Keywords: humanization of care; quality of care; patient-provider relationship; human factors; patient-centeredness

KEY POINTS

- Respect for patient's dignity, uniqueness, individuality, and humanity as well as adequate working conditions, and sufficient human and material resources are the most discussed key elements of humanization of care according to the different explored areas (i.e., relational, organizational and structural, respectively).
- The identified key elements are expected to help patients, caregivers, healthcare providers and institutions in implementing humanized care.
- Future studies fully examining implementation strategies of humanized care and quantitatively testing their effectiveness are warranted.

INTRODUCTION

In the last decades, there has been a progressive increase in the use of technology in the prevention, diagnosis, treatment and rehabilitation of disease¹. The aim is generally to increase the quality, efficiency, and safety of care. Further, there has been an increase in specialization and subspecialization in medical settings in order to provide greater expertise in treating specific, complex diseases and conditions².

Although these medical developments have improved some elements of the care of patients such as safety, effectiveness, and efficiency³, they come with new problems. The automatization and standardization of care, the fragmentation of work and care pathways, often linked to time and staff rationing, can lead to a dehumanization and depersonalization of care¹. There is a tendency to treat the patient as a “group of symptoms” rather than a human with individual needs⁴. This can negatively affect the doctor-patient relationship, and undermine patients’ and caregivers’ trust in the healthcare system^{5,6}. Further, healthcare providers are mainly evaluated on the basis of their professional performance⁷ and are often not seen as a valuable resource but as a risk in healthcare⁸. As a consequence, healthcare providers may experience stress, burnout, and compassion fatigue⁷.

To overcome this counter-productive approach to healthcare, the concept of *humanization of care* has been introduced into the scientific literature⁹. This is still a vague concept, overlapping with existing approaches to healthcare such as patient-centered care^{3,10,11}, and person-focused care¹². Introduced by Balint in 1969¹⁰, patient-centered care has been developed as an alternative to the traditional, paternalistic, disease-centered model^{10,13}. Instead of focusing in the clinical encounter primarily on symptoms, the physician shows compassion and empathy towards the patient, respects her/his individual values, needs and preferences, and involves the patient in the decision-making process^{3,11,14}. While patient-centered care is mainly visited- and episode-oriented¹², person-focused care adopts a more holistic perspective, considering the patient as a person with a unique personal history, and treating symptoms and diseases in the context of the course of life¹².

Humanization of care embraces the above described principles but also considers the other stakeholders involved in the process of care (i.e., patients, patients’ caregivers,

healthcare providers, policy makers) and their interactions¹⁵⁻¹⁷. This approach aims to humanize the overall healthcare system by focusing on relational as well as organizational and structural aspects in healthcare, involving all medical tasks and procedures^{16,17} (see Figure 1).

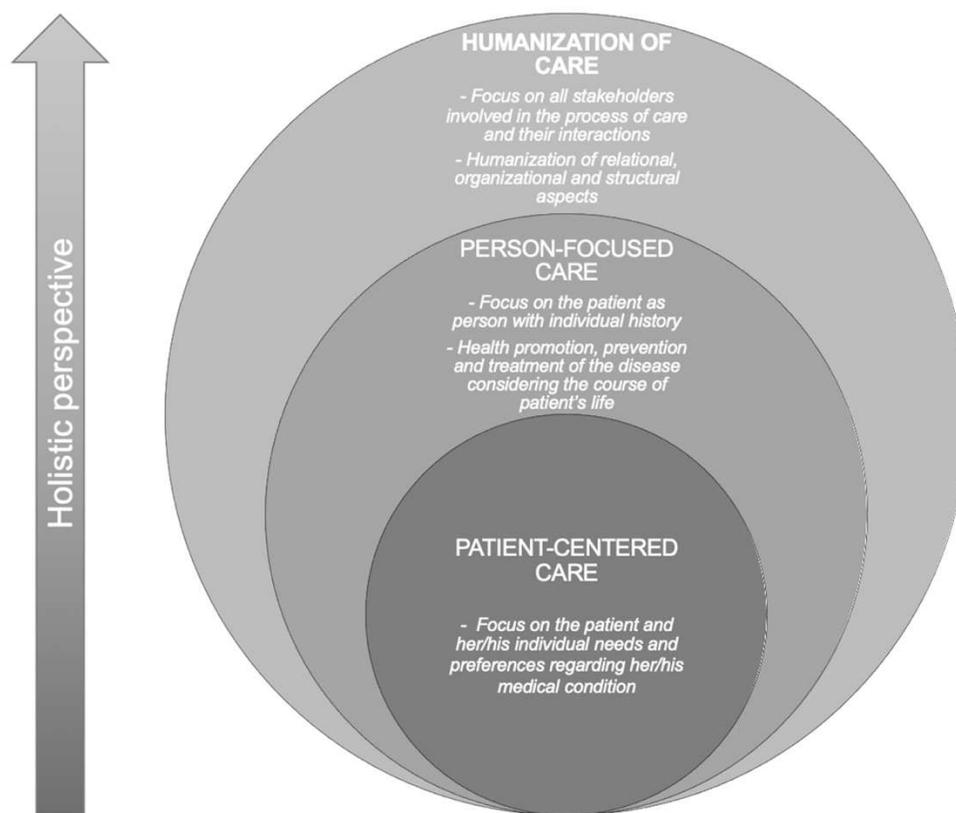


Figure 1. Development from patient-centered care to person-focused care to humanization of care

Patient-centered and person-focused care have been widely acknowledged in the literature. Conversely, the “humanization of care” still lacks conceptual clarity and well-defined dimensions. Consequently, its implementation in clinical practice has received less study. Todres et al.¹⁸ introduced a theory-driven, philosophically based framework for

humanizing healthcare. Following the existential-phenomenological theory, the authors define eight forms of humanization and dehumanization of care, such as “Insiderness - Objectification”, “Agency - Passivity”, and “Uniqueness - Homogenization”.

Attempts to review the concept of humanization of care have been made in some clinical areas, such as in critical and pediatric care^{19,20}. However, up to now, there has not been a comprehensive review including different settings of care and capturing the voices of different stakeholders. Thus, this systematic review aimed to clarify the concept of humanization of care and identify its key elements by exploring the main features, barriers to and strategies for its implementation according to different stakeholders’ (i.e., healthcare providers, patients, patients’ caregivers) perspectives.

METHODS

Search Strategy and Selection Criteria

We conducted a systematic search of five electronic databases (i.e., Web of Science, PubMed, Medline, PsycInfo, Cumulative Index of Nursing and Allied Health Literature (CINAHL)) using the search terms *humanization of care*, *humanisation of care*, *dehumanization of care*, and *dehumanisation of care* up to December 31, 2017. To detect additional studies, we searched three databases of gray literature (i.e., PsycEXTRA, Open SIGLE database, Grey Literature Project). A detailed record of the applied search strategy for the electronic and gray literature databases is provided in Online Resource 1 and 2.

Articles were included if a) stakeholders’/participants’ (i.e., healthcare providers, patients or patients’ caregivers) understanding of the concept of humanization/dehumanization of care and/or its role in the process of care were reported and b) papers were published in English, Italian, or German. The following types of articles were excluded: editorials, general discussion papers, commentaries, letters, book chapters, reviews.

The search and selection process have been recorded according to the Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement by Moher et al.²¹.

Data Extraction

Two reviewers (I.M.B. and G.T.) independently screened titles and abstracts of the records for inclusion using the reference management software Mendeley (Mendeley Software, 2009-2013 Mendeley Ltd). The full texts of the records considered as eligible by either one of the two reviewers were then independently evaluated. In cases of disagreement, the appropriateness of the inclusion/exclusion was debated, and the selection performed in consensus. If necessary, a third reviewer (F.M.) was involved.

Two investigators (I.M.B. and F.M.) independently collected study characteristics (i.e., publication year, country, study design, setting, type of participants, sample size) and results, extracted from the sections “Results”, “Findings” or “Results & Discussion” in the texts and the abstracts of the included studies, using a data collection form. In case of discrepancies, the two investigators reassessed the respective articles together.

Quality Assessment

Two appraisers (I.M.B. and F.M.) independently assessed the quality of the included studies using the *Joanna Briggs Institute Critical Appraisal Checklist for Qualitative Research* [22], a standardized rating tool based on 10 criteria, such as *congruity between the stated philosophical perspective and the research methodology*, *locating the researcher culturally or theoretically*, and *representation of participants and their voices*. The criteria can be rated as *yes* (i.e., met), *no* (i.e., unmet), *unclear*, and *not applicable*. Cases of dissent were solved through discussion.

Data Synthesis

We performed a thematic synthesis based on Thomas and Harden [23] aiming to organize and summarize the results of the included studies. Using this method, we identified *descriptive themes* from which we subsequently derived *key elements* (see Figure 2). Two investigators (I.M.B. and F.M.) performed all steps independently. They resolved any disagreement in consensus and/or by involving a third investigator (M.R.).

Here follows a description of the three stages of the thematic synthesis process:

1st and 2nd Stage: text coding and developing descriptive themes

We performed free line-by-line coding of the findings of the included studies, by extracting distinct text sections and coding each of them regarding their meaning and content.

Related codes were then clustered in order to develop descriptive themes. Each descriptive theme was identified as *main feature*, *barrier*, or *implementation strategy*.

3rd Stage: generating key elements

We grouped the descriptive themes (i.e., main feature, barrier, implementation strategy) that portrayed highly similar content into newly generated key elements. We then assigned each key element to the *relational*, *organizational* or *structural area*.

Absolute numbers and frequencies of the occurrence of key elements (i.e., overall and subdivided in healthcare providers' and patient'/patients' caregivers' perspective) across the primary studies are reported.

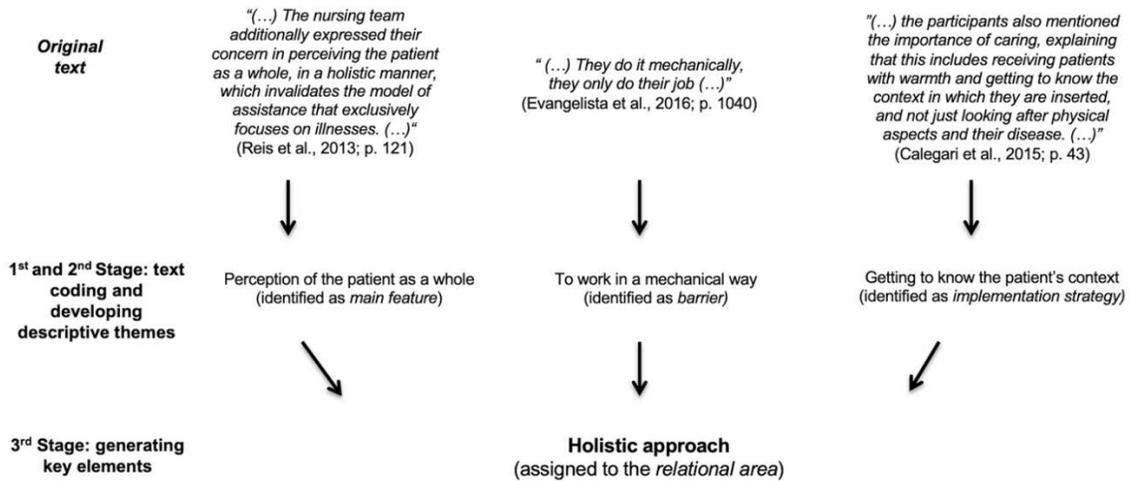


Figure 2. Example of the applied thematic synthesis (based on three text sections)

RESULTS

A total amount of 1,327 records was retrieved from the selected databases and additional sources (1,324 and 3, respectively). After screening for title and/or abstract, 54 full-text articles were assessed for eligibility. Thirty-four studies were then excluded (see Online Resource 3) and 20^{4,16,17,24-40} included (see Figure 3).

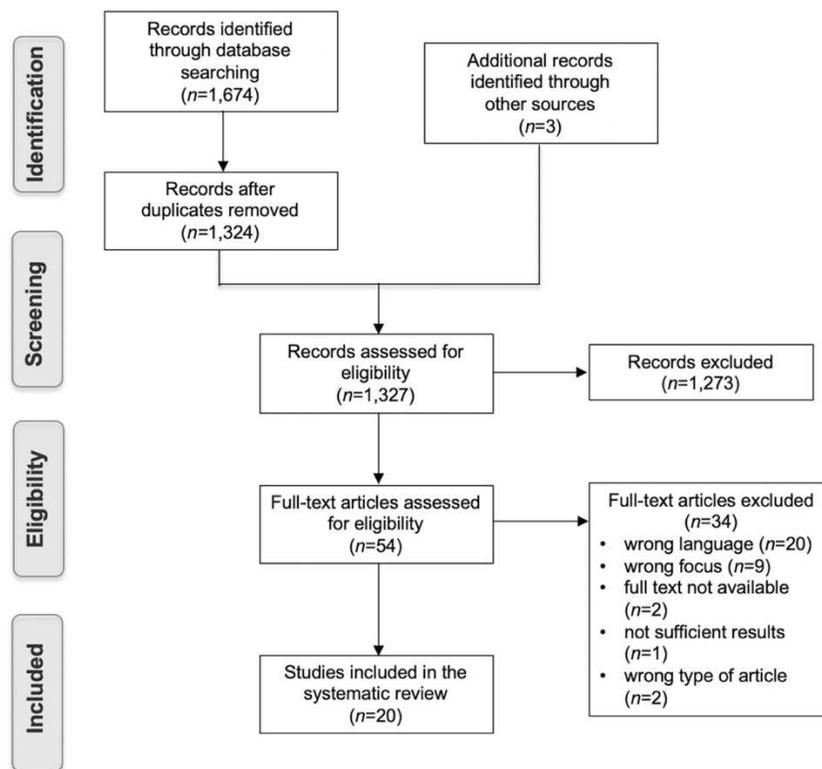


Figure 3. Preferred reporting items for systematic reviews and meta-analyses (PRISMA) flowchart

Quality Assessment

The quality of the included studies varied. All primary studies met more than half of the quality criteria, but only one study¹⁶ met all. All studies received ethical approval by an appropriate body and demonstrated congruity between the stated philosophical perspective and the research methodology as well as between the research methodology and the research questions or objectives. The representation of the participants and their

voices^{26,28}, the link between the research methodology and the data collection methods²⁹ as well as the relationship of conclusions to analysis, or interpretation of the data³⁹ remained unclear for only few studies. Several articles did not clearly locate the researchers culturally or theoretically^{4,30,32,40} and did not draw clear connections between research methodology and data collection methods²⁹, and data representation and analysis^{28-30,32,33,35,38,40}.

Just two studies^{4,16} explicitly addressed the influence of the researcher on the research, and vice-versa. A detailed overview of appraisers' judgments of each included study can be found in Online Resource 4.

Study Characteristics

The included studies were published between 2007 and 2016 (see Table 1) and mostly conducted in Brazil (n=16, 80%), followed by other four countries (i.e., Colombia, Canada, Japan, and Australia). A qualitative design was applied in most of the cases (n=18, 90%) whereas a mixed-method approach was used only twice. Sample sizes ranged from four^{17,24} to 70 participants²⁹. Thirteen studies focused on the point of view of healthcare providers (e.g., physicians, nursing professionals, midwives), four on the perspective of patients and their caregivers (e.g., family, partner), one just on patients' perspective and two on both healthcare providers' and patients' point of view. Different medical settings (e.g., mental health, obstetrics/gynecology) were investigated.

Table 1. Characteristics of included studies

Authors	Year	Country	Study design	Setting	Type of participants	Sample size
Backes, Koerich, Erdmann ¹⁶	2007	Brazil	qualitative; grounded theory approach	different settings	healthcare providers	17
Baratto, Ferreira, Ilha, Santos Nunes, Backes, Asta Pereira ²⁴	2016	Brazil	qualitative; descriptive-exploratory approach; discursive textual analysis technique	oncology	healthcare providers	4

Behruzi, Hatem, Fraser, Goulet, Ii, Misago ²⁵	2010	Japan	qualitative field research design	obstetrics & gynecology	patients, healthcare providers	27
Behruzi, Hatem, Goulet, Fraser ⁴	2014	Canada	qualitative; single case study design	obstetrics & gynecology	patients, healthcare providers	44
Brito, Carvalho ²⁶	2010	Brazil	qualitative-quantitative; descriptive-exploratory approach	oncology	patients	10
Brophy, Roper, Hamilton, Tellez, Mc Sherry ²⁷	2016	Australia	qualitative; general inductive approach	mental health	patients, patients' caregivers	66
Calegari, Massarollo, Santos ²⁸	2015	Brazil	qualitative; descriptive-exploratory approach	different settings	healthcare providers	19
Cassiano, Araujo, Holanda, Costa ¹⁷	2015	Brazil	qualitative; descriptive-exploratory approach; thematic content analysis	obstetrics & gynecology	healthcare providers	4
Chernicharo, Silva, Ferreira ²⁹	2014	Brazil	qualitative-quantitative; descriptive-exploratory approach; statistical method and content analysis technique	different settings	healthcare providers	70
Coscato, Villela Bueno ³⁰	2015	Brazil	qualitative; descriptive-exploratory approach; action research method	different settings	healthcare providers	49
Evangelista, Domingos, Siqueira, Braga ³¹	2016	Brazil	qualitative; descriptive-exploratory approach; content analysis	intensive care	healthcare providers	24
Grisales-Naranjo, Arias-Valencia ³²	2013	Colombia	qualitative; grounded theory approach	oncology	patients; patients' caregivers	23
Marin, Storniolo, Moravcik ³³	2010	Brazil	qualitative; hermeneutic-dialectic approach	general practice	healthcare providers	20

Oliveira, Silva, Medeiros, Queiroz, Giumarães ³⁴	2015	Brazil	qualitative; exploratory approach	mental health	healthcare providers	5
Reis, Silva, Waterkemper, Lorenzini, Cecchetto ³⁵	2013	Brazil	qualitative; descriptive-exploratory approach; thematic content analysis	neonatal and pediatric intensive care	healthcare providers	11
Santos, Fernandes, Oliveira ³⁶	2012	Brazil	qualitative; descriptive-exploratory approach; collective subject discourse	anesthesia	healthcare providers	16
Silva, Santos, Silva, Reis, Andrade ³⁷	2015	Brazil	qualitative; descriptive-exploratory approach; thematic content analysis	oncology	healthcare providers	10
Silva, Oliveira, Pereira ³⁸	2015	Brazil	qualitative; descriptive approach; content analysis	different settings	healthcare providers	24
Spir, Soares, Wei, Aragaki, Kurcgant ³⁹	2011	Brazil	qualitative; descriptive-exploratory approach; content analysis	obstetrics & gynecology	patients, patients' caregivers	18
Versiani, Barbieri, Gabrielloni, Fustinoni ⁴⁰	2015	Brazil	qualitative; descriptive, phenomenological approach	obstetrics & gynecology	patients, patients' caregivers	15

Thematic Synthesis

Overall, using a thematic synthesis approach, 357 descriptive themes, defined as main features, barriers or implementation strategies, emerged. Since numerous descriptive themes were very similar to each other, we generated only 30 key elements (e.g., regarding the key element *empathy towards the patient*, the descriptive theme *put oneself in the patient's shoes* was identified seven times).

Specifically, we assigned 17 key elements to the relational (e.g., *relational bonding*), ten to the organizational (e.g., *vertical and horizontal communication*), and three to the structural area (e.g., *adequate physical structure*) and calculated the frequencies with which these key elements were discussed by the different stakeholders (patients, patients' caregivers, healthcare providers) (see Table 2).

Table 2. Frequencies of key elements (relational, organizational, structural area) discussed by the different stakeholders

Key element	Studies investigating patients' and patients' caregivers perspective (n=5) ^{26, 27, 32, 39, 40}	Studies investigating healthcare providers' perspective (n=13) ^{16,17,24,28-31,33-38}	Studies investigating healthcare providers' as well as patients' perspective (n=2) ^{4,25}	Total amount of included studies (n=20)
<i>Relational area</i>				
Respect for patient's dignity, uniqueness, individuality, and humanity	80 % (4/5)	92 % (12/13)	100 % (2/2)	90 % (18/20)
Empathy towards the patient	80 % (4/5)	77 % (10/13)	/	70 % (14/20)
Relationship bonding	80 % (4/5)	69 % (9/13)	/	65 % (13/20)
Holistic approach	20 % (1/5)	69 % (9/13)	50 % (1/2)	55 % (11/20)
Respect for patient's autonomy & patient involvement	60 % (3/5)	46 % (6/13)	100 % (2/2)	55 % (11/20)
Verbal and non-verbal communication	60% (3/5)	46 % (6/13)	50 % (1/2)	50 % (10/20)
Meeting patient's needs/demands	60 % (3/5)	39 % (5/13)	50 % (1/2)	45 % (9/20)
Commitment	60 %	23 %	/	30 %

	(3/5)	(3/13)		(6/20)
Moral and ethical principles	20 % (1/5)	39 % (5/13)	/	30 % (6/20)
Relational support for the patient and patient's caregivers	40 % (2/5)	23 % (3/13)	50 % (1/2)	30 % (6/20)
Being attentive / interested / concerned towards the patient	40 % (2/5)	23 % (3/13)	/	25 % (5/20)
Healthcare provider's competence	80 % (4/5)	8 % (1/13)	/	25 % (5/20)
Patience	60 % (3/5)	15 % (2/13)	/	25 % (5/20)
Transparency regarding the treatment	40 % (2/5)	15 % (2/13)	/	20 % (4/20)
Fair-mindedness/equity	20 % (1/5)	8 % (1/13)	/	10 % (2/20)
Healthcare provider's personal characteristics	40 % (2/5)	8 % (1/13)		15 % (2)
Psychological support for healthcare providers	/	8 % (1/13)	50% (1/2)	10 % (2/20)
<i>Organizational area</i>				
Adequate working conditions	20 % (1/5)	62 % (8/13)	50 % (1/2)	50 % (10/20)
Adequate training	20 % (1/5)	46 % (6/13)	50 % (1/2)	40 % (8/20)
Team work	40 % (2/5)	39 % (5/13)	50 % (1/2)	40 % (8/20)
Continuity of care	20 % (1/5)	23 % (3/13)	100 % (2/2)	30 % (6/20)

Appropriate medical treatment	60 % (3/5)	8 % (1/13)	50 % (1/2)	25 % (5/20)
Organizational support for the patient and patient's caregivers	20 % (1/5)	15 % (2/13)	100 % (2/2)	25 % (5/20)
Facilitated access to healthcare	60 % (3/5)	8 % (1/13)	/	20 % (4/20)
Vertical and horizontal communication	/	23 % (3/13)	/	15 % (3/20)
Pleasant hospital stay	40 % (2/5)	8 % (1/13)	/	15 % (3/20)
Adequate priority assessment	/	8 % (1/13)	50 % (1/2)	10 % (2/20)
<i>Structural area</i>				
Human and material resources	20 % (1/5)	54 % (7/13)	50 % (1/2)	45 % (9/20)
Adequate physical structure	40 % (2/5)	31 % (4/13)	50 % (1/2)	35 % (7/20)
Pleasant environment	/	15% (2/13)	/	10 % (2/20)

Table 3 provides examples of the descriptive themes (i.e., main features, barriers, implementation strategies) representing each key element. However, for some key elements, main features, barriers, or implementation strategies did not emerge. For instance, regarding the key element *psychological support for healthcare providers*, participants just mentioned its lack without reporting any strategies to tackle this issue.

Relational Area

The relational area includes all key elements and related descriptive themes focusing on the aspects of humanization of care that may directly influence the personal relationship between healthcare providers and patients and their caregivers.

The following key elements were mentioned in more than half of all papers (see Table 2): *Respect for patient's dignity, uniqueness, individuality and humanity* (90 %), *empathy towards the patients* (70 %), *relationship bonding* (65 %), *holistic approach* (55 %), *respect for patient's autonomy & patient involvement* (55 %), *verbal and non-verbal communication* (50 %). Other key elements, such as *healthcare provider's personal characteristics* (15 %), *fair-mindedness/equity* towards patients (10 %) and *psychological support for healthcare providers* (10 %) were mentioned only in few studies.

Participants noted that dehumanizing behavior, such as “othering” (i.e., treating the patient as subhuman)²⁷ can undermine *patient's dignity, uniqueness, individuality and humanity*. On the contrary, strategies, such as referring to the patient by his/her name³⁶ can help the patient to feel respected and seen as an individual.

Organizational Area

The organizational area includes all key elements and related descriptive themes linked to the work environment (e.g., workload) and the organizational and administrative practices of healthcare institutions (e.g., visiting hours).

While the key elements *adequate working conditions*, *adequate training*, and *team work* were mentioned in more than one third of all papers (50 %, 40 % and 40 %, respectively), other key elements, such as *vertical and horizontal communication*, *pleasant hospital stay* and *adequate priority assessment* were covered much less (15 %, 15 % and 10 %, respectively) (see Table 2).

While the fragmentation of the work process³¹ was seen as a barrier, the efficient use of time²⁹ was considered as a strategy to improve the working conditions.

Structural Area

The structural area encompasses all key elements and the associated descriptive themes that focus on the structure of healthcare institutions (e.g., hospital design) and the work environment (e.g., material resources) regarding humanization of care.

Two of the three key elements in this area were mentioned in more than one third of the included studies: *human and material resources* (45 %) and *adequate physical structure* (35 %). The third key element (*pleasant hospital stay*) was mentioned only twice (10 %) (see Table 2).

It has been often reported [e.g., ^{17,19}] that sufficient *human and material resources* are required for providing humanized care. Nevertheless, in many healthcare institutions there was a lack of material resources²⁹ and health professionals^{24,31,33,34}. Including volunteers in the routine hospital practice²⁶ was considered as a strategy to overcome this obstacle.

Table 3. Key elements and examples of the related descriptive themes (i.e., main feature, barrier or implementation strategy) in the relational, organizational and structural area

Key element	Main feature	Barrier	Implementation strategy
<i>Relational area</i>			
Respect for patient's dignity, uniqueness, individuality, and humanity	Patient seen as a person with his own values ¹⁶	"Othering"(being treated as sub-human) ²⁷	Referring to the patient by his/her name ³⁶
Empathy towards the patient	Capacity of taking the other's position ³⁵	/	Accepting and understanding what the patient is going through and his/her emotions ³²
Relationship bonding	Closeness ²⁶	Lack of physical contact ³²	Welcoming patients in a kind way ³⁶
Holistic approach	Patient seen as whole person ³⁶	To work in a mechanical way ³¹	Getting to know the patient's context ²⁸
Respect for patient's autonomy & patient involvement	Consideration of patient's rights ³⁶	Lack of decision-making by women ²⁵	Obtaining women's consent ²⁵
Verbal and non-verbal communication	Effective verbal and non-verbal communication ³⁵	Not looking into the eyes ²⁶	Actively listening to the patient ³⁴

Meeting patient's needs/demands	Personalized care ⁴	No consideration of women's needs ⁴⁰	Verifying patient's needs ²⁹
Commitment	Responsibility ²⁶	/	Being fully present ³⁹
Moral and ethical principles	Respect for ethical principles ³³	/	/
Relational support for the patient and patient's caregivers	Comfort ³⁵	/	Providing emotional support throughout the transplant process ³⁷
Being attentive / interested / concerned towards the patient	Receptiveness ³⁶	Negligence and lack of attention ³⁹	Showing concern about women's well-being ³⁹
Healthcare provider's competence	Professional suitability ³²	/	Demonstrating certainty and confidence ³⁶
Patience	Patience ³⁵	Being annoyed ³⁹	Not getting exasperated with the patient ³²
Transparency regarding the treatment	Truthfulness ³²	Not willing to answer questions ³⁹	Explaining the adverse effects of treatment ³²
Fair-mindedness/equity	Equity ³²	/	Doing good to any patient independently from her/his personality and behavior ³⁰
Healthcare provider's personal characteristics	Personal characteristics ²⁹	Bad-tempered ³²	/
Psychological support for healthcare providers	/	Lack of psychological support for healthcare providers ³⁵	/
<i>Organizational area</i>			
Adequate working conditions	Consideration of staff conditions ³⁸	Fragmentation of the work process ³¹	Good use of time ²⁹
Adequate training	Technical & scientific knowledge ⁴⁰	Lack of professionals trained in HoC ³³	Training professionals according to HoC's principles ³³

Team work	Multidisciplinary team ²⁸	Lack of midwife authority in hospitals ²⁵	Defining adequate roles of healthcare professionals ³³
Continuity of care	Presence of the same professionals ²⁶	Change of professionals ²⁶	Close monitoring after transplantation ³⁷
Appropriate medical treatment	Differentiated treatment ²⁶	/	Preventing unnecessary medical interventions ²⁵
Organizational support for the patient and patient's caregivers	Family participation ⁴⁰	Companion restriction ²⁵	Monitoring of labor and delivery by family members ⁴⁰
Facilitated access to healthcare	Facilitated access to health services ³³	Limited access to secondary care ³³	Reducing waiting time ³³
Vertical and horizontal communication	Institution/professional relation ²⁹	Lack of cooperation from management ¹⁷	/
Pleasant hospital stay	Moments of leisure ³⁷	Interruptions of sleep ²⁶	Flexible visiting hours ³⁷
Adequate priority assessment	Compromise between security and humanity ⁴	Life threatening and emergency situations (high-risk pregnancies & deliveries) ⁴	/
<i>Structural area</i>			
Human and material resources	Sufficient human and material resources ¹⁷	Lack of health professionals ³³	Performing volunteer work ²⁶
Adequate physical structure	Adequate infrastructure ¹⁷	Lack of space ³⁵	Modifying the structure of the units ³³
Pleasant environment	Pleasant hospital environment ³⁷	/	Providing opportunities for entertainment ³⁷

Stakeholders' Perspectives

Comparing the studies focusing either on patients' and patients' caregivers' perspective (n=5) or on healthcare providers' perspective (n=13) alone, it emerged that when patients' and patients' caregivers were assessed, the key elements *psychological support for healthcare providers* (relational area), *vertical and horizontal communication*, *adequate priority assessment* (organizational area), and *pleasant environment* (structural area) were not discussed. Some other key elements, such as *Holistic approach* (20 % vs 69 %), *adequate working conditions* (20

% vs 62 %), and *Human and material resources* (20 % vs 54 %) were mentioned notably less, and some more, such as *Commitment* (60 % vs 23%), *Patience* (60 % vs 15 %), *Healthcare provider's competence* (80 % vs 8 %) and *personal characteristics* (40% vs 8%), *Appropriate medical treatment* (60 % vs 8 %), *Facilitated access to healthcare* (60 % vs 8 %), and *pleasant hospital stay* (40% vs 8%) (see Table 2). However, some key elements were discussed by patients and patients' caregivers as well as by healthcare providers to a similarly small (e.g., *fairmindedness/equity, organizational support for the patient and patient's caregivers*) or great extent (e.g., *respect for patients' dignity, uniqueness, individuality, and humanity, empathy towards the patient, relationship bonding*).

Further, regarding the two studies investigating both patients and healthcare providers, it was found that several key elements of the relational, organizational as well as structural area (e.g., *empathy towards the patient, relationship bonding, facilitated access to healthcare, pleasant environment*) were not mentioned at all.

DISCUSSION

To our knowledge, this is the first systematic review examining the concept of humanization of care from the perspective of the involved stakeholders and aiming to create a shared understanding about *what* delivering humanized care *means* and *how* it can be implemented. Our analysis revealed that gaps between the expectations of all the protagonists involved in the process of care and the routine clinical practice still exist.

Relational Area

The relational area turned out to be the one most explored and discussed which demonstrates the importance of relationships in humanized care.

The key elements *relationship bonding*, discussed in two thirds of the included studies, and *relational support for the patient and patient's caregivers* reflect the need of a genuine relationship between healthcare providers, patients and caregivers. This highlights that it is not sufficient to simply treat the disease or the symptoms. As mentioned by the participants, *being attentive/interested/concerned towards the patient* and a

sensitive *verbal/nonverbal communication* are important means for establishing such a connection, as previously demonstrated⁴¹⁻⁴³. According to the National Patient Safety Foundation's Lucian Leape Institute, "the experience of trust and partnership is itself valuable, satisfying, and fulfilling to patients, families, clinicians, and staff alike." (p.6)⁴⁴. Besides relationship bonding, *empathy towards the patient* and *respect for patient's dignity, uniqueness, individuality and humanity* were also highly discussed by the large majority of stakeholders in the included studies (70% and 90%, respectively) as elements of humanization of care. In agreement with such evidence, several authors already linked empathy to an improved therapeutic relationship⁴⁵ and to higher patient satisfaction⁴⁵⁻⁴⁷. According to our results, the latter above mentioned key element points to the understanding that every patient is a unique person with own values, expectations, and life experiences, which shaped the patient's identity and relational style and might have been shattered by the disease. A severe disease might also reduce patient's perceptions of dignity due to a loss of functionality and a reduced control over the body and daily activities⁴⁸⁻⁴⁹. Healthcare providers can promote patient's dignity by developing a deep understanding on how conditions to the disease affect patient's life, by emphatically acknowledging patient's suffering and, at the same time, by trying to emphasize the characteristics less affected by the disease. A study by Beach et al.⁵⁰ showed that being treated with dignity is linked to higher patient satisfaction and therapy adherence. Closely related is the key element *holistic approach* that was mainly mentioned by healthcare providers who might have been more familiar with this medical concept than patients and their caregivers. The concept refers to the need to take into account all the biopsychosocial and spiritual dimensions of the patient, the disease and the care and to see the patient as a biopsychosocial being. Such an approach recognizes that the mind has a strong impact on the body and that we need to ensure a form of care addressing both body and mind in order to be effective⁵¹. Already in 1996, the WHO Study Group saw integrated care, in which all the components of a health system play a complementary role to ensure patients' wellbeing, as a way to approach health holistically and to foster personalized services^{52,53}. Further, showing *respect for patient's autonomy and involving* them and *meeting their needs and demands* were mentioned in half of the included studies (55% and 45%,

respectively) as means in humanizing healthcare. Thus, excluding, for instance, women from decision-making processes in their own care²⁵ or ignoring women's needs⁴⁰ can represent barriers to the humanization of care. Overwhelming evidence indicates that engaging patients in their own care and thus taking patients' preferences and needs seriously improves patient satisfaction, empowerment, quality of life, and treatment outcomes⁵⁴⁻⁵⁶. **Transparency regarding the treatment** was considered, more so by patients and their caregivers than by healthcare providers, another key element. Consequently, not being willed to answer patient's questions³⁹ can impede humanized care. A complete understanding of one's own medical condition and treatment option gives the patient the feeling of autonomy, of being respected and seen as equal partner. As highlighted by the NPSF Lucian Leape Institute⁵⁷, greater transparency is linked to higher patient satisfaction, better health outcomes, lower costs and also fewer medical errors.

Healthcare provider's characteristics and **healthcare provider's competence** were rarely mentioned in studies exploring healthcare providers' perspective, probably because they did not question themselves. On the contrary, almost all studies analysing patients' view reported competence as aspect of humanized care. *Psychological preparation to understand the patient* was reported as one strategy to convey such competence. Thus, professional competence should be understood not only in terms of technical but also in terms of non-technical skills. Equipping healthcare providers with such psychosocial abilities should become an integral aim of medical education.

Moreover, according to our findings, healthcare providers should follow **moral and ethical principles**, be **fair-minded**, treat all patients **equally** and show **patience** and **commitment** to their jobs. However, being committed, patient and empathic towards patients is challenging when experiencing distress or even burnout^{58,59} due to seemingly overwhelming work demands and time constraints. Healthcare providers may then rush through patient encounters while experiencing a loss of enthusiasm, dedication, and meaning⁶⁰. Given these circumstances, it is surprising that only two studies^{25,35} pointed out that healthcare organizations do not sufficiently provide **psychological support for healthcare providers**. Healthcare staff will just be able to truly care for patients and deliver humanized care if also their own human needs are addressed.

Organizational Area

Adequate working conditions was the most discussed key element in the organizational area. According especially to healthcare providers' opinion, fragmentation of the work process, lack of time, intense routine at work, excessive demands on healthcare providers, excessive bureaucratic activities and additional activities out of professionals' scope impose significant barriers to achieving humanized care. When organizations are able to overcome these barriers, establish proper working conditions, and thus demonstrate that healthcare providers' well-being is of great importance, healthcare providers will experience higher levels of job satisfaction, be less susceptible to burnout, and provide better care⁶¹.

Even though less frequently reported, *adequate training* opportunities for healthcare providers, effective interdisciplinary *team work* as well as proper *vertical and horizontal communication/collaboration* in the institution were listed especially by healthcare providers as organizational requirements for providing humanized care. However, as pointed out by the participants of the included studies, several barriers to these key elements still exist in healthcare institutions, such as a still widespread traditional approach to medical education and training³³, a strict hospital hierarchy²⁵, and lack of cooperation from the management¹⁷.

On the contrary, regarding patient care itself, mostly patients and their caregivers called for *appropriate medical treatment* tailored to patients' needs and *facilitated access to healthcare* to ensure humanized care. Open and easy access to primary care has been demonstrated to play also a significant role in reducing, for instance, healthcare inequalities, mortality, morbidity, and costs⁶². Healthcare organisations should also guarantee *continuity of care*, by avoiding, for example, a frequent change of healthcare professionals²⁶ and provide *organizational support for the patients and their caregivers*. Further, a *pleasant hospital stay*, without, for instance, interruptions of sleep²⁶ or long intervals between lunch and dinner³⁹, was valued by patients and their caregivers, as already shown in the literature⁶³. Two studies highlighted also the importance of an *adequate priority assessment* of medical care (i.e., to find a compromise between ensuring effective care and life-saving treatment, such as in intensive care situations⁴ and delivering humanized care), as also discussed by Todres et al.^{18,64}.

Structural Area

Due to economic imperatives and increased demands (e.g., aging population, increase of chronic diseases), healthcare systems have been struggling lately with a critical shortage of health care personnel and lack of material resources⁶⁵⁻⁶⁷, which were considered in the included studies as barriers to humanized care. According to the American Association of Colleges of Nursing, insufficient staffing leads to increased stress levels among nurses, reduced job satisfaction, and to drop-outs⁶¹. Meaningful personal relationships with patients have become challenging tasks carried out under immense time pressure⁶¹. Thus, to give healthcare providers the chance to spend time directly engaging with patients and caring for them, healthcare institutions must provide sufficient *human and material resources*.

Healthcare settings, not lacking in space³⁵ and with *adequate physical structures* and *pleasant environments* were also considered as structural aspects of humanized care. Indeed, factors such as floor and room layouts and lighting have been shown to positively influence health outcomes⁶⁸⁻⁷⁰.

Limitations

A number of limitations may have influenced our results. All primary studies applied qualitative or quantitative-qualitative methods and had small sample sizes, thus limiting data rigidity and replicability, and reducing the generalizability of the findings. However, by using qualitative approaches, such as focus groups and interviews, each of the included studies was able to provide an insight into healthcare practices and the “lived experience” of patients and healthcare providers in the field of humanization of care^{71,72}.

Intrinsic limitations associated with the applied methodology of our study have to be considered as well. First, despite extensively searching published and gray literature in the medical field, we may have nevertheless missed relevant studies in the field of humanities which could have impacted our results. It is also likely that our applied search terms “humanization/humanisation of care” and “dehumanization/dehumanisation of care” did not capture studies that investigated elements of humanized care (e.g., liberal visitation policies in pediatric care) but did not specifically use the terms “humanization” and “dehumanization”. Further, because of our restriction to include only studies published in

English, German or Italian, we may have missed otherwise eligible studies which could have contributed to a broader geographical and cultural scope of the findings.

Moreover, the methodological steps of the thematic analysis can be prone to subjectivity. To limit this potential bias, two reviewers performed all steps independently and resolved any disagreement in consensus and/or by involving a third reviewer. One might argue that summarizing and synthesizing the results of the primary studies, conducted in different medical settings with participants from various backgrounds, could lead to a decontextualization of the findings²³. Following Thomas and Harden²³, we therefore tried to preserve context by providing detailed characteristics (e.g., study design, setting, type of participants) and quality assessment for each study. Further, we consistently examined whether the results that emerged from our synthesis could be translated into other medical settings without loss of meaning²³.

Lastly, the generalizability of our findings is hampered by the fact that most of the research was conducted in Brazil. This geographical predominance is not surprising given the fact that since the introduction of the Brazilian National Policy of Humanization of Care and Management in 2003, Brazil has devoted great efforts to establishing humanized care, specifically in medical settings which deal with very fragile patients (e.g., newborn/infants or oncological patients) or where risk of dehumanization (e.g., extensive use of technology in intensive care) is high^{73,74}.

Future Studies

Further research around humanization of care is warranted.

Even though we were able to extract numerous key elements of humanization and point out similarities and differences between patients' and professionals' perspectives, we identified only a few implementation strategies, which were often insufficient to add actionable information. Thus, future studies need to fully examine specific practices of humanized care and to test quantitatively their effectiveness by examining psychosocial and health outcomes. Moreover, to examine how the concept of humanization of care might be shaped by the culture we live in, research on humanization of care should be increased in many countries providing a global perspective. To ensure that future literature reviews on humanization of care are able to capture all potentially eligible studies from

around the world and thus to provide an even clearer picture of the key elements of humanized care, the search criteria of this study might be expanded. Indeed, the literature search could be extended to other scientific areas, language restrictions might be omitted, and the search strategy could include more terms. The key elements identified by our study may even serve as additional search terms. Future research aiming to identify an even more articulated structure composed of additional sub-constructs within the relational, organizational and structural area could be beneficial for formalizing a model of humanization of care and for assessing model-consistent interventions to improve outcomes.

Conclusions

By synthesizing and thematically analyzing the different perspectives of patients, caregivers, and healthcare providers, our systematic review contributes to a better understanding of the concept of humanization of care. An empathic and respectful approach to patients, sufficient human and material resources in the healthcare institutions, and a balanced workload for healthcare providers are important prerequisites for establishing meaningful, mutually beneficial relationships with patients and delivering humanized care. The proposed key elements can be considered as preliminary guidance that can help patients, caregivers, healthcare providers, and healthcare institutions in this endeavor.

Compliance with Ethical Standards

Informed consent: For this type of study formal consent is not required.

Ethics Approval: For this type of study ethics approval is not required.

Conflicts of Interest: The Authors declare that they have no conflict of interest.

Source of Funding: The Authors received no specific funding for this work.

Data Availability Statement

The full datasets of the systematic review can be made available upon reasonable request.

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* = studies included in the systematic review

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3. Patient Empowerment in Risk Management: a Mixed-Method Study to Explore Mental Health Professionals' Perspective

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This chapter contains an *Additional File* which can be found in Appendix B.

¹ **Acknowledgement of author contributions:**

MR and FM conceived the idea for the study, developed the coding system, and, together with IMB and AP, wrote the draft of the manuscript. MAM performed the statistical analysis. VD and EB transcribed and coded the focus groups. All authors read and approved the final manuscript.

ABSTRACT

Background: In the last years, patients' empowerment has been increasingly recognized as a crucial dimension of patient-centered healthcare and patient safety. Nevertheless, little work has been done so far in the field of patient safety to investigate strategies for empowering psychiatric patients. Therefore, the aim of this study was to identify, by using focus groups, whether and how psychiatric patients' empowerment can improve risk management according to the perspective of healthcare providers (HPs).

Methods: A mixed-method approach composed of a qualitative data collection method (i.e., focus groups) and a quantitative analysis technique (i.e., inductive content analysis) was applied. HPs working in mental health settings shared their perspectives on psychiatric patients' empowerment in risk management. After the transcription of the audio-taped discussions and the subsequent development of a hierarchical four-level coding system (strategy versus critical issue, thematic area, category, subcategory), two independent raters codified the transcripts and synthesized the content. Absolute frequencies are reported for quantitative data.

Results: Twelve focus groups consisting of six to ten participants, each with an overall sample size of 95 participants (65 women; average age \pm SD 47 ± 9 yrs), were enrolled. A total of 1252 participants' verbal contributions (i.e., units of analysis) were assessed. Strategies and critical issues (Level 1) were mentioned almost equally (52 and 48%, respectively) by the HPs. Most of the contributions at Level 2 referred to the thematic areas 'Treatment and Cure (69%) and Emergency Management (21%). In the area Treatment and Cure, the category Therapeutic Compliance (Level 3) was discussed in one third of all contributions.

Conclusions: Our results suggest that HPs consider patients as crucial partners in risk management and expect them to play a key role in actively enhancing safety. Policy makers should be aware that risk management in mental health settings particularly relies on the therapeutic relationship between HPs and patients. Therefore, allocating sufficient human

and financial resources to mental health care aiming to further support the relationship between patients and HPs is of utmost importance.

Keywords: patient-safety, risk management, risk assessment, psychiatry, mental health, patient empowerment, focus group, mixed-method.

BACKGROUND

In the last years, patients' empowerment has been increasingly recognized as a crucial dimension of patient-centered healthcare¹ that can improve patients' understanding and control over their health and healthcare process². Instead of only passively receiving healthcare assistance, patients can become, to some extent, self-determining and independent^{3,4} with a potential positive impact on several health outcomes such as treatment adherence and self-care practices^{5,6}. Furthermore, improving the quality of care through the involvement of patients may lead to positive outcomes also in terms of patient safety. Already in 2004, the World Health Organization (WHO)⁷ declared patients' active role and involvement in their own path of care as essential for enhancing patient safety; the same approach, aiming to guarantee a better patients' safety, was postulated in 2009 also by the European Council⁸.

Despite the increasing acknowledgement of the importance of patients' role in healthcare, patients' perspective in risk management is still underestimated⁹. Recently, intending to overcome this misestimation, Peat et al.¹⁰ proposed a framework to conceptualize possible routes by which patients may be involved in their care and give a substantial contribution to improve their own safety. For instance, patients can help to assure that an appropriate treatment is correctly administered by sharing significant health information with healthcare providers and by asking questions regarding the chosen type of treatment.

The necessity to further promote patient empowerment in risk management is also underlined by the key role that the human factor may play in ensuring safety¹¹. Indeed, according to the traditional risk management approach, *human fallibility* exists and can be efficiently addressed by introducing changes in the system and improving defenses which can avert adverse events and mitigate their effects¹². Such an approach assumes that human variability represents a potential threat to patient safety and needs to be reduced by appropriate systemic changes. On the contrary, the most recent literature proposed a different view of *human variability*, addressing it as a precious resource strengthening system flexibility and resilience (i.e., the capability of a system to handle unexpected, unsafe variations by rapidly restoring an acceptable level of variability able to prevent the occurrence of adverse events)¹¹.

According to this evidence, not only healthcare providers but also patients and patients' caregivers, representing the sharp end of any healthcare process, are supposed to play a key role in actively carrying out tasks and enhancing safety¹¹. For instance, Weingart and colleagues¹³ demonstrated that patients were able to identify medical errors (i.e., potential source of system variations) not recognized by their physicians or any other healthcare provider involved in their care. Despite these recognized advantages of patients' involvement in risk management, also potential intrinsic challenges have to be fully considered and faced. For instance, the fear of healthcare providers of a power shift to patients¹⁴ may impede the implementation of patient empowerment. Considering the current focus on performance accountability¹⁵ and the insurmountable expectation of perfection^{11,16} affecting healthcare providers, the "empowered" patient, who actively participates in her/his own safety may then be seen not as a partner but rather as a threatening figure pointing out healthcare providers' wrongdoing or even taking legal action¹⁷. At the same time, it also has to be considered, as highlighted by Doherty and Stavropoulou¹⁸, that patients perceive themselves as vulnerable as well as dependent on their healthcare providers. For some patients, the feeling of being co-responsible for safe treatment delivery may lead to increased anxiety and may represent a burden¹⁰. These barriers might be particularly challenging in the mental healthcare setting in which the proper balance between a safe level of control and an approach taking into account patients' perspective is difficult to achieve.

While many principles of patient safety – mostly derived from studies performed in medical health care settings such as acute and emergency care – have been directly transferred to mental health settings, several patient safety aspects, unique to mental health care (e.g., self-harm, suicide, restraint use), still have to be fully addressed¹⁹⁻²², especially considering that adverse events are common^{23,24} and carry a high socio-economic impact²⁵. Additionally, to the necessity to further investigate the unique challenges of safety in mental health care, the need to increase the active involvement of patients suffering from psychiatric disease have been widely acknowledged as a priority^{2,26,27}. Nevertheless, little work has been done to investigate strategies to empower mentally ill patients in the field of patient safety considering healthcare providers²⁸ and patients' perspectives.

Therefore, the main aim of this study is, by using focus groups, to identify whether and

how psychiatric patients' empowerment can improve risk management according to the perspective of healthcare providers (HPs). In particular, our study aims to investigate the critical issues and strategies related to psychiatric patients' empowerment in risk management, since, as above-mentioned, this group of patients is especially vulnerable.

METHODS

Recruitment and Focus Groups

Ethical approval for the present study was obtained by the Ethical Committee of the Verona University Hospital (Protocol n.16160; 31/03/2016).

The study was conducted within the Verona Mental Health Department (MHD) in the Northeast of Italy (459,536 inhabitants). Specifically, four mental health services and one "specialized penitentiary mental healthcare unit" (i.e., a small-scale facility for prisoners with mental health problems that, according to Italian law, has recently replaced forensic hospitals) were included. The MHD includes: 1) four 15-bed acute inpatient wards (i.e., open wards with dedicated staff where patients can be admitted on a voluntary or compulsory basis) located in three general hospitals; 2) four community mental health centers providing day care and rehabilitation; 3) 13 outpatient clinics, providing emergency care and continuity of care as well as scheduled domiciliary visits; 4) one liaison service offering psychiatric and psychological consultations for other departments of the general hospital, 5) one 24-hour emergency department, and 6) 36 sheltered accommodations. We recruited participants from various MHD settings to encourage different perceptions and points of view and to thus increase representativeness and generalizability of our findings. All the HPs of the MHD having attended a continuing educational course on risk management in 2016 were invited to participate in the study. Indeed, we considered such a common background in risk management as a useful prerequisite for guiding participants more easily during the focus group discussions. All recruited participants signed the informed consent form and were then divided into twelve focus groups of six to ten participants.

Experienced focus group facilitators introduced the rules highlighting the importance of confidentiality. Participants were then encouraged to provide their opinions derived from

their professional experiences and knowledge in the field of mental health and patient safety. According to the aims of this study, the following questions were proposed one by one to stimulate the discussion:

1. What do you think about patients' involvement in risk management in psychiatry?
2. Which are the potential limits/risks of involving psychiatric patients in risk management?
3. Which are the potential benefits/strengths of involving psychiatric patients in risk management?
4. Which strategies do you usually apply in your daily practice in order to engage patients in their safety?

In the subsequent one-hour discussion, participants exchanged their opinions but were asked to adhere as much as possible to the themes proposed by the facilitators and to respect turn-taking. Facilitators had also to promote the debate and ensure the active involvement of each participant without interfering with the content of the discussion.

Inductive Content Analysis and Development of the Four-level Hierarchical Coding System

We applied a mixed-method approach, since it is one of the most effective methodologies able to “capture the complexity of healthcare processes and to gather advanced insight into healthcare communication phenomena” (p.281)²⁹. By combining quantitative and qualitative techniques, a large amount of information, collected in flexible and iterative ways, can be synthesized and analyzed.

The rationale for using multiple forms of research is based on the understanding that all methods have strengths and limitations and that the advantages of quantitative research can outweigh the disadvantages of qualitative research and vice versa.

All focus group discussions, including facilitators' questions and comments, were audiotaped and fully transcribed. In order to synthesize the transcriptions, two researchers (MR and FM) independently analyzed the discussion of one randomly selected focus group following the guidelines for qualitative content analysis³⁰. Each researcher preliminarily labeled all verbal contributions (i.e., phrases, comments, opinions, suggestions of each participating HP) according to the above-mentioned questions and then sub-grouped

them in areas conveying similar concepts. After this first round of individual text analysis, the researchers discussed and merged their preliminary labels into a unique coding system, organized in a hierarchical structure of four levels (see Figure 1).

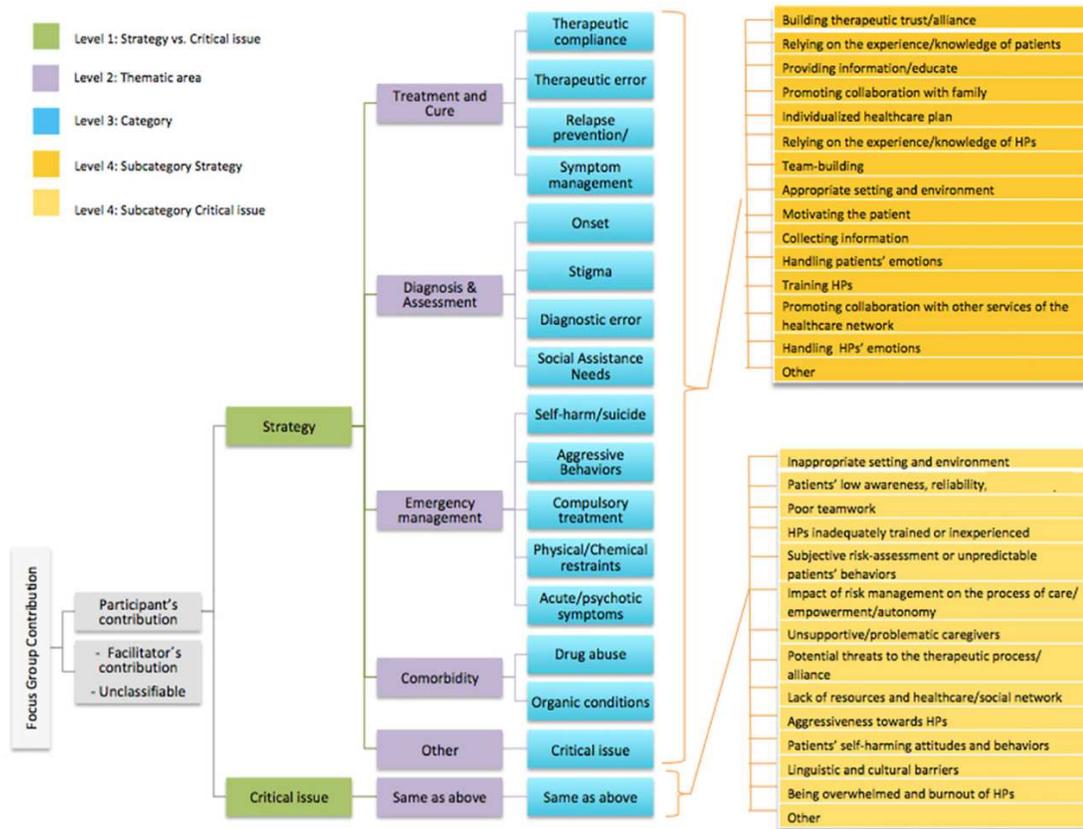


Figure 1. Hierarchical structure of the coding system developed in order to synthesize the focus group content

In order to verify if all topics raised by the participants could be captured by the coding system, two researchers separately coded the transcripts of two additional focus group discussions. Since no additional topics emerged, the coding system was considered exhaustive (i.e., saturation criterion) and the four levels were confirmed as follows:

Level 1 aims to distinguish between HPs' contributions describing or referring to a strategy (i.e., a statement underlying a way patient empowerment may improve risk management) and HPs' contributions pointing out a critical issue (i.e., a statement underlying critical aspects that may hinder patient empowerment in risk management). Level 2 (*thematic areas*)

refers to different aspects of the process of care (i.e., *Treatment and cure, Diagnosis and assessment, Emergency management, Comorbidity, Other*). Level 3 (*Categories*) consists of specific issues related to certain thematic areas (e.g., the thematic area *Comorbidity* was divided into the two categories *Drug abuse* and *Organic Conditions*). Finally, level 4 lists specific strategies or critical issues applicable to each category at level 3 (e.g., the strategy *Handling HPs emotions* might be referred to several categories, such as *Therapeutic compliance, Diagnostic error, or Compulsory treatment*).

In order to ensure that facilitators' interventions did not influence the course of participants' discussion, one researcher (MR) verified facilitators' neutrality by analyzing all their verbal turns in the transcripts. To provide definitions and rules for coding each transcript of each focus group, a manual was developed (MR and FM) (see additional file 1 for the definitions of thematic areas and categories).

Two independent raters (VD and EB) then coded all the contributions of all focus groups according to the established four-level hierarchical coding system and by using the above-mentioned manual.

Aiming to evaluate the reliability of the coding system, the inter-rater agreement was evaluated for one randomly selected focus group transcript. The inter-rater agreement turned out to be good at Level 1 (87%, $\kappa=0.73$, 95% CI [0.607, 0.862]), moderate at level 2 (72%, $\kappa=0.55$, 95% CI [0.420, 0.686]) and at level 3 (64%, $\kappa=0.55$, 95% CI [0.425, 0.673]). The fourth and last level was characterized by skewed data and empty cells, inter-rater reliability analysis could therefore not be performed. The overall inter-rater agreement was considered satisfying. In order to further improve the quality of the coding process, in particular for level 4, it was established that unsure codings had to be discussed and resolved in consensus.

To further assess the robustness of the coding system, one year after data collection (i.e., 2017), all study participants were invited to a meeting. A subsample of the study participants (n=50) attended this encounter and discussed the coding system, the thematic areas and a synthesis of the study results. The majority of participants' comments was positive, and no additional areas of interest were suggested, demonstrating the comprehensiveness of the applied coding system.

Statistical analysis

Interrater reliability of the coding system has been performed with Cohen's Kappa by using STATA module Kappaetc³¹.

Following a mixed-method approach³⁰, a frequency distribution of each thematic area, category, and subcategory is provided together with fragments of text extracted from the focus group transcripts. In order to check if all participants contributed to the focus groups discussions, we ensured to maintain the link between each contributing statement and its author in a sub-sample of four focus-groups. Rates of occurrence of all the expressions by participant were calculated.

RESULTS

Twelve focus groups with an overall sample size of 95 participants (65 women, 30 men; average age \pm SD 47 \pm 9 yrs) were enrolled. Participants were psychiatric nurses (n=67), healthcare and social assistance operators (n=10), and other mental health professionals (e.g., psychiatrists, clinical psychologists). Most of the participants (59%) had 10 to 30 years of work experience, 19% more than 30 years, and 19% one to nine years, the remaining (3%) were HPs hired during the last year. Most of the participants (68.4%) reported to have already experienced at least one adverse event in their career.

The total number of HPs' verbal contributions and facilitators' interventions was 1252. Seven hundred sixty-three and 348 out of 1252 were HPs' contributions and facilitators' interventions, respectively. The analysis of the occurrence rate of each participant's verbal contributions confirmed that all HPs contributed to the focus groups (range of contributions: 9-59). One hundred forty-one contributions were excluded since they consisted of very short, unclassifiable sentences (e.g., *"I don't know... actually it depends... it is a difficult topic"*).

Facilitators' most frequent interventions were open, general questions (e.g., *"anything else? Do you all agree?"*), back channel responses (e.g., *"hmm, please continue..."*), reassurance (e.g., *"there are no right answers for this discussion."*), transitions (e.g., *"sorry to interrupt the discussion, but this content doesn't fully fit to the topic of risk management..."*), and synthesis (e.g., *"correct me if I'm wrong, but according to your opinion the main strategies applied during compulsory treatments are...."*).

Regarding level 1 of the coding system, HPs almost equally addressed strategies (52%) and critical issues (48%) (see Table 1).

At level 2, the most frequently discussed thematic area was *Treatment and cure* (69%) that included all participants' verbal contributions regarding patients' empowerment in risk management during the process of care (i.e., referring either to pharmacological treatment or any other therapeutic approach planned for the patient). Participants discussed also the involvement of patients in the safety management during acute phases of the disease (e.g., severe psychotic symptoms) and in emergency settings (e.g., patient receiving compulsory medical treatment) (*Emergency management*, 21%). Finally, strategies and critical issues regarding patients' role in risk reduction related to the diagnosis and assessment of mental disorders were only rarely addressed (*Diagnosis and Assessment*, 7 %).

At level 3, the role of *Therapeutic compliance* in ensuring patient safety (i.e., regarding both compliance to pharmacological therapy and to any other aspect of the management of disability) was discussed in one third (34%) of all the HPs' contributions. Other categories frequently mentioned as relevant in risk management were: *Relapse prevention/symptom management* (26%), *Therapeutic error* (i.e., errors occurring in the administration and management of the pharmacological therapy, 10%), and *Aggressive behaviors* toward others (e.g., states of psychomotor agitation, 8%).

Table 1. Frequency distribution and percentages of HPs' contributions coded at Level 1, 2 and 3

Thematic area	Category	Strategy	Critical issue	Total
Treatment and Cure	Therapeutic compliance	142 (35.4 %)	114 (31.5 %)	256 (33.6 %)
	Therapeutic error	50 (12.5 %)	28 (7.7 %)	78 (10.2 %)
	Relapse prevention/symptom management	114 (28.4 %)	81 (22.4 %)	195 (25.6 %)
Diagnosis and Assessment	Onset	0 (0 %)	6 (1.7 %)	6 (0.8 %)
	Stigma	3 (0.7 %)	4 (1.1 %)	7 (0.9 %)

	Diagnostic error	5 (1.2 %)	2 (0.6 %)	7 (0.9 %)
	Social assistance needs	13 (3.2 %)	24 (6.6 %)	37 (4.8 %)
Emergency management	Self-harm/suicide	19 (4.7 %)	17 (4.7 %)	36 (4.7 %)
	Aggressive behaviors	23 (5.7 %)	42 (11.6 %)	65 (8.5 %)
	Compulsory treatment	10 (2.5 %)	11 (3 %)	21 (2.8 %)
	Physical/Chemical restraints	5 (1.2 %)	7 (1.9 %)	12 (1.6 %)
	Acute/Psychotic symptoms	13 (3.2 %)	12 (3.3 %)	25 (3.3 %)
Comorbidity	Drug abuse	0 (0 %)	5 (1.4 %)	5 (0.7 %)
	Organic conditions	1 (0.2 %)	3 (0.8 %)	4 (0.5 %)
Other		3 (0.7 %)	6 (1.7 %)	9 (1.2 %)
Total		401	362	763

Table 2 and 3 show, respectively, the frequency distribution of strategies and critical issues (subcategories at level 4) independently from the thematic area.

Building *therapeutic trust/alliance* was considered as the main strategy of HPs facilitating patients' participation in risk management (18%). Two of the core elements underlying patient empowerment in the clinical process were also identified by HPs as crucial for patient safety: *relying on the experience/knowledge of patients* (14%) and *providing information/educate* (14%).

Additionally, *promoting collaboration with family* (9%), *individualized healthcare plan* (8%) and *relying on the experience/knowledge of HPs* (8%) were also mentioned (see Table 2).

The six most frequent critical issues identified as potential threats to patients' participation in risk management turned out to be: *inappropriate setting and environment* (e.g., unsafe spaces in hospital psychiatric units, 12%), *patients' low awareness, reliability* (e.g., ego-syntonic disorders leading to dysfunctional behaviors, beliefs, and feelings perceived as acceptable by the patient, 12%), followed by aspects referring directly to healthcare providers, such as *poor teamwork* (e.g., poor communication/coordination among the team members, 10%),

HPs inadequately trained or inexperienced (e.g., HPs not sufficiently skilled to enable patients' engagement in risk management, 10%), and the *subjectivity of risk-assessment or the unpredictability of patients' behaviors* (e.g., risk assessment varies according to risk perceptions and risk tolerability, which are partially determined by HPs' individual characteristics, 10%).

Finally, also the *impact of risk management on the process of care/empowerment/autonomy* was mentioned as critical aspect (e.g., in some cases, pursuing patient safety may lead HPs to take decisions that limit patients' autonomy and therefore threaten their empowerment, 10%) (see Table 3).

According to participants' comments, the relevance of each strategy and critical issue varies depending on the context (i.e., thematic area). Thus, the strategies most frequently applied to facilitate patients' empowerment in the management of therapeutic errors may be inappropriate in other situations, such as dealing with patients' aggressive behaviour. Additional file 1 shows how specific strategies and critical issues are linked to the thematic areas.

Table 2. Frequency distribution and examples of the focus groups contributions included in the Strategies subcategory (Level 4)

Strategy	n	Examples
Building therapeutic trust/alliance	73	<i>“Often patients are aggressive because they are scared. In order to face these reactions and to gain patients' trust and alliance, it is important that all HPs are self-confident and convey reassurance...”</i>
Relying on the experience/knowledge of patients	58	<i>“When patients know their pharmacological therapy, they may be able to recognize and report eventual administration errors.”</i>
Providing information/educate	58	<i>“We organize patient group meetings, in which we discuss about the effects of the drugs and the potential side effects in terms of pros and cons. The aim is to favour the autonomy, these groups work, patients have shown more self-awareness.”</i>
Promoting collaboration with family	35	<i>“Team working does not refer only to the collaboration between HPs and patients. It deserves also family involvement because it is important for patients to feel supported by their relatives and, on the other hand, family member can provide important information to clinicians.”</i>

Individualized healthcare plan	34	<i>“It’s important to listen to patients without prejudice. Sometimes you might have a project for that patient, which then turns out to be far away from his expectations. During rehabilitation you can’t follow your own direction without taking into account what patients want, can do and would like to do. Otherwise, the risk of failure is very high”</i>
Relying on the experience/knowledge of HPs	33	<i>“Human factor in dealing with patients’ aggressive behaviours is crucial, since it is difficult to have a rule that can be applied to all patients. HPs decide to react to patients’ aggression on the basis of the knowledge that they have about that specific person.”</i>
Team-building	25	<i>“It is important that the team has a common goal, since it is not the single person that can make a difference...”</i>
Appropriate setting and environment	18	<i>“It is important that patients can be welcomed in an comfortable environment, maybe with a garden where they can smoke...”</i>
Motivating the patient	17	<i>“Helping patients to understand the importance of respecting the rules may lead to better results instead of simply imposing prohibitions”</i>
Collecting information	17	<i>“...in order to involve patients in risk management, it would be a good idea to directly ask them what they expect. Collect their advices and requests may let us understand needs that we may not expect”</i>
Handling patients’ emotions	12	<i>“The risk of aggressions is reduced by encouraging patients to express their emotions. For example, if they are feeling some aggressive drive against other people and they are free to express and discuss it, then this is a first step for reducing internal tension.”</i>
Training HPs	8	<i>“Professionals who want to work in psychiatry have to be well trained. It’s inappropriate to select them randomly from internal rankings. If you want to reduce risk in psychiatry, the first step is healthcare providers training.”</i>
Promoting collaboration with other services of the healthcare network	5	<i>“Before an involuntary treatment it’s important to inform the police that will be present in order to share information on the patient and on the reasons underling this intervention”</i>
Handling HPs’ emotions	5	<i>“...to recognize and prevent burnout, help HPs to better cope with their feelings, eliminate the elements that might have brought the HP to the physical and mental exhaustion, like excessive workload...”</i>
Other	3	<i>“I think that another area in which patients might be involved regarding their safety is the personal hygiene...most of our patients are reluctant to take a shower, but in that</i>

		<i>moment, you might teach them how to get out from the shower box without falling...</i>
Total	401	

Table 3. Frequency distribution and examples of the focus groups contributions included in the Critical Issue subcategory (Level 4)

Critical Issue	n	Examples
Inappropriate setting and environment	45	<i>“The environment would be adequate for a medical setting rather than a psychiatric setting; a psychiatric patient needs more open spaces to move safely and get relaxed...”</i>
Patients’ low awareness, reliability	43	<i>“We can share the responsibility with the patient only when he has totally understood and accepted what is happening to himself, otherwise it is very difficult...”</i> ;
Poor teamwork	38	<i>“Another risk is the lack of communication between different members of the team...the team communicates only regarding the diagnosis... each healthcare professional brings his personal point of view and works with the patient focusing only on his specific field.. there is no space for sharing different perspectives...”</i>
HPs inadequately trained or inexperienced	37	<i>“I have never done any training on this topic. I know that I may change my attitude towards the patients, but I don’t know how to do it”</i>
Subjective risk-assessment or unpredictability of patients’ behaviors	37	<i>“There is a wide subjectivity in the evaluation of psychiatric patients: her evaluation and her behaviors may change according to the healthcare professional they are referring to in a certain moment”</i>
Impact of risk-management on the process of care/empowerment/autonomy	36	<i>“For example, restrictions to outdoor access for some inpatients. They would like to go out at all hours; they would like to have coffee every time they want it and they would like to do all the others things they can’t due to the limitations. It is difficult to create a collaborative relationship. How can you tell them ‘You can’t go out’. They don’t understand why.”</i>
Unsupportive/problematic caregivers	34	<i>“If a caregiver see his relative sedated may get angry..”</i>
Potential threats to the therapeutic process/alliance	25	<i>“Sometimes we avoid to involve patients in order to preserve his saneness. In the psychiatric field is difficult to evaluate how much information the patient may tolerate”</i>

Lack of resources and healthcare/social network	14	<i>“They often ask us for a cigarette because they get bored. It would be much better to have a walk or a chat with the patient instead than giving him a cigarette. But unfortunately we don’t always have time to do it, even if we are aware it would be the best for the patient.”</i>
Aggressiveness towards HPs	14	<i>“If I don’t feel myself safe as an healthcare operator it is difficult to care for patient safety; I need to prior ensure my safety in order to work well.”</i>
Self-harming patients’ attitudes and behaviours	13	<i>“It is difficult when they (the patients) do not want to collaborate and it looks like they are doing their best the get things going wrong.”</i>
Linguistic and cultural barriers	12	<i>“It is difficult to involve foreign patients, both because of the language and the different culture. They generally stay in contact until they are feeling bad but as soon as they get a bit better they disappear”</i>
Being overwhelmed and burnout of HPs	8	<i>“Verbal aggression is generally underestimated. It may become unpleasant if you (health operator) can't leave such a feeling at work and you take it at home with you”</i>
Other	6	<i>“it is difficult to control the door of the ward and to check if patients have lighters...”</i>
Total	362	

DISCUSSION

Our study addresses psychiatric patients’ involvement in risk management by investigating the opinions of HPs. Applying a multi-level codification system, we provided a precise overview of the complex role of psychiatric patients in risk management during the diagnostic and therapeutic process.

Our results are represented by the evidence that there is still the necessity to tailor the acquired knowledge about risk management and patient safety as well as the respective protocols, developed in the generic medical setting, to the context of psychiatry, since in this latter setting specific needs and challenges have to be faced. According to HPs contributions, a profound change of perspective is necessary in this adaptive process.

In the following, the key themes/elements as well as the critical issues and strategic implications derived from the focus group discussion have been summarized.

Patient Adherence to Risk Management Activities

In most of the medical fields, patients' willingness to adhere to safety protocols can be presumed. In psychiatry, this aspect is more controversial, as highlighted also in our study by the high percentage of critical issues discussed in the categories *Therapeutic compliance*, *Self-harm/suicide*, and *Acute/psychotic symptoms*. Indeed, some psychopathological conditions^{20,22,32,33}, such as severe depression, may undermine patients' willingness to take care of their own health and safety and, in the worst cases, even existence (i.e., suicide). Furthermore, psychotic symptoms (e.g., hallucinations) may alter patients' perceptions of reality and consequently affect the perception of potential sources of risk. Lastly, even personality traits can compromise patients' compliance to risk management as demonstrated, for instance, by self-harming behaviors occurring in patients with borderline disorder.

Even if the three most frequently cited strategies to promote patients' involvement turned out to be *Building therapeutic trust/alliance*, *Providing information/educate*, and *Relying on the experience/knowledge of patients*, HPs considered *Patients' low awareness, reliability, accessibility* as one of the most significant limitations to the process. These results underline that HPs value patients' perspective and collaboration considering it as a mean to ensure higher level of safety but, at the same time, feel that this collaboration may be easily questioned and compromised.

This topic has been already widely discussed in the literature³⁴. For instance, Tambuyzer and colleagues³⁵ demonstrated that the process of patient involvement might be affected by both "the person's *ability* to be involved and his *motivation* or desire to be involved" (p.142³⁵). Even if several authors consider patient involvement as a continuum rather than an "all-or nothing" process^{36,37}, it seems that HPs still present difficulties in moving along this continuum when they have to decide how and to what extent to involve psychiatric patients with low insight. Thus, this patients' vulnerability may lead HPs to avoid their involvement instead of trying to tailor the level of empowerment to each patient in each specific phase of the disease.

Subject at Risk

Some of the psychopathological conditions described above determine also another peculiar challenge, which HPs working in psychiatric and emergency departments have to face: the risk of personal aggressions^{38,39}. Therapeutic relationships usually rely on the implicit assumption that patients are in a fragile position and look for HPs' care and support. Therefore, interpersonal conflicts, even aggressive reactions, may happen but are generally rare and in most of the cases expressed just at a verbal level. In the focus group discussions, critical issues, referring to the category *Aggressive Behavior*, were mentioned twice as much as strategies, suggesting that HPs' consider this aspect particularly challenging. The element that, according to their suggestion, represents the main strategy in handling patients' aggressive behavior was hosting patients during the acute phases of their disease, in an in-patient psychiatric ward characterized by a comfortable environment, where their privacy, freedom and safety are protected and guaranteed (see the subcategories of additional file 1: *Appropriate/Inappropriate setting and Environment*). In a recent systematic review on the role of the psychiatric ward as a therapeutic space⁴⁰, it has been suggested that psychiatric facilities should be aligned to the current policy on patient-centered healthcare and should therefore be designed following a more holistic approach taking into account structural, organizational, symbolic, and social dimensions. In particular, van der Schaaf et al.⁴¹ found that the availability of private spaces and a high level of comfort were associated with a lower risk of violence.

Nevertheless, it has to be considered that the strategic value attributed by the HPs to the environment might have been determined by the fact that they considered their wards particularly inappropriate. The subcategory *Inappropriate setting and environment* (critical issue) was indeed the most frequently discussed, mentioned also as relevant in referral to other specific categories like *Relapse prevention/symptom management* or *Self-harm/suicide*.

Objectiveness of Risk Assessment and Standardizability of Patient Safety Protocols

The subcategory *Subjective risk assessment or unpredictable behaviours* (critical issue) is seen as another peculiar challenge that HPs have to face in dealing with mental illness. Risk assessment of a surgery procedure can be mostly standardized, as it relies on the analysis of objective parameters like cardiac status, type of operation, and level of urgency^{42,43}.

Further, the risk of errors in the administration of drugs has been widely reduced in the last few decades with the introduction of some standardized strategies (e.g., double check, guidelines to deal with Look Alike, Sound Alike drugs, the implementation of strategies to reduce interruptions) that have been also mentioned by our participants when commenting the category *Therapeutic error*. Unfortunately, this approach cannot be fully transferred to the psychiatric setting, especially when decision-making affects the risk assessment of patients' behaviors. For instance, deciding if a patient can leave the in-patient ward for a walk alone or if she/he can receive visits from friends or parents are therapeutic decisions strictly related to the process of care and in some cases also very relevant for patient safety. Obviously, some objective parameters and clinical protocols guide clinicians' decisions in these circumstances⁴⁴ but, considering that part of these measures are based on HPs' observation, it is implicitly accepted that they are partially affected by the subjective perspective of the observer. Blumenthal and colleagues⁴⁵ investigated the relative impact of actuarial and emotive information on mental health professionals' rating of the risk of violence. In this paper, actuarial risk assessment was based on records, measures, and historical information (e.g., criminal history, family history), while the emotion-based assessment was considered as driven by emotionally laden information (e.g., empathy, insight). The Authors showed that emotive information had a greater impact on risk assessment compared to actuarial information. Thus, these findings call into question the reliability and applicability of safety protocols and guidelines, one of the core tools in safety culture. The issue of subjectivity in risk evaluation has significant implications for the implementation of the so-called "Just Culture"⁴⁶⁻⁴⁸ in patient safety. This approach aims to find a balance between the strictly non-punitive safety culture, that followed and mitigated the previous tendency to blame individuals involved in medical error, and HPs' accountability and responsibility⁴⁸. According to our results, "drawing the line between blameless and blameworthy actions", thus defining HPs' objective responsibility in adverse events¹², seems to be more problematic and challenging than in other settings.

Impact of Risk Management on the Process of Care and Patient Empowerment

“... *They would like to go out at all hours; they would like to have coffee every time they want it and they would like to do all the other things they can't, due to the limitations. It is difficult to create a collaborative relationship. How can you tell them: You can't go out. They don't understand why.*” Many verbal contributions in the subcategory *Impact of risk-management on the process of care/empowerment/autonomy* (critical issue) similarly addressed HPs' dilemma in finding the right balance between protecting and empowering the patient. Promoting autonomy and at the same time protecting from risk, is another challenge of the therapeutic relationship in psychiatry, which strongly affects the effectiveness of the intervention. Ethical issues may derive from the necessity to balance patients' autonomy and safety by limiting patients' choices. Taking care of mentally ill patients, especially in the acute phases of their disease, implies taking decisions that interfere and limit their freedom and autonomy, contravening the core principle of empowerment, as also admitted by HPs during the focus groups (categories *Compulsory Treatment* and *Physical/ Chemical restraints*).

This balancing act is acknowledged by the theory of *Protective Empowerment*²¹, which states that the therapeutic relationship, relying on HP's sensitivity and openness to the interplay between protective and empowering actions, is the basis for fulfilling the simultaneous responsibility for ensuring patient safety and autonomy. Protection is therefore defined as a set of actions, such as reassurance, valuing patients' needs and expectations or providing information aimed to help the subject to better meet her/his individual needs, including the need to be protected from risk.

Following this theory²¹ and based on our results, therapeutic interventions in risk management can be defined on two axes (see Figure 2): Restriction vs. Freedom and Safety vs. Risk.

A “defensive” approach where HPs' priority is to control and reduce all sources of potential risk for patients - and consequently for themselves (e.g., adverse events, lawsuit) - may lead to the development of an overprotective attitude towards patients (*Overprotective Disempowerment*). In this approach, active involvement and personal freedom are sacrificable, independently from the real level of risk patients might be exposed to. As shown on the opposite quadrant of Figure 2, excessive freedom in conditions of high risk leads to a misinterpretation of the concept of empowerment and exposes patients to

potentially harmful or dangerous conditions (*Unprotective Disempowerment*). What determines the inappropriateness of HPs' interventions in these two attitudes is, as indicated in the figure, a low or absent connection with the patient. This is another meaningful result that emerged from the analysis of our focus groups: the connection, which refers to the doctor-patient relationship, is the principal assessment and therapeutic tool of clinicians. *Therapeutic compliance* is the category with the highest number of comments and *Building a therapeutic trust/alliance* is, in the subcategory *strategies*, the one most frequently discussed. Connecting with patients provides the clinicians a better estimation of the emotional and cognitive internal world of the patient and consequently reduces the subjectivity in the assessment of risk. An *Empowering connection* and a *Protective connection* are the expression of a real encounter between two persons. Thus, even though they determine very different set of actions, both can be considered appropriate according to the given context. The other strategies, following *Building therapeutic trust/alliance* in terms of frequency, similarly highlight the importance of tuning with patients, by acknowledging their contribution (*Relying on the experience knowledge of patients*), promoting their medical literacy (*providing information educate*), and the centrality of their personal world (*promoting collaboration with family and individualized healthcare plane*). Most of these strategies are indicated by the above-mentioned theory of *Protective Empowerment*²¹ as key elements in the process of balancing patient safety with patients' freedom of choice in mental health.

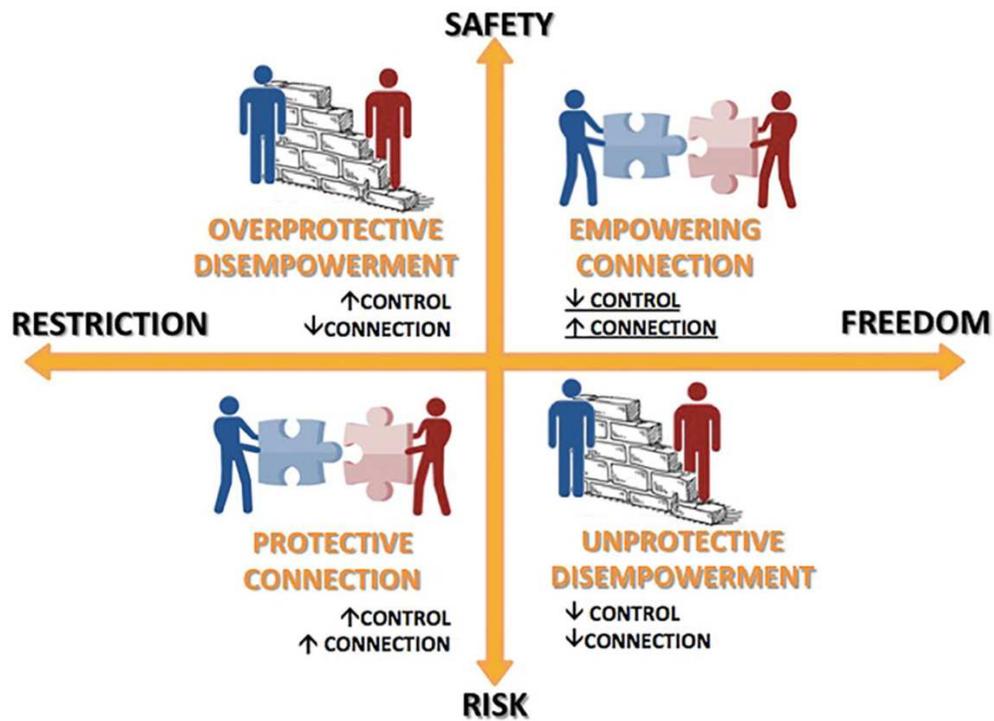


Figure 2. Healthcare providers' control and emotional connection as mediators of patients' empowerment in risk management

Limitations

Despite our promising results, there are some limitations that need to be considered in the interpretation of our findings.

First of all, our convenience sample was recruited in the same Mental Health Department. Even if the organization of in- and out-patient services is representative of the Italian services, some organizational and contextual elements, related to the Department, may have affected the discussed topics and therefore limited the generalizability of the results. Moreover, the sample was mainly composed of nurses. Therefore, the discussions during the focus groups may have been affected by their specific perspective. For instance, the thematic area *Diagnostic and Assessment* was poorly discussed, probably because nurses are not primarily involved in these tasks. Although a higher number of doctors in the focus groups may have increased the generalizability of our results and probably deepened the exploration of certain areas, investigating the perspective of the healthcare providers (i.e.,

nurses) who usually spend a lot of time with patients, has, in our opinion, fostered the robustness of our findings.

The high number of facilitators' interventions might represent another potential limitation, which may lead to questioning their neutrality. However, from the text analysis of their contributions, many of their interventions aimed to refocus participants to the topics of the discussion. Indeed, in several cases, HPs tended to shift from the concept of patients' involvement in their own safety to more general considerations about patients' empowerment in the process of care. This was probably due to the fact that, as above stated, in psychiatry, these two aspects are strongly related and therefore jointly represented in the opinions of participants.

It has also to be taken into account that our results might be seen as unspecific and simply intuitive but up to now, to the best of our knowledge, no previous studies addressed psychiatric patient empowerment in their own safety. Therefore, our results represent a primary summary of the current evidence, which could then be used as background for future quantitative projects assessing for instance the extent of psychiatric patients' involvement in risk management.

Further, we have to consider the impact of translating our findings from Italian to English. Thus, to reduce the potential loss of meaning and to avoid limitations in the analysis of data, we stayed in Italian (i.e., the original language) as long as possible, as suggested by Van Nes et al.⁴⁹. Since all participants, facilitators, and researchers spoke Italian, no language differences hindered the collection of data, the transcription of the focus group discussions, and the development of the coding system. Only in the last phase, preparing the manuscript, one of the authors, fluent in both languages, translated participants' quotes and the labels of the coding system from Italian to English.

Implications for Research, Policy, and Clinical Practice

The results of our study have several implications for the quality of mental health services and for the direction of future research in risk management.

The most meaningful implication for direct clinical practice and policy makers is the acknowledgement of the key role played by single HPs in the process of risk assessment, adverse event prevention and, more generally, in promoting patient safety in the

empowering relationship with the patient. Safety protocols and guidelines can be correctly applied in a therapeutic relationship, only if HPs are sufficiently supported in their daily practice. To reach this goal, several actions have been suggested by the participants of the study, such as improving the quality of mental health services' environment or increasing HPs' training and supervision. Regarding this last aspect, our results may be considered as reference point in the implementation of educational programs aiming to 1) raise HPs' awareness of the synergic but also potentially controversial interconnection between empowerment and safety in mental health, and 2) increase the application of patient-centered skills enabling the development of a protective/empowering connection with patients during the process of care and risk management.

Finally, considering that patients' empowerment is an action requiring the joint collaboration of the two involved parties, patients and HPs, our results have also implications for future research. In particular, the application of our coding system in studies, in which psychiatric patients will be engaged in focus groups discussions on this topic, will permit to evaluate if the strategies and critical issues outlined by HPs are similarly perceived by patients.

Conclusion

In conclusion, safety, although recognized as a crucial element, should not undermine other values or become the singular purpose of psychiatric care. *Empowering* and *protective connection* are the two dimensions, in which the process of care and risk management find a mutually beneficial integration. Our results confirm that not just healthcare providers but also patients are supposed to play a key role in enhancing safety. Further studies, actively involving psychiatric patients and even their caregivers as participants, are necessary to fully address the needs of this vulnerable category of patients.

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Abbreviations

HP: Healthcare provider; MHD: Mental health department; WHO: World Health Organization

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Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Ethical approval for the present study was obtained by the Ethical Committee of the Verona University Hospital (Protocol n.16160; 31/03/2016).

All recruited participants signed the informed consent form.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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4. Putting the Patient in Patient Safety Investigations: Barriers and Strategies for Involvement

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AW and AS initiated the project. IB and AS performed the literature search. IB and AS jointly drafted the initial manuscript which was then critically revised by AW. All co-authors approved the final manuscript.

ABSTRACT

Objectives: In an adverse event investigation, the patient has the potential to add a unique perspective because he or she can identify contributing factors that providers may miss. However, patients are rarely included in patient safety investigations. We aimed to identify the barriers to patient involvement in patient safety investigations and propose strategies to overcome them.

Methods: We reviewed literature on active participation by patients in safety investigations to construct a framework for healthcare institutions to use in approaching patients about a potential role in investigating an error in their care. We searched three electronic databases (Pubmed, PSNet, Web of Science) for the years 1990-2018, without restrictions to language. Search terms included: “patient empowerment”, “patient involvement”, “patient participation”, “patient safety investigation”, “root cause analysis”, “error analysis”. We also examined reference lists of relevant studies to identify additional articles.

Results: Our electronic search produced 10,624 records with 30 potentially eligible articles. However, we identified only six relevant published papers. We used these as the basis for a proposed framework which is predicated on the thoughtful disclosure of adverse events and has three main levels (i.e., patient, clinician, and institutional level). For each level we identify barriers to patient participation and potential strategies to overcome them.

Conclusions: The proposed framework can be used as a starting point to promote patient involvement in error investigations. Involving patients in patient safety investigations could increase patient-centeredness, patient autonomy and transparency, and make analyses more effective by adding unique and potentially actionable information.

Keywords: Incident reporting and analysis; patient-centered care; adverse events; patient involvement; patient participation; patient empowerment; transparency

INTRODUCTION

Medical errors are common, with one in five Americans reporting on a recent survey that they have experienced a medical error in their own care¹. In nearly two decades since the publication of *To Err is Human*, tools have been developed to improve patient safety². There are efforts to improve transparency around patient safety between clinicians and patients, among clinicians and healthcare organizations, and with the public³. Standardized methods for investigating events have been adopted widely, but their application does not consistently lead to error reduction^{4,6}, perhaps because the methods have a narrow focus. It is often wrongly assumed that adverse events are due to easily identifiable causes, rather than to a complex interaction of factors⁶. Further, the recommended corrective actions are often too weak, too focused on individual behaviors (e.g., introduction/improvement of checklists, cognitive aids, warnings, labels) rather than systems (e.g., culture change, equipment/environment (re-)design)⁵⁻⁷. It has been suggested that new approaches encompassing the entire work environment are necessary to implement real change⁷.

One promising way to improve the effectiveness of patient safety investigations might be to include the patient perspective, consistent with the maxim “Nothing about me without me” (p.631)⁸. Given the central position of patients in the process of healthcare, it is evident that there are some things that they know best, such as their own motivation, attitudes and behavior. However, in some cases, such as for pediatric patients or for patients with cognitive impairments, family caregivers may have more insight into what caused an adverse event than the patient⁹. A few studies have shown that patients and also their family caregivers are able to correctly recognize and report adverse events during or after hospitalization and identify unsafe conditions that healthcare providers may miss¹⁰⁻¹². For instance, Weingart et al.¹² demonstrated that numerous patient-reported safety incidents had not been tracked by the hospital. In a study by Zhu et al.¹¹, patients offered additional information regarding the sequelae of the incidents, thus influencing to a small degree reviewers’ categorization of serious adverse events. It is clear that this applies only to specific types of adverse events. For instance, the classic error of retained foreign bodies in surgery cannot be identified by patients themselves.

Depending on patients' ability and on existing laws and policies, there are different ways in which patients and also their caregivers may provide their individual perspective, such as in meetings designed for event discussion and action planning, in one-on-one interviews, or in the form of an opening statement in the beginning of the incident investigation^{13,14}. If the patient and/or the caregivers are unable or unwilling to participate in the incident investigation, other persons might be included instead, such as patient advocates or representatives of the organization's patient and family advisory council, or "proxy patients", who experienced a similar incident^{13,14}.

Despite growing prominence of the patient viewpoint in healthcare and safety^{15,16}, the current practice approaches patient involvement in error investigation with trepidation. Indeed, there are few evidence-based recommendations on how to actually involve patients in investigations⁶. In addition, some would worry that involving patients in investigations could increase exposure to liability claims¹³. We aimed to identify barriers to patient involvement in investigations and to propose strategies to overcome them.

METHODS

We reviewed the literature on patients' active participation in safety investigations in order to construct a framework for healthcare institutions to approach patients about a potential role in investigating an error made in their own care. We searched three electronic databases (Pubmed, PSNet, Web of Science), for the years 1990-2018, without restrictions to language. Search terms included: "patient empowerment", "patient involvement", "patient participation", "patient safety investigation", "root cause analysis", "error analysis". We also examined reference lists of relevant studies to identify additional articles.

We used the identified studies as the basis for a framework for approaching patients and family caregivers about a potential role in investigating an error in their own care. To construct the framework, we examined the current theories and research findings, identified the critical variables discussed in the retrieved studies, and reflected on their relationships^{17,18}. We modified a flowchart described in a previous study¹⁹ outlining steps in the process of adverse event disclosure.

RESULTS

Our electronic search produced 10,624 records with 30 potentially eligible articles. However, we identified only six relevant papers^{10, 13, 14, 20-22}. Notably, Iedema and Allen²⁰, presenting a case, stressed the importance of beginning with incident disclosure and of a "shared dialogue" giving patients and caregivers the chance to provide their point of view. They suggested seven principles to guide the disclosure process and the incident investigation. Another case report¹⁰ demonstrated that patient's perspective adds to incident reporting by complementing provider point of view. Based on conference discussions and on interviews with patients, caregivers, and healthcare professionals, Etchgeray et al.¹³ highlighted the need for disclosure and increased involvement of patients in error investigations. Kok et al.²¹ reached similar conclusions examining strategies and challenges associated with patients' and caregivers' involvement in error analyses in Dutch hospitals. Zimmerman and Amori¹⁴ discussed the psychological and legal implications of including patients in investigations and provided an algorithm to guide the decision process of involving patients. By incorporating the patient's perspective in root cause analysis (RCA) for adverse drug events, Gertler et al.²² demonstrated the unique insight patients can offer.

Informed by these six papers^{10,13,14,20-22} and predicated on the thoughtful disclosure of adverse events¹⁹, the proposed framework outlines barriers at three different levels (i.e., patient, clinician, institutional level) which must be overcome by applying specific strategies to include patients in investigations (see Figure 1).

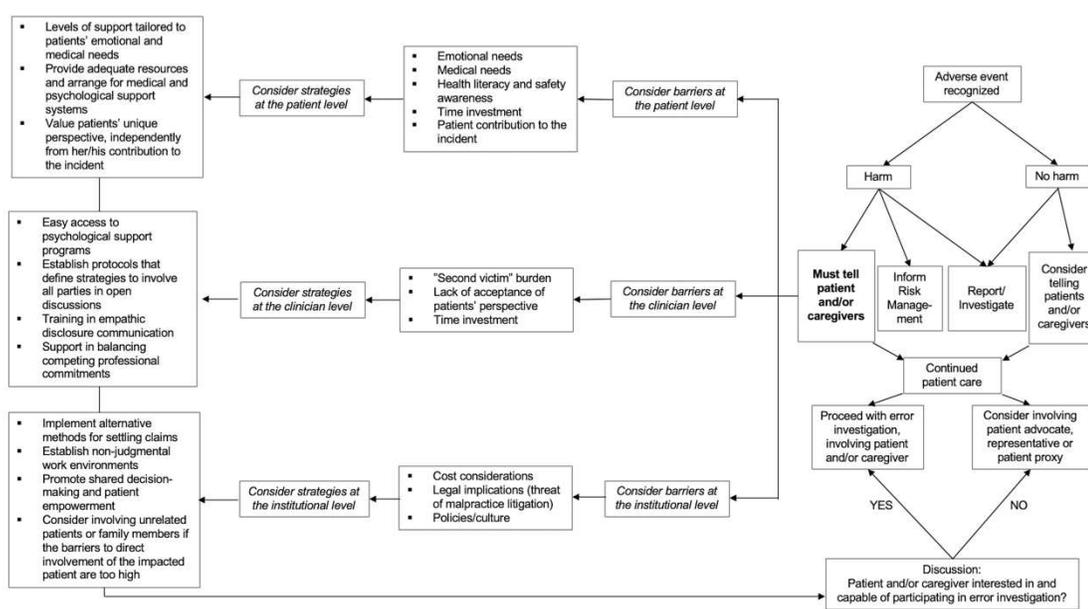


Figure 1. Conceptual framework for approaching the discussion with patients regarding their role in error investigation, predicated on the thoughtful disclosure of adverse events¹⁹

Note. Part of this figure contains a previously published illustration. Reprinted from Bluebond-Langner R, Rodriguez ED, Wu AW. Discussing adverse outcomes with patients and families. *Oral Maxillofac Surg Clin North Am.* 2010;22:471-479, with permission from Elsevier.

DISCUSSION

Adverse Event Disclosure

Although most healthcare organizations have policies in place requiring disclosure, hospitals sometimes fail to communicate adequately with patients after an event, and may even try to cover up²³. Barriers to disclosure include clinicians' feelings of shame and fear of the consequences, lack of institutional support, and worries related to patients' reactions, including fear of litigation²⁴⁻²⁶. However, it has been demonstrated that disclosure is generally appreciated by patients and their families who, once properly informed, are less likely to take legal actions against the respective institution²⁷⁻²⁹. It is recommended, if the patient was harmed, to disclose the event comprehensively, to deliver an apology, if indicated, and to offer prompt compensation^{20, 26}, prior to broaching the topic of incident investigation. However, it has to be considered that it might be more challenging to involve the patient if the adverse event was due to medical negligence or if the patient suffered injuries¹³.

Barriers and Strategies at the Patient Level

Emotional Needs

Since medical errors are emotionally challenging for patients and their families and often impair trust the patient had in the doctor or in the healthcare system in general^{13, 14}, it is important to delineate ways to adequately address patients' feelings (e.g., anger, frustration)²⁰. Patients require sufficient time to emotionally process the disclosure before participating in the investigation²⁰. It is recommended that hospitals offer psychological support where, in a safe space, patients are given sufficient attention and their reactions are met with empathy and respect²⁰.

Patients may be comforted when family members are involved in their care, and this may also apply to involvement in an investigation. This could make it easier for the patient to participate and offer the additional perspective of a family member. A well-conducted, thoughtful incident investigation may facilitate healing by helping patients and their caregivers in sharing and processing their emotions and by reestablishing trust towards healthcare providers^{13, 14, 21}. However, as Zimmerman et al.¹⁴ and Etchegaray et al.¹³ have pointed out, this does not apply to all patients and their families. For some, being included in incident investigations may have a negative emotional impact. By discussing the medical error in all its details, feelings of grief and vulnerability and fear of future error could increase^{13, 14}. Thus, it is critical to look carefully at every patient and her/his individual circumstances before involving her/him in the investigation. If the emotional impact on the patient and the family is too strong, a patient advocate, representative, or proxy patient may be involved instead.

Medical Needs

Many harmful errors directly increase patients' medical needs, which may impede their participation in error analyses given the need for a timely investigation. Even if an adverse event itself does not have direct medical consequences, patients may also have debilitating conditions impeding their involvement. Thus, healthcare providers' and their organizations' first obligation is to ensure that patients' medical needs are accommodated prior to the incident investigation. Furthermore, patients with progressive diseases or

cognitive deficits may not be able to participate at all even if they would like to. In such cases, family caregivers, a patient representative, or a proxy patient may substitute the patient.

Health Literacy and Safety Awareness

Patients' health literacy and understanding of patient safety can influence their willingness to participate in error investigations. For instance, patients with low health literacy levels may shy away from group discussions fearing that they cannot provide substantial information¹⁴. Overall, patients better informed about their medical conditions and with greater safety awareness might be more willing to participate in and voice concerns during safety investigations. Care should be taken that direct patient involvement does not create an undue burden on patients or decrease providers' and institutions' responsibility to carefully investigate the adverse event.

Discussions with patients should address potential burdens and misconceptions and determine the role patients would like to play (e.g., sharing their perspective in one-on-one interviews, attending RCA meetings investigating their own or a similar event)¹³. Providers should emphasize that all patients, regardless of health literacy level, can play an important part in the error analysis¹⁴.

Time Investment

Involving patients in investigations, while potentially leading to increased recognition and correction of root causes of errors, requires a time commitment. Error investigations can last days, or even months and the duration can be difficult to predict. As consequence, patients may drop out. Scheduling the time commitment required from patients, together with flexibility on the part of the hospitals and risk management teams. may help to overcome this issue.

Patient Contribution to the Incident

Patients who contributed to the occurrence of an error through their own behavior (e.g., non-adherence with instructions) may provide great insight into the type and nature of the error and ways to prevent its reoccurrence²². However, in such cases patients may feel

guilty or blamed for the error and may be reticent. Therefore, it is important to present a blame-free climate that extends to the patient. Investigations need to focus on identifying gaps in the system rather than assigning blame to the people involved in the incident. Investigators should value patient's perspective independently from his/her contribution to the incident.

Barriers and Strategies at the Clinician Level

“Second Victim” Burden

Clinicians directly or indirectly involved in adverse events can become the so-called “second victims”, a term introduced by Wu in 2000³⁰ which recently has been controversially discussed³¹⁻³⁴. These healthcare providers are likely to experience emotional distress³⁵, which may prevent them from participating fully in the investigation or supporting their patients through this process. If they do participate, interactions with the patient may be colored by inner turmoil and fear of consequences.

As a partial solution, clinicians should have easy access to support programs tailored to their needs. Further, educational programs should be implemented to raise awareness among providers about patient safety, stresses faced by providers, and the second victim phenomenon.

Lack of Acceptance of Patients’ Perspective

Clinicians may be hesitant to talk openly about the adverse event and to share important information in front of the patient¹³ for several reasons. First, they may fear the shift of power to patients³⁶, and consider the patient as a threatening figure²¹ who may learn about provider errors and take legal action even if several studies suggest that by being honest and transparent, healthcare providers are less likely to be sued²⁷⁻²⁹. In addition, healthcare providers may not appreciate the potential value of patients’ perspective²¹. Finally, they may fear a negative impact on patients’ physical and mental health (e.g., upsetting the patient and intensifying the grieving process)^{13,14}.

Protocols should be set up that establish expectations and define strategies to involve all parties in open discussion. Clinicians may need to be coached on communication skills.

Strategies for articulating empathy could help to elicit the patient's perspective during error analyses²⁶. However, training healthcare providers in empathic disclosure communication may enable them to receive 'cheap grace'³⁷. Such 'cheap grace' may result from healthcare providers' expertise in making their empathy towards the patient and the family caregivers come across as genuine interest while in fact it serves the organizational aim of inviting the patient to feel cared for and therefore more inclined to collaborate with the healthcare organization and its staff than she/he otherwise might. It is important that healthcare providers are aware of this potential pitfall. They should not consider these protocols as a way to mitigate the patient's concerns about the care received but to enable the patient to more freely express such concerns which should be taken as seriously as the perspectives of other involved parties (e.g., healthcare providers, management). While such a mindful approach cannot prevent the risk that patients experience harm as a result of incomplete, inadequate and unsatisfactory incident discussions²⁰, it may at least reduce it.

Time Investment

Similar to patients, clinicians may also have time commitment barriers. The disclosure discussion is usually conducted by the provider responsible for the patient's care. Patients generally expect to hear from this individual – if he or she cannot commit time to meet patient's needs, the patient is less likely to participate or have a positive experience. Policies should be clarified at the institutional level to place a high priority on having clinicians engage in this discussion, which may help to remove this obstacle.

Barriers and Strategies at the Institutional Level

Cost Considerations

Involving patients in error analysis and providing appropriate medical and mental health support is likely to have costs. Support staff may need to be designated and compensation may be needed to offset the time and effort spent by clinicians and patients to participate in these additional duties¹⁴. The argument to provide funds for such programs might be challenging since the evidence base for including patients in investigations has not been

established. Empirical studies on the potential positive impact of patient involvement in investigations are needed.

Legal Implications

Another significant barrier to patient involvement is the fear of liability. Potential negative consequences to the health care organization include settlements or awards, related claim costs, and also critical attention from media.

In most cases, fear of these risks is exaggerated, since the incidence of litigation is generally low. In a classic study of over 30,000 patients, only 2% of those with adverse events due to medical negligence filed a malpractice claim³⁸. However, it should be noted that rates of patients' legal complaints may differ from one culture to another. For example, patients from collectivistic, nonconfrontational cultures may file fewer malpractice claims than patients from individualistic cultures³⁹. Further, several studies suggest that patients are actually less likely to sue when adverse events are addressed promptly and transparently²⁷⁻²⁹. Evidence on a variety of alternative methods for settling claims suggests communication-and-resolution programs, "judge-directed negotiation programs" and other proactive methods that can prevent court involvement or expedite and save costs on claims that do reach the court system²⁶.

Policies and Culture

The extent of patient involvement will be defined by specific institutional policies and operating procedures. Reporting requirements, definitions of incidents and medical errors, components of RCA, and the actual application of safety-related processes, such as RCA and incident reporting, vary among healthcare institutions and professional groups^{4,40}. For example, some organizations conduct RCA for sentinel events only and merely discuss near misses⁴. It is evident that there are no clear policies promoting patient participation in the error analysis. Further, there are only few studies exploring current practices of such an involvement. For instance, Kok et al.²¹ showed that in Dutch hospitals patients or their caregivers are usually only invited to participate in one-time interviews.

Aside from the type of involvement, healthcare institutions should ensure that both patients and healthcare providers receive the appropriate psychological and organizational

support throughout the entire investigation process. Reassurance about non-judgmental work environments and raising the awareness of shared decision-making and patient empowerment are crucial elements to consider in the development of such policies. Patient empowerment, one of the key principles of patient-centered care^{41,42}, is particularly important in this regard. Indeed, patients who feel empowered and thus more autonomous might be more confident to speak up when they encounter errors and to get involved in incident investigations.

Finally, if the direct involvement of the impacted patient and her/his family comes with too many challenges, institutions may consider an alternative approach, which has been discussed by several authors^{13,14}. This approach involves unrelated patients or family members who are, for example, members of patient and family advisory councils. While not directly affected by the investigated event, they may nevertheless add critical perspectives, observations, and opinions.

CONCLUSIONS

Patient safety investigations are crucial in identifying, analyzing, and preventing medical errors. We believe that involving patients and family caregivers in investigations is a natural next step based on trends of increasing patient autonomy in healthcare and growing emphasis on transparency. Aiming to further promote this culture, we proposed a framework outlining specific paths to disclose the error, identify the barriers to involving patients and their caregivers, and apply strategies to overcome them. It can be used as starting point to promote patient involvement in error analyses. Involving patients and their caregivers in investigations would increase patient-centeredness, patient autonomy and transparency, and could make analyses more effective by adding unique and potentially actionable information. Future studies should test the feasibility and effectiveness of the suggested model, which could be then further improved and adapted to different settings.

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The Authors declare that there is no conflict of interest.

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Informed consent: For this type of study formal consent is not required.

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Data Availability Statement:

Our manuscript has no associated data.

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5. Psychological and Psychosomatic Symptoms of Second Victims of Adverse Events: a Systematic Review and Meta-Analysis

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This chapter contains *supplemental data files* which can be found in Appendix C.

¹ Acknowledgment of author contributions:

All authors jointly designed the study. IB, FM, and MR were involved in the search and selection process, the quality assessment, the data extraction and synthesis. MP and CB contributed with their expertise in the methodology of systematic reviews and meta-analysis and performed the statistical analyses. IB and MR drafted the initial manuscript, which was then critically revised by AW and approved by all co-authors.

ABSTRACT

Objectives: Despite growing interest in the second victim phenomenon and greater awareness of its consequences, there has not been a meta-analysis quantifying the negative impact of adverse events on providers involved in adverse events. This study systematically reviewed the types and prevalence of psychological and psychosomatic symptoms among second victims.

Methods: We conducted a systematic review of nine electronic databases up to February 2017, without restrictions to publication date or language, examining also additional sources (e.g., grey literature, volumes of journals). Two reviewers performed the search, selection process, quality assessment, data extraction, and synthesis. We resolved disagreements by consensus and/or involving a third reviewer. Quantitative studies on the prevalence of psychological and psychosomatic symptoms of second victims were eligible for inclusion. We used random effects modeling to calculate the overall prevalence rates and the I^2 statistic.

Results: Of 7,210 records retrieved, 98 potentially relevant studies were identified. Full-text evaluation led to a final selection of 18 studies, based on the reports of 11,649 healthcare providers involved in adverse events. The most prevalent symptoms were troubling memories (81%, 95%CI 46-95), anxiety/concern (76%, 95%CI 33-95), anger toward themselves (75%,95%CI 59-86), regret/remorse (72%,95%CI 62-81), distress (70%, 95%CI 60-79), fear of future errors (56%, 95%CI 34-75), embarrassment (52%, 95%CI 31-72), guilt (51%, 95%CI 41-62), and sleeping difficulties (35%, 95%CI 22-51).

Conclusions: Second victims report a high prevalence and wide range of psychological symptoms. More than two-thirds of providers reported troubling memories, anxiety, anger, remorse, and distress. Preventive and therapeutic programs should aim to decrease second victims' emotional distress.

Keywords: Human factors, second victim; mental health, adverse event; risk management

INTRODUCTION

Recent decades have been characterized by improvements and innovations in medicine as well as the progressively increasing use of health information technology and specialization and subspecialization of healthcare providers¹⁻³. Due in part to the rise of technology and fragmentation of care, the human aspects of clinical practice are undervalued for both patients and providers. While patients' emotions and individual needs as human beings have long been underappreciated^{4,5}, healthcare providers now face unprecedented time pressures and performance accountability in highly complex environments^{6,7}.

There is a high expectation of perfection in medicine, and medical errors are often viewed as a personal failure of the healthcare providers involved^{7,8}. However, research has shown that unsafe acts are rarely isolated from their system context⁹. Usually, it is a cluster of active failures and latent systemic conditions that causes a patient safety incident (i.e., adverse events harming or potentially harming a patient)¹⁰, as illustrated in Reason's *Swiss Cheese Model*⁹.

Although patient safety incidents are common (i.e., between 4% and 17% of hospital admissions are linked to adverse events)¹¹, they are still stigmatized, with a strong negative impact for physicians^{12,13}. Historically, it has been overlooked that adverse events affect not only the patient as *first victim* but also are also highly stressful for the involved providers, thus commonly considered as *second victims*⁸. Although there has been recent controversy over use of the term *second victim*, an alternative, more appropriate term has not been established^{14,15}. Second victims often feel responsible for the adverse event and may doubt their professional skills and knowledge¹⁶, suffer from psychological and psychosomatic symptoms, and may consider career changes¹⁷, take sick leave¹⁸, transition to a different department¹⁹, or even leave their profession after²⁰. Quillivan et al.²¹ pointed out that the second-victim experience may incite a vicious cycle, leading to further medical errors and affecting patient safety.

There has been growing interest in the second-victim phenomenon¹⁹, with more research on the topic, greater awareness of its negative impact on healthcare^{15,22} and successful implementation of psychosocial support programs especially in the United States (e.g., *RISE – Resilience in Stressful Events*, Johns Hopkins Hospital, Maryland, USA²³; *forYou*,

University of Missouri Health Care, Columbia, Missouri, USA²⁴; *Medically Induced Trauma Support Services*, Chestnut Hill, Massachusetts, USA²⁵). To gain further knowledge about second victims and to reduce the punitive culture still existing in many countries²⁶, several systematic reviews have been conducted^{27–29}. However, there has not been a meta-analysis quantifying the psychological impact of adverse events on second victims. To fill this gap, we aimed to provide a comprehensive synthesis and critical analysis of second victims' emotional distress.

METHODS

The protocol of the study is registered in the *International Prospective Register of Systematic Reviews (PROSPERO)*, Registration Number CRD42016053239.

Search and Selection Process

A systematic search of nine electronic databases (i.e., PubMed, Cochrane Library, Web of Science, Scopus, PsycINFO, EMBASE, ScienceDirect, MEDLINE, CINAHL) was conducted up to February 2017, without restrictions to publication date and language, using the following search strategy: (medical error OR patient safety incident OR adverse event OR near miss OR human error) AND (health personnel OR second victim OR health professional OR health care provider) AND (psychological impact OR experienc* OR psychological response OR psychological symptom OR feeling OR emotion* OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building). A detailed record of the applied search strategy for each database is provided in supplemental data file 1.

To identify additional studies, we screened databases of gray literature (e.g., PsycEXTRA), volumes of journals, reference lists of books, book chapters, systematic reviews, and white papers (see supplemental data file 2 for a comprehensive overview of the additional searches). Furthermore, to detect newly published, potentially eligible articles, automatic, weekly e-mailed search alerts were set up for the databases Web of Science and PubMed for the time period 02/12/2012 – 04/15/2018.

Studies were eligible for inclusion if (a) the participants were healthcare providers involved in adverse events/patient safety incidents (i.e., harmful incidents, near misses, and no-

harm incidents), as defined by the Canadian Patient Safety Institute,¹⁰ and (b) the prevalence of psychological and psychosomatic symptoms in this population was reported. There were no restrictions on age, gender, healthcare profession, and setting (i.e., inpatient or outpatient care).

Editorials, general discussion papers, comments, letters, book chapters, systematic reviews, single case studies, case series, and qualitative studies were excluded since we did not expect original, quantitative findings (i.e., prevalence rates of psychological or psychosomatic symptoms of healthcare providers involved in adverse events) to be reported in these types of articles.

Two independent reviewers (IB and FM) screened titles and abstracts of the records using *Rayyan*, a Systematic Reviews web app³⁰. The full texts of records considered as eligible by at least one of the two reviewers were then independently evaluated. In cases of dissent about the inclusion of the full texts, the appropriateness of the inclusion/exclusion was debated and a third reviewer (MR) was involved. As suggested in the Cochrane Handbook³¹, all the excluded studies and the reasons for exclusion were recorded.

The entire search and selection process has been recorded according to the *Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)* Statement by Moher et al³².

Quality Assessment

The quality of the included studies was assessed by two appraisers (IB and FM), independently and then by consensus, using the *Joanna Briggs Institute Critical Appraisal Checklist for Studies Reporting Prevalence Data*³³, a standardized tool based on nine quality criteria (i.e., appropriate sample frame to address target population, appropriate method of recruitment, adequate sample size, detailed description of study subjects and setting, data analysis with sufficient coverage of the identified sample, use of valid methods to identify the condition, measurement of condition in a standard and reliable way, appropriate statistical analysis, adequate response rate/appropriate management of low response rate) that can be scored as *yes* (i.e., met criterion), *no* (i.e., unmet criterion), *unclear*, and *not applicable*. Disagreements were discussed and resolved, involving a third appraiser (MR) to adjudicate.

Outcome Measure

The primary outcome measure was the prevalence of psychological (i.e., at the emotional and cognitive level, such as guilt and difficulty concentrating) and psychosomatic symptoms (e.g., sleep disturbance) among healthcare providers involved in an adverse event.

Data Extraction and Synthesis

Two investigators (IB and FM) independently collected study characteristics (e.g., publication year, country, study design, setting, sample size of the participants involved in an adverse event, type of adverse event, patient's outcome) and outcome measures, using a data collection form.

Cases of dissent were discussed and, if necessary, a third investigator (MR) was involved to reach consensus. If missing data were identified, the authors of the primary study were contacted.

Aiming to synthesize the extracted findings, we applied the following rules:

1. If symptoms were expressed only as percentages, without any absolute frequency (required for the applied software *Comprehensive Meta-Analysis V* [Biostat Inc, Englewood, NJ]), we calculated frequency by converting the percentage to a decimal and then by multiplying the decimal by the sample size. If then the calculated absolute frequency included decimals, we rounded it according to standard rules.
2. To calculate the overall prevalence of psychological and psychosomatic symptoms, we grouped the variables of interest, retrieved from the primary studies, that corresponded in terms of content and wording. If variables of interest were similar thematically but differed from each other in terms of wording (e.g., *fear of repeating the mistake*³⁴, *anxiety about the potential for future errors*³⁵, *anxious about potential for future errors*³⁶), we considered them as a single group (see supplemental data file 3 for a comprehensive list of all groups of variables of interest included in the meta-analyses).
3. If more than one variable of interest, extracted from the same paper and thus based on the same sample, would have potentially fit into the same group, we selected—aiming to prevent overlap—the variable that was most appropriate in terms of content and wording

(e.g., the variable of interest *anxiety*³⁷ was considered more appropriate than *panic/worries*³⁷ for the group “anxiety”).

Meta-Analyses

Since we expected considerable heterogeneity across studies due to several factors, such as a variety of applied instruments, participants' professions, and medical settings, we used random effects modeling for all analyses. We (MP and CB) calculated the overall prevalence (i.e., average effect size) of psychological and psychosomatic symptoms with 95% confidence interval (CI) by pooling the individual prevalence rates (i.e., individual effect sizes) of at least two primary studies. Regarding the investigation of statistical heterogeneity, we visually assessed forest plots, calculated and interpreted the I^2 statistic as recommended in the Cochrane Handbook³⁸: I^2 estimates might not be important from 0% to 40%, may represent moderate heterogeneity from 30% to 60%, substantial heterogeneity from 50% to 90%, and considerable heterogeneity from 75% to 100%. The meta-analyses were performed using *Comprehensive Meta-Analysis V3* (Biostat Inc, Englewood, NJ).

RESULTS

Selection and Inclusion of Studies

The search of the electronic databases (see supplemental data file 1) and additional sources (i.e., databases of gray literature, volumes of journals, reference lists of books, book chapters, systematic reviews, and white papers) (see supplemental data file 2) initially produced 7,210 records (7,195 and 15 records, respectively). After screening title and/or abstract, 98 full-text articles were assessed for eligibility. We contacted the authors of the primary study in six cases to request additional information. Eighty studies were then excluded for various reasons such as mismatch with the inclusion criteria, mixed population, wrong focus of the study, or insufficient information (see supplemental data file 4 for a comprehensive overview of the excluded studies). Finally, 18 studies, all meeting the inclusion criteria, were included (see Figure 1).

Quality Assessment

All primary studies met more than half of the quality criteria (i.e., between 5 and 8) of the Joanna Briggs Institute Critical Appraisal Checklist for Prevalence Studies³³. All studies used an appropriate sample frame to address the target population, analyzed the data with sufficient coverage of the identified sample, and measured the conditions in a standard, reliable way. However, the adequacy of the sample size and the use of valid methods remained unclear for several studies; others did not recruit the participants appropriately or did not describe the characteristics of the participants and the setting in sufficient detail. In some articles, the statistical analyses were not entirely appropriate (e.g., prevalence rates expressed only by percentages). A detailed overview of appraisers' judgments of each included primary study is given in supplemental data file 5.

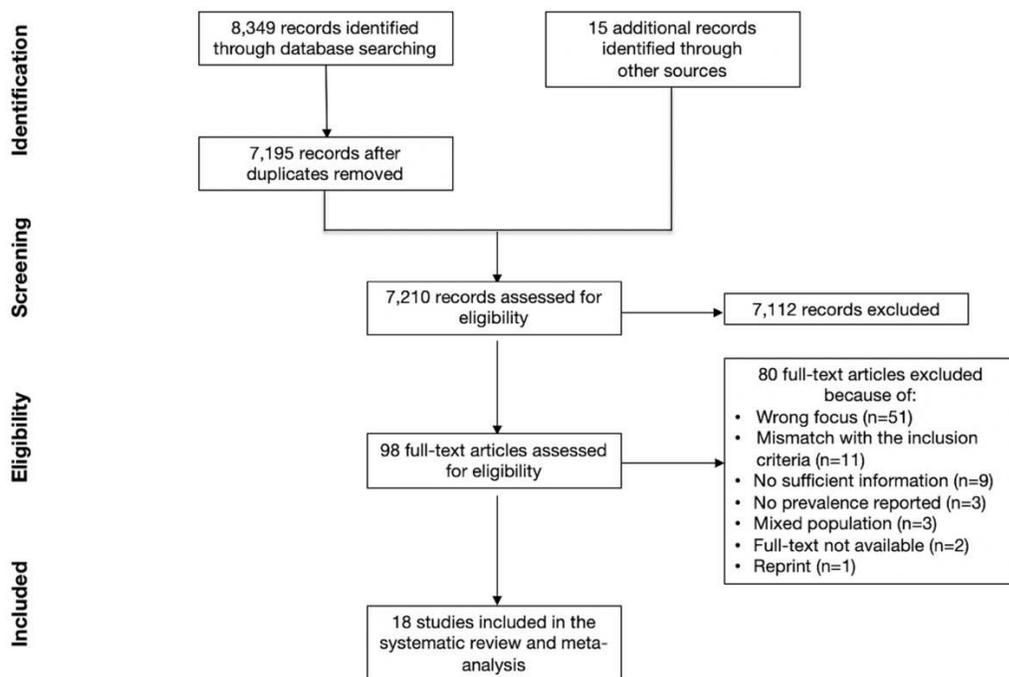


Figure 1. Prisma flow diagram

Characteristics of the Included Studies

The 18 included primary studies (see Table 1)^{18,34–37,39–51}, all written in English except for one in German³⁴, were published between 1991 and 2016. Six were conducted in the USA,

two in the UK, and one study each in Australia, Canada, Greece, Iran, Denmark, Sweden, Germany, Switzerland, and Turkey. One study³⁵ was conducted both in Canada and in the USA. Aside from O'Beirne et al.⁴⁸ who collected patient safety incident records for 3 years, all other studies applied a cross-sectional survey design. Although some authors calculated only descriptive statistics, others additionally applied inferential statistics (e.g., correlational or regression analyses). All authors used paper-and-pencil or web-based/electronic self-report questionnaires with predominantly closed-ended questions.

Table 1. Characteristics of the included studies

Authors	Year	Country	Study design	Setting (Inpatient vs. outpatient)	Participants' profession	Sample size of healthcare providers involved in an adverse event	Point in time of adverse event	Type of adverse event	Categorization of adverse event severity	Patient outcomes
Cebeci et al.	2015	Turkey	Cross-sectional study design applying descriptive and inferential statistics; self-report questionnaire (developed by the research team; not specified if paper-and-pencil or web-based; closed-ended and open-ended questions)	Inpatient care	Nursing students	124	Not specified	Medication errors	Medication Administration Errors by MEDMARX Category [#] : No Error (defined as <i>Circumstances or events that have the capacity to cause error</i>) – Error, no harm – Error, harm	Not specified
Chard	2010	USA	Cross-sectional study design applying descriptive and inferential statistics; paper-and-pencil, self-report 'Perioperative Nurse Questionnaire' (developed by the author;	Inpatient care	Perioperative nurses	158	Most errors occurred more than four years before the time of the study	Intraoperative nursing errors (e.g., unclear about surgical site, break in sterile technique)	Not specified	Not specified

			closed-ended questions)							
Cramer et al.	2012	Germany	Cross-sectional study design applying descriptive and inferential statistics; paper-and-pencil, self-report questionnaire (developed by the research team; closed-ended and open-ended questions)	Inpatient care	Nurses, nursing auxiliaries (also in pediatric and geriatric care) working in different hospitals and nursing homes	1,100	Not specified	Nursing errors (not further specified)	Not specified	Not specified
Dhillon et al.	2015	USA	Cross-sectional study design applying descriptive and inferential statistics; web-based, self-report questionnaire (developed by the research team; closed-ended and open-ended questions)	Not specified	Anesthesiologists (members of the American Society of Anesthesiologists)	245	Not specified	Perioperative errors (e.g., drug error)	Not specified	e.g., death, anaphylaxis, anoxic brain injury, massive hemorrhage, venous air embolism
Harrison et al.	2014	UK	Cross-sectional study design applying descriptive statistics;	Not specified	Physicians in internal medicine (members and fellows of the	1,463	At any point in the entire career	Not specified	Adverse event with serious patient harm – adverse event with minor patient harm – near miss with potential for serious	Not specified

			web-based, self-report questionnaire (modified version of the questionnaire used by Waterman et al.; closed-ended questions)		Royal College of Physicians)				patient harm – near miss with potential for minor patient harm – none of these	
Hobgood et al.	2005	USA	Cross-sectional study design, applying descriptive and inferential statistics; paper-and-pencil, self-report questionnaire (developed by the research team; closed-ended and open-ended questions)	Inpatient care	Emergency medicine residents	40	Not specified	Medication errors, diagnostic errors, evaluation and treatment errors, procedural errors, communication errors	Not specified	Death, clinical deterioration, severe disability, physical discomfort, emotional distress, need for additional therapy, monitoring and procedures, increased length of stay
Joesten et al.	2015	USA	Cross-sectional study design applying descriptive statistics; web-based, modified version of the self-report 'Medically Induced Trauma Support Services Staff Support Survey' (closed-ended questions)	Inpatient care	Nurses, physicians (Doctors of Medicine, Doctors of Osteopathic Medicine) working in a children and adult community teaching hospital	120	Within the previous three years (between 2008-2010)	Wrong site surgery as only example mentioned	Patient safety event with actual adverse outcome – near miss	e.g., unexpected patient death, transfusion reaction, adverse drug reaction, patient fall, other unanticipated outcomes

Karga et al.	2011	Greece	Cross-sectional study design applying descriptive and inferential statistics; paper-and-pencil, self-report questionnaire (modified version of the questionnaire by Wu et al. 1991 and Meurier et al. 1997, respectively; closed-ended and open-ended questions)	Inpatient care	Nurses working in different hospital departments (e.g., hemodialysis, surgery, intensive care)	536	At any point in the entire career	Medication errors, errors linked to haemodialysis practices, surgical practices, or other tasks (e.g., documentation and blood transfusion)	Perceived error severity (high – medium – low – none)	Patient death, prolonged hospital stay, need for additional therapeutic interventions and monitoring
Leinweber et al.	2017	Australia	Cross-sectional study design applying descriptive and inferential statistics; web-based, self-report questionnaires (inter alia ‘Traumatic Events in Perinatal Care List’, ‘PTSD Symptom Scale Self-Report version’; closed-ended questions)	Inpatient and outpatient care	Midwives (members of Australian College of Midwives)	687	Not specified	Non-interpersonal birth trauma (death and injury of mother and infant), interpersonal birth trauma (abusive care or management, poor care, interpersonal disrespect)	Not specified	e.g., death and injury of mother and infant

McLennan et al.	2015	Switzerland	Cross-sectional study design applying descriptive and inferential statistics; web-based, self-report questionnaire (modified version of questionnaire by Waterman et al. 2007; closed-ended questions)	Inpatient care	Anesthesiologists	281	Not specified	Not specified	Serious error – minor error – near miss	Not specified
Meurier et al.	1997	UK	Cross-sectional study design applying descriptive and inferential statistics; paper-and-pencil, self-report questionnaire (modified version of the questionnaire by Wu et al. 1991; closed-ended and open-ended questions)	Inpatient care	Nurses working on different wards in a district general hospital	129	Not specified	Errors related to communication, assessment, planning, intervention and evaluation	Severe effects – moderate effects – mild effects – no consequences	Severely compromised functioning – moderately compromised functioning – mildly compromised functioning
O’Beirne et al.	2012	Canada	Analysis of two questions from confidential patient safety incident reports collected from September 2007 to August 2010; application of	Outpatient care	Physicians, clinic staff (nurses, office staff, managers) in family medicine	238	Not specified	Adverse events related to documentation, medication, clinical process	Severity of incident (fatal – severe – moderate – mild – none – not sure)	Not specified

			descriptive and inferential statistics							
Schröder et al.	2016	Denmark	Cross-sectional mixed-method study design (i.e., data generated from a national survey and a qualitative interview study) ~ applying descriptive statistics; self-report questionnaire with closed-ended questions & semi-structured interviews (developed by the research team)	Not specified	Obstetricians, midwives (members of the Danish Medical Association and the Danish Association of Midwives)	1,027*	At any point in the entire career	Traumatic childbirth	Not specified	Fatal, permanent, and severe injuries for infant or mother
Shanafelt et al.	2010	USA	Cross-sectional study design, applying descriptive and inferential statistics; electronic, self-report questionnaires (inter alia 'Maslach Burnout Inventory', 'Primary Care Evaluation of Mental Disorders',	Not specified	Surgeons (members of the American College of Surgeons)	700	Within the previous three months	Not specified	Not specified	Not specified

			'Medical Outcomes Study Short Form'; closed-ended questions)							
Taifoori & Valiee	2015	Iran	Cross-sectional study design applying descriptive statistics; paper-and-pencil, self-report questionnaire ('Perioperative Nurse Questionnaire'; closed-ended questions)	Inpatient care	Perioperative nurses	153	Not specified	Perioperative errors (e.g., not following sterile technique, incorrect counts of surgical gauze, incorrect counts of surgical tools, leaving a foreign body in the patient)	Not specified	Not specified
Wahlberg et al.	2016	Sweden	Cross-sectional study design applying descriptive and inferential statistics; web-based, self-report questionnaire (inter alia modified version of the 'Screen Questionnaire Post-traumatic Stress Disorder'; closed-ended questions)	Not specified	Obstetricians, midwives (members of the Swedish Society of Obstetrics and Gynecology and the Swedish Association of Midwives)	1,628	Not specified	Traumatic childbirth (e.g., death or severe injury of the child during delivery, maternal near-miss, maternal mortality, violence, threat)	Not specified	Not specified
Waterman et al.	2007	Canada/ USA	Cross-sectional study design applying	Inpatient and outpatient care	Physicians in internal medicine,	2,909	Not specified	Not specified	Serious error – minor error - near miss	Not specified

			descriptive and inferential statistics; paper-and-pencil or web-based, self-report questionnaire (developed by the research team; closed-ended questions)		surgery, pediatrics, family medicine					
Wu et al.	1991	USA	Cross-sectional study design applying descriptive and inferential statistics; paper-and-pencil, self-report questionnaire (developed by the research team; closed-ended and open-ended questions)	Inpatient care	Internal medicine house officers	114	Within the previous year	Errors in diagnosis, evaluation and treatment, prescribing and dosing, procedural complications, faulty communication	Serious consequences – potentially serious consequences	e.g., death, delayed treatment, stroke, amputation, respiratory failure, small amount of bleeding, fatal tension pneumothorax, resuscitation performed against the patient's wishes

*We used for the meta-analyses slightly varying sample sizes according to the respective variable of interest ($n_1 = 1019$, $n_2 = 1022$, $n_3 = 1024$).

#Categories as defined by the National Coordinating Council for Medication Errors Reporting and Prevention.^{52,53}

~We used for this study only the quantitative data generated from the national questionnaire survey.

Schröder et al.⁴⁹ additionally conducted semi-structured interviews; however, we included only the quantitative data reported by Schröder et al.⁴⁹ in our study. Many authors created also own questionnaires or adapted already existing ones, such as the one developed and validated by Wu et al.⁴⁴ or Waterman et al.³⁵ Well-established clinical questionnaires, such as the *PTSD Symptom Scale Self-Report version*⁵⁴ and the *Primary Care Evaluation of Mental Disorders*⁵⁵, were also used. The selected studies investigated participants with various occupational roles (e.g., nurses, midwives, physicians), working both in inpatient and outpatient care in different medical settings (e.g., surgery, obstetrics, internal medicine). The sample size of the respondents/healthcare providers involved in an adverse event ranged from 40⁴¹ to 2,909³⁵ reaching a total of 11,649 participants. Seven studies provided information about the time of occurrence of the adverse event: some reported a long time frame (e.g., *at any point in the entire career*³⁶), whereas others mentioned a narrow one (e.g., *within the previous 3 months*⁵⁰). The adverse events, though heterogeneous, were mostly related to errors in diagnosis, evaluation, treatment, and communication. Categories describing the severity of the adverse events (e.g., *serious error – minor error – near miss*) were used in nine articles. In addition, eight studies gave examples of patient outcomes, ranging from physical discomfort through prolonged hospital stay to severe disability and death.

Prevalence of Psychological and Psychosomatic Symptoms

Meta-Analyses

We calculated the overall prevalence rates for 21 symptoms experienced by second victims in the aftermath of adverse events (see Table 2). The most prevalent symptoms were troubling memories (81%, 95% CI 46 to 95) (see Figure 2), anxiety/concern (76%, 95% CI 33 to 95), anger toward themselves (75%, 95% CI 59 to 86), regret/remorse (72%, 95% CI 62 to 81), distress (70%, 95% CI 60 to 79), fear of future errors (56%, 95% CI 34 to 75), embarrassment (52%, 95% CI 31 to 72), guilt (51%, 95% CI 41 to 62), and sleeping difficulties (35%, 95% CI 22 to 51), which was the only psychosomatic symptom we were able to pool (see Figure 3). All forest plots can be found in the supplemental data file 6.

I² estimates ranged between 0% and 53.1% indicating negligible to moderate heterogeneity across studies. We did not conduct subgroup analysis given the small amount of data available for this purpose.

Table 2. Overall Prevalence Rates of Second Victims' Psychological and Psychosomatic Symptoms

Symptom	Overall prevalence rate	95 % CI	I ²	Studies (n)
Troubling memories	81%	46 – 95	27.8%	3
Anxiety/concern	76%	33 – 95	46.1%	3
Anger towards oneself	75%	59 – 86	4.8%	5
Regret / Remorse	72%	62 – 81	0%	3
Distress	70%	60 – 79	0 %	2
Fear of future errors	56%	34 – 75	0%	5
Embarrassment	52%	31 – 72	13.6%	4
Guilt	51%	41 – 62	53.1%	12
Frustration	49%	43 – 55	0%	2
Anger	44%	6 – 91	0%	3
Fear	43%	32 – 54	0%	3
Feelings of inadequacy	42%	27 – 59	0%	7
Reduced job satisfaction	41%	36 – 47	52.2%	3
Concern regarding colleagues' reactions	39%	14 – 71	0%	3
Symptoms of depression	36%	20 – 56	48.6%	9
Fears of repercussions / official consequences	36%	21 – 54	0%	6
Sleeping difficulties	35%	22 – 51	5.0%	5
Anger towards others	33%	18 – 52	0%	4
Loss of confidence	27%	18 – 38	6.5%	10
Concern regarding patients' reactions	8%	0 – 70	0%	2
Self-doubts	6%	2 – 14	0%	2

TROUBLING MEMORIES

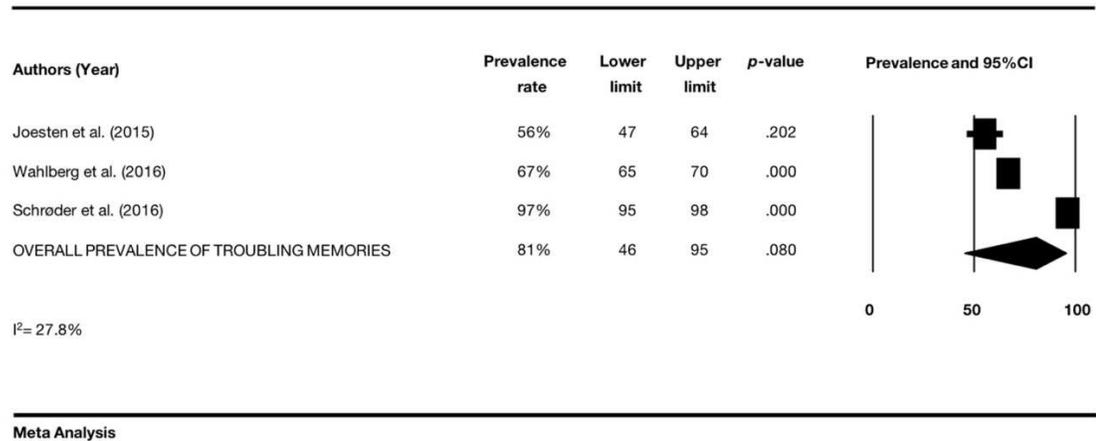


Figure 2. Forest plot showing the overall prevalence of troubling memories, the prevalence rates for the primary studies, the respective 95% CI, the *p*-values, and the I^2 statistic

SLEEPING DIFFICULTIES

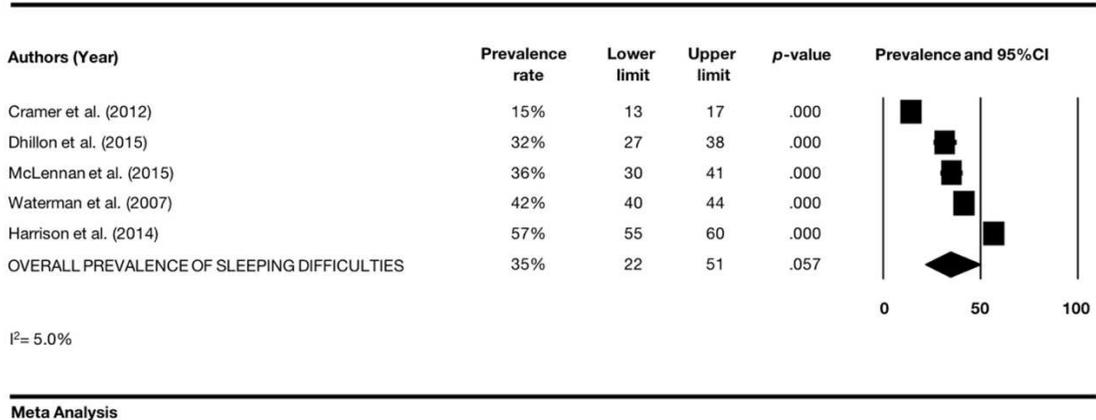


Figure 3. Forest plot showing the overall prevalence of sleeping difficulties, the prevalence rates for the primary studies, the respective 95% CI, the *p*-values, and the I^2 statistic.

Unpooled Prevalence Rates

Because of a lack of sufficient data from different studies and/or too heterogeneous variables of interest, and in order to prevent overlaps, we did not pool all prevalence rates reported in the primary studies (see supplemental data file 7 for an overview of the ungrouped variables and their prevalence rates).

Two studies^{18,46} explicitly assessed the occurrence of posttraumatic stress disorder (PTSD), each using a different questionnaire. These showed 5% (95% CI 4 to 7; 81/1628)¹⁸ and 17% (95% CI 14 to 20; 102/601)⁴⁶ prevalence rates of probable PTSD, respectively. Dhillon et al.⁴⁰ evaluated the impact of adverse events on cognitive functioning, reporting difficulty concentrating (79% of the participants; 26/33) and that 9% (22/245) of the enrolled anesthesiologists experienced the psychosomatic symptom of change in appetite.

DISCUSSION

This study expands on previous research on the psychological impact of adverse events on healthcare providers by providing precise estimates of the prevalence of the symptoms affecting second victims. To our knowledge, this is the first systematic review and meta-analysis quantifying psychological and psychosomatic symptoms of these providers. Our results confirm that healthcare providers involved in adverse events are highly affected by a wide range of psychological symptoms. More than two-thirds of providers reported troubling memories, anxiety, anger, remorse, and distress. More than half reported fear of future errors, embarrassment, and guilt. A third reported difficulty sleeping.

Troubling memories had the highest overall prevalence with 81% reporting this symptom. It is well known that unwanted upsetting memories and flashbacks are common after traumatic experiences in general^{56,57}. Although we did not pool the results of the two primary studies specifically focusing on the prevalence of probable PTSD^{18,46}, the overall high prevalence of troubling memories, anxiety/concern, distress, symptoms of depression, sleeping difficulties, and loss of confidence suggests symptoms commonly associated with PTSD^{58,59}.

Three quarters of providers studied experienced anxiety, and a similar number reported anger at themselves. The intensity, duration, and clinical relevance of these emotional reactions were not systematically explored in the primary studies, but these symptoms have been demonstrated to reduce professional performance. Anxiety can negatively influence cognitive functioning (e.g., working memory and concentration difficulties, attentional lapses, intrusive thoughts) in turn leading to difficulties in social and work settings⁶⁰.

Moreover, anxiety and the fear of future errors may result in overcontrolling behaviors (e.g., excessive double-checking), which may undermine healthcare providers' efficiency and actually increase error-proneness³⁴. It is also well known that anger directed toward oneself or toward others is a feature of dysfunctional coping strategies⁶¹ and linked to the risk of burnout⁶². Anger represents an emotion that, if not properly addressed, tends to reinforce defensive attitudes⁶³ and to negatively affect interpersonal relationships⁶⁴ as well as the quality of communication in the workplace⁶⁵. These may impede risk management⁶⁶ and lead to medical errors^{41,44,45}.

Consistent with Wu⁸ and Scott et al.⁷, our results showed that healthcare providers often experience medical errors as a personal failure. Emotional reactions such as embarrassment, fear of future errors, frustration, and the feeling of inadequacy are often associated with adverse events. The occurrence of these symptoms might be the consequence of the common expectation for perfection, shaped by external punitive attitudes in the health care system or by internalized norms^{8,21}. It also demonstrates that effort is needed to reduce the distress caused by this culture of perfection^{8,67} and to promote instead the concept of “Just Culture.” Just Culture focuses on system failures in order to improve patient safety and recognizes at the same time individual behaviors as contributors to risk for which the involved healthcare provider should accept responsibility.⁶⁸ While there is growing agreement that it is important to shift healthcare away from the traditional approach of blame and judgment^{26,69}, these attitudes are persistent as it is shown by the high prevalence of concern regarding colleagues' reactions. Interestingly, our results also suggested that this self-critical attitude did not take into account the role of the patient. Indeed, despite frequently described feelings of guilt, regret, and remorse by second victims, we found a relatively low overall prevalence (8%) of second victims' concerns about patients' reactions (i.e., *anxiety about loss of patient's trust*³⁷ and *fear of having to speak to the patient and/or family*⁴²). This result seems to suggest that healthcare providers are much less concerned about patients as self-determining partners in the process of care⁷⁰ and that they place a higher priority on the risk posed by the reactions of their colleagues. However, this finding needs to be interpreted with caution because second victims' self-doubts were explored in only two studies, limiting generalizability. Future studies should further explore this provocative finding.

Implications for Clinical practice and Policy

Our results highlight the importance of recognizing the significant distress experienced by second victims, and addressing those needs in practice, education, and policy. The first priority is to support health care workers. As recently acknowledged by the Joint Commission in the US, health care managers should provide easily accessed support programs tailored to the specific needs of the second victim, following already successful approaches, such as *RISE* at the Johns Hopkins Hospital^{23,71}. *RISE* provides peer-to-peer support to health care workers who have experienced a stressful patient-related incident or adverse event. The *RISE* team is composed of trained responders from different disciplines (e.g., physicians, nurses, chaplains, social workers) who deliver psychological first aid to peers in a confidential, nonjudgmental environment.

Broad education can provide a foundation for a more supportive health care environment. It will be important to raise awareness of work stress, the second victim phenomenon, and patient safety, through informational campaigns and educational programs for healthcare workers. Those individuals interested in playing a more active role can be trained to provide peer support and psychological first aid⁷². Such programs should acknowledge the role of human factors in work and safety, as also recommended by Hollnagel et al.⁶⁷ Policy makers should require health care organizations to make these programs available to staff, and monitor their implementation and use. These preventive and supportive strategies are expected to reduce second victims' psychological distress and to help create a Just Culture. Indeed, the humanity and fallibility of health care workers need to be acknowledged and accounted for in the design of the system while simultaneously maintaining the expectation that they deliver high-quality care.

Such a culture may also make it easier for the involved healthcare providers to initiate open, transparent discussions with the patients and their families about the adverse event, a step that has been shown to be highly appreciated⁷³.

Limitations

Our study had some limitations. First, the primary studies included in our review were heterogeneous in terms of instruments used, participants' profession, medical setting, and characterization of the adverse event (i.e., definition, point in time, type, severity, patient

outcomes). In some cases, the articles differed from one another in reported prevalence, as reflected by the wide confidence intervals around overall estimates of prevalence. However, quantitative analyses did not indicate substantial heterogeneity across studies. Second, the study is subject to the limitations related to the included cross-sectional, self-report studies. Biases due to self-selection by respondents⁷⁴ and recall⁷⁵ may have affected the results of the primary studies, which were reflected in our meta-analyses. Third, the primary studies did not capture the intensity, duration, and clinical relevance of individual symptoms, and if the healthcare providers had prior history of mental disorders. These limitations could be overcome by future longitudinal studies of healthcare providers to record the incidence and the impact of adverse events and to clinically evaluate symptoms before and after an adverse event. To gain a better understanding about the predictors of psychological distress after adverse events^{18,35,47}, personality characteristics and contextual variables (e.g., existence of punitive culture at workplace, severity of adverse event) could be assessed in such longitudinal studies. Fourth, due to insufficient data and heterogeneous variables of interest, some prevalence rates of psychological and psychosomatic symptoms reported in the primary studies were not grouped and thus were excluded from the meta-analyses. Notably, we were only able to meta-analyze the prevalence rates of one psychosomatic symptom, namely, sleeping difficulties, because additional psychosomatic symptoms were examined in only one study⁴⁰. A recent qualitative study⁷⁶ suggests that second victims experience a broad range of psychosomatic symptoms, such as extreme fatigue, increased respiratory rate and blood pressure, tachycardia, and muscle tension. Given the paucity of research on psychosomatic symptoms of second victims, future studies should explore this aspect further. In particular, quantitative methods, such as diagnostic tests or questionnaires, should be applied to thoroughly study the type and prevalence of psychosomatic symptoms experienced by second victims. Using quantitative instead of qualitative methodology would allow for greater objectivity and reliability of the results and would enhance their generalizability. Finally, this study focused only on the psychological impact of adverse events on second victims, without investigating the use of coping strategies in the aftermath of such an event. To overcome this limitation, we are planning to conduct an additional meta-analysis in the future.

CONCLUSIONS

Our meta-analysis, which included information from 11,649 healthcare providers involved in adverse events, provides an accurate overview of the severe psychological burden affecting second victims. These symptoms have serious repercussions for the well-being and fitness of the healthcare workforce. This evidence should be useful to develop and implement and evaluate support programs tailored to the specific needs of second victims. Such programs, in the long run, might have the potential to decrease the incidence of medical errors and increase patient safety, improving the overall quality of medical care.

Acknowledgements

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Conflict of Interest

The authors disclose no conflict of interest.

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6. Dealing with Adverse Events: a Meta-analysis on Second Victims' Coping Strategies

This is a non-final version of an article published in final form in the Journal of Patient Safety.

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This chapter contains supplemental data files which can be found in Appendix D.

¹ Acknowledgement of author contributions:

All authors jointly designed the study. IB, FM, and MR were involved in the search and selection process, the quality assessment, the data extraction and synthesis. MP and CB contributed with their expertise in the methodology of systematic reviews and meta-analysis and performed the statistical analyses. IB, FM, and MR drafted the initial manuscript, which was then critically revised by AW and approved by all co-authors.

ABSTRACT

Objectives: Despite the critical need to understand the diverse responses by second victims to adverse events, there has not been a meta-analysis examining coping by second victims. We aimed to analyze the coping strategies applied by second victims in the aftermath of adverse events.

Methods: We performed a systematic search of nine electronic databases up to October 2018 and screened additional sources, such as grey databases. Two independent reviewers conducted the search, selection process, quality appraisal, data extraction, and synthesis. In case of dissent, a third reviewer was involved to reach consensus. Quantitative studies of the frequency with which coping strategies were applied by second victims were eligible for inclusion. We calculated the overall frequency of coping strategies and I^2 statistic using random effects modeling.

Results: Of 10,705 records retrieved, 111 full-text articles were assessed for eligibility and 14 studies eventually included. The five most frequent coping strategies were *Changing work attitude* (89%, 95% CI 80-94), *Following policies and guidelines more accurately and closely* (89%, 95% CI 54-98), *Paying more attention to detail* (89%, 95% CI 78-94) (task-oriented), *Problem-solving/Concrete action plan* (77%, 95% CI 59-89) (task-oriented), and *Criticizing or lecturing oneself* (74%, 95% CI 47-90) (emotion-oriented).

Conclusions: Second victims frequently employed task-oriented, emotion-oriented coping strategies and, to a lesser degree, avoidance-oriented strategies. To better support second victims and ensure patient safety, coping strategies should be evaluated considering the positive and negative effects on the clinician's personal and professional well-being, relationships with patients, and the quality and safety of healthcare.

Keywords: Human factors; second victim; mental health; adverse event; risk management; coping.

INTRODUCTION

Despite major improvements in patient safety in the last decades¹, adverse events remain a threat to the quality of care and an urgent global problem^{2,3}. Adverse events harm first and foremost patients and caregivers^{4,5} and include severe physical harm⁶, psychological distress^{7,8}, and even death⁹. Moreover, patient safety incidents inflict a heavy financial burden on the healthcare system; for example, medication errors cost an estimated \$42 billion per year¹⁰. Patients and caregivers are described as the *first victims* of these incidents whereas the involved healthcare providers who can be emotionally affected as well¹¹ are frequently called *second victims*, a term coined by Wu in 2000⁴ and controversially discussed in recent years^{5,12-14}. Indeed, while it has generated discomfort among many patients and healthcare providers who argue that the term *victim* implies that healthcare providers who were involved in an adverse event are not responsible and cannot be held accountable and that it may downplay the experience of the patients^{5,12,14}, others, for instance Petersen¹³, a first victim himself, consider the term appropriate. However, a more suitable term has not successfully established itself until now^{12,14}.

A recent meta-analysis by Busch et al.¹¹ demonstrated that second victims strongly suffer from various psychological and psychosomatic symptoms in the aftermath of adverse events, such as anxiety, sleeping difficulties, and troubling memories. Furthermore, the involved health care workers, in response to these stressful events^{15,16}, apply coping strategies, which as defined by Folkman and Lazarus represent “cognitive and behavioral efforts to manage (master, reduce, or tolerate) a troubled person-environment relationship.” (p.152)¹⁷. Coping mechanisms vary and can be more or less adaptive¹⁸. For instance, second victims may consider career changes, try to distance themselves from the incident, seek social support, change their attitude to work, or practice defensive medicine¹⁹⁻²¹. Coping, a shifting, non-static process^{15,22-24}, is influenced by individual aspects (e.g. personality traits, regulatory control processes) and situational factors (e.g., severity and duration of the stressor, stressor perceived as controllable or uncontrollable, organizational culture of the healthcare institution)^{17,25-27}. There is a large body of research on the different types of coping mechanisms^{15,17,22-24,28, 29}. For instance, while Folkman and Lazarus^{17,22} differentiated only between problem-focused (actively approaching a

problem) and emotion-focused coping (trying to regulate one's own emotions accompanying the perceived stressor), Endler and Parker^{15,23,24} suggested a third type, avoidance-oriented (trying to avoid the factors causing the psychological distress). A distinction between adaptive/functional and maladaptive/dysfunctional coping strategies is often discussed as well^{25,30-32}.

As highlighted by Waterman et al.³³, a deep understanding of second victims' diverse responses to adverse events is vital for developing adequate psychological support programs and to help guarantee patient safety and well-being and a high quality of care. Although some literature reviews^{18,19,34-37} have described the coping of healthcare providers involved in an adverse event, to date there has not been a meta-analysis focusing on the type and frequency of coping strategies. In this study, we aimed to quantify and critically analyze the coping strategies applied by healthcare providers in the aftermath of adverse events.

METHODS

The protocol of this study is registered in the *International Prospective Register of Systematic Reviews (PROSPERO)*, Registration number CRD42016053239. Here follows the description of the main methodological steps. For further explanation, we refer to Busch et al.¹¹.

Search and Selection Process

We performed a systematic search of nine electronic databases (e.g., PubMed, Cochrane Library, Web of Science) up to October 2018, without restrictions to publication date and language, using the same search strategy as in our previous study¹¹. We examined also additional sources (e.g., databases of grey literature, reference lists of systematic reviews). Supplemental data file 1 and 2, respectively, provide a precise record of the applied search strategies for each database and of the additional searches.

Studies were eligible for inclusion if (a) the participants were healthcare providers involved in adverse events/patient safety incidents (i.e., harmful incidents, near misses, and no-harm incidents)³⁸ and (b) the frequency of coping strategies in this population in the

aftermath of a reported adverse event. We did not set any restriction on age, gender, healthcare profession and setting.

We excluded systematic reviews, single case studies, case series, qualitative studies, general discussion papers, book chapters, editorials, letters, and comments because we assumed that original, quantitative data (i.e., frequency rates of coping strategies used by healthcare providers involved in an adverse event) would not be presented in such papers.

Two reviewers (IB and FM) screened study titles and abstracts independently using *Rayyan*, a Systematic Reviews web app³⁹ and retrieved full texts of the records considered as eligible. In case of dissent, a third reviewer (MR) was involved to reach a consensus. We recorded all excluded studies and the reasons for exclusion as recommended in the Cochrane Handbook⁴⁰.

Two appraisers (IB and FM) rigorously assessed, first independently and then by consensus, the quality of the included studies, applying the *Joanna Briggs Institute Critical Appraisal Checklist for Studies Reporting Prevalence Data*⁴¹ comprised of nine quality criteria (e.g., appropriate method of recruitment, use of valid methods to identify the condition). Any potential dissent was discussed and resolved, involving a third appraiser (MR) when consensus was not reached.

Data Analysis

We considered the frequency of coping strategies applied by healthcare providers who had been involved in an adverse event as the primary outcome measure. We categorized the identified coping strategies according to Endler and Parker's framework^{15,23,24} as either task-oriented, emotion-oriented, or avoidance-oriented. All attempts to actively tackle a problem, to solve it or reduce its impact were categorized as task-oriented coping strategies. All endeavors to deal with emotions, including self-absorption and imagining reactions were labeled as emotion-oriented coping strategies. All efforts to avoid stressors, such as getting distracted or avoiding certain situations were defined as avoidance-oriented coping strategies. The methodological steps of data extraction and synthesis are shown in Supplemental data file 3.

Taking into account potential heterogeneity across studies, we used random effects modeling to perform the meta-analyses. We calculated the overall frequency of coping

strategies with 95% Confidence interval (CI) by pooling the individual frequencies of at least two primary studies. To assess statistical heterogeneity, we visually examined forest plots and calculated the I^2 statistic (0%-40%: not important; 30%-60%: moderate heterogeneity; 50%-90%: substantial heterogeneity; 75%-100%: considerable heterogeneity)⁴². We used *Comprehensive Meta-Analysis V3* (Biostat Inc., Englewood, NJ) to conduct the meta-analyses.

RESULTS

Selection and Inclusion of Studies

The search of the electronic databases (see supplemental data file 1) and additional sources (e.g., databases of grey literature, volumes of journals) (see supplemental data file 2) yielded a total of 10,721 records, of which 111 full-text articles were assessed for eligibility (see supplemental data file 4). In seven cases, the authors of the selected studies were contacted to request further data. After the exclusion of 97 articles due to various reasons (e.g., mixed population, lack of sufficient information) (see supplemental data file 5), we included 14 studies^{20,43-55}, all meeting the inclusion criteria, in the systematic review and meta-analysis. All included studies met more than half of the criteria listed in the *Joanna Briggs Institute Critical Appraisal Checklist for Prevalence Studies*⁴¹ (see supplemental data file 6). All studies used an appropriate sample frame and performed satisfactorily the data analysis and the measurement of the condition. Some studies, however, showed limitations or lacked clarity regarding the method of sampling, sample size, descriptions of study subjects and settings, use of valid methods, the analysis (e.g., frequency rates expressed only by percentages), and the response rate.

Characteristics of Included Studies

The fourteen included studies^{20,43-55} (supplemental data file 7) were published between 1991 and 2016 and conducted in several countries (i.e., Belgium, Denmark, Finland, Germany, Greece, Iran, UK, USA). All studies had a cross-sectional study design and applied descriptive and, in some cases, inferential statistics. Aside from Schröder et al.⁵² who administered not only a questionnaire with closed-ended questions but also conducted

semi-structured interviews, all other authors applied only self-report questionnaires with predominantly closed-ended questions. Only the quantitative findings by Schröder et al.⁵² were used for our analyses. Sample sizes ranged from 40 to 1,463 (total of 6,351 participants). Participants worked in different professions (e.g., nurses, midwives, physicians, residents) and settings (e.g., intensive medicine, general medicine, emergency department).

Regarding the adverse event itself, several studies assessed the point in time that it occurred (e.g., in the previous six months, more than four years before the study), its type (e.g., medication error, diagnostic error, procedural error), and categorized its severity (e.g., high, medium, low, no perceived error severity) and patient outcomes (e.g., need for additional therapy, clinical deterioration, serious injury, death).

Meta-Analyses

After categorizing the coping strategies according to the criteria listed above, we identified 26 coping strategies adopted by healthcare providers who had been involved in an adverse event (supplemental data file 8). We calculated the overall frequencies for these coping strategies (CB and MP) (Table 1 and supplemental data file 9) and categorized them as task-oriented, emotion-oriented or avoidance-oriented (IB, FM, MR). Three coping strategies (i.e., *Disclosing the error/talking to/support from staff*, *Apologizing or doing something to make up*, *Disclosing the error and talking to the patient and the family*) were categorized as both task-oriented and emotion-oriented.

The use of the specific coping strategies varied, ranging from 8% to 89%. The four most frequently used strategies were task-oriented, and the four strategies least frequently used were avoidance-oriented.

Table 1. Overall frequency rates of second victims' coping strategies

Coping strategy	Type	Overall frequency rate	95 % CI	I ²	Studies (n)	Number of participants applying the respective coping strategy (Overall sample size of the primary studies included in the respective meta-analysis)
Changing work attitude	T	89%	80-94	40.5%	5	n= 1,596 (N=1,928)
Following policies and guidelines more accurately and closely	T	89%	54-98	0%	2	n=265 (N=311)
Paying more attention to detail	T	89%	78-94	51%	6	n= 906 (N=1,130)
Problem-solving/Concrete action plan	T	77%	59-89	16.8%	4	n =675 (N=976)
Criticizing or lecturing oneself	E	74%	47-90	0%	2	n=203 (N=272)
Disclosing the error to/talking to/support from medical staff	T/E	72%	58-83	0%	8	n=1345 (N=1,919)
Better monitoring of the patient/paying better attention to the patient	T	69%	52-82	69.8%	4	n=581 (N=976)
Apologizing or doing something to make up	T/E	65%	43-82	27.5%	5	n=772 (N=1,090)
Disclosing the error/talking to/support from (unspecified) person	E	63%	48-76	25.1%	6	n=736 (N=1,130)
Personally confirming data	T	62%	40-81	0%	2	n=102 (N=154)
Seeking (more) advice from colleagues and senior staff	T	60%	46-72	52.1%	6	n=640 (N=1,130)
Emotional self-control	E	56%	30-79	36.4%	3	n=421 (N=823)

Wishing the situation away	A	55%	29-78	11.6%	3	<i>n</i> =239 (<i>N</i> =440)
Working more slowly and carefully	T	54%	34-73	0%	2	<i>n</i> =167 (<i>N</i> =311)
Disclosing the error to/talking to/support from friends/partner/family	E	47%	29-66	0%	6	<i>n</i> =663 (<i>N</i> =1,170)
Trusting others less	A	39%	32-46	8%	6	<i>n</i> =434 (<i>N</i> =1,130)
Disclosing the error and talking to the patient and the family	T/E	38%	25-53	4.3%	6	<i>n</i> =352 (<i>N</i> =813)
Reading more	T	36%	20-56	0%	3	<i>n</i> =219 (<i>N</i> =690)
Distancing	A	28%	19-40	18%	4	<i>n</i> =260 (<i>N</i> =976)
Changing one's data organization	T	27%	4-77	0%	2	<i>n</i> =63 (<i>N</i> =154)
Positive reappraisal	E	21%	8-43	19.3%	3	<i>n</i> =782 (<i>N</i> =3,585)
Ordering more tests	T	20%	10-36	0%	2	<i>n</i> =36 (<i>N</i> =154)
Trying to hide error/refusing to talk about it	A	18%	12-26	48%	7	<i>n</i> =282 (<i>N</i> =1,295)
Avoidance of patients, procedures, situations	A	15%	8-28	36.2%	5	<i>n</i> =243 (<i>N</i> =1,001)
Turnover intentions	A	14%	9-22	21.6%	6	<i>n</i> =403 (<i>N</i> =2,555)
Use of alcohol/drugs/medication	A	8%	3-23	0%	3	<i>n</i> =148 (<i>N</i> =1,346)

Task-oriented Coping Strategies

Task-oriented strategies were reported by 89% of second victims. The most frequent coping strategies were *Changing work attitude* (89%, 95% CI 80-94), *Following policies and guidelines more accurately and closely* (89%, 95%CI 54-98). *Paying more attention to detail* (89%, 95% CI, 78-94). *Ordering more tests* (20%, 95% CI 10-36) was used the least.

Emotion-oriented Coping Strategies

Criticizing or lecturing oneself (74%, 95% CI 47-90) was the most frequently adopted emotion-oriented coping strategy. *Positive reappraisal* (21%, 95% CI 8-43) was employed the least.

Avoidance-oriented Coping Strategies

While the avoidance-oriented coping strategy *Wishing the situation away* was used by 55% of the second victims (95% CI 29-78), only 8% reported *Use of alcohol/drugs/medication* (95% CI 3-23).

I^2 estimates, ranging between 0% and 69.8%, showed negligible to moderate heterogeneity across studies, with one exception ($I^2=69.8\%$ for *Better monitoring of the patient/paying better attention to the patient*). There was insufficient data to perform subgroup analyses (e.g., according to different types of healthcare profession or adverse event).

DISCUSSION

This study adds to a growing body of literature on second victims' responses after patient safety incidents. As far as we know, this is the first systematic review and meta-analysis providing a precise overview of second victims' coping in the aftermath of adverse events that quantifies the frequencies of the applied coping strategies. Our findings demonstrate that a large proportion of second victims employs different types of coping strategies to deal with the emotional impact of medical errors. This evidence has a relevance not only for healthcare providers' well-being and prevention of burn-out, but also regarding the quality of the patient-provider relationship and risk management in general.

In particular, we found that the most frequently reported coping strategies were task-oriented, suggesting that second victims are strongly committed to managing the consequences of the event (e.g., *Problem-solving*) and improving their own work performance (e.g., *Following policies and guidelines more accurately and closely*). Interestingly, on the contrary, the least applied coping strategies were avoidance-oriented (e.g., *Trying to hide error/refusing to talk about it*, *Avoidance of patients, procedures, situations*, *Turnover intentions*, *Use of*

alcohol/drugs/medication). Although it is possible that these strategies were underreported, it appears that second victims tend to accept the responsibilities related to their role in the adverse event (e.g., *Trying to hide error*). Moreover, the emotional impact of the adverse event, which previous studies have indicated as highly present and characterized by a wide range of psychological symptoms^{19,34,37}, is managed mainly by admitting personal responsibility and showing awareness of the implication of this event for patients and their families. Indeed, the most frequent emotion-oriented coping strategies resulted to be *Criticizing or lecturing oneself*, *Disclosing the error/talking to/support from medical staff*, and *Apologizing or doing something to make up*. This attitude is supported by our recent meta-analysis¹¹ that identified anger toward oneself, regret/remorse, embarrassment and guilt as common psychological reactions of second victims. The fact that many healthcare professionals aim to improve their performance to prevent future errors, take responsibility for their doing and attempt to make amends is an encouraging indication that the majority of these people respond to adverse events in an overall constructive, proactive way. Thus, our results do not seem to suggest that these healthcare providers show the traits the term *second victim* may imply, namely, passivity, powerlessness, lack of responsibility and accountability^{5,12}. Considering also the recent controversy over the use of this term^{5,12-14} as pointed out earlier, it would be of great interest to quantitatively explore, using a large sample of healthcare providers from different disciplines, if they see themselves as “victims” or feel uncomfortable being referred to as such, as a qualitative study by Tumelty¹² indicates.

In a systemic approach to risk management, the healthcare provider is considered only as the sharp end a chain of events eventually leading to an incident⁵⁶⁻⁵⁸. Indeed, even if adverse events are directly caused by healthcare providers’ active, unintentional failures, usually, medical errors are triggered by *latent conditions* of the healthcare institution including decisions taken by the top-level management⁵⁶. Following such a systemic approach, second victims’ actions and decisions in response to stress and professional requirements in the aftermath of adverse events should not only be seen in relation to their personal and professional life including the relationship with patients but also in relation to the overall healthcare system. Figure 1 shows that coping strategies can influence healthcare

providers, patients and the healthcare system in a positive or negative way (*adaptive* vs *maladaptive* for healthcare providers; *appropriate* vs *inappropriate* for patients, and *functional* vs *dysfunctional* for the healthcare system).

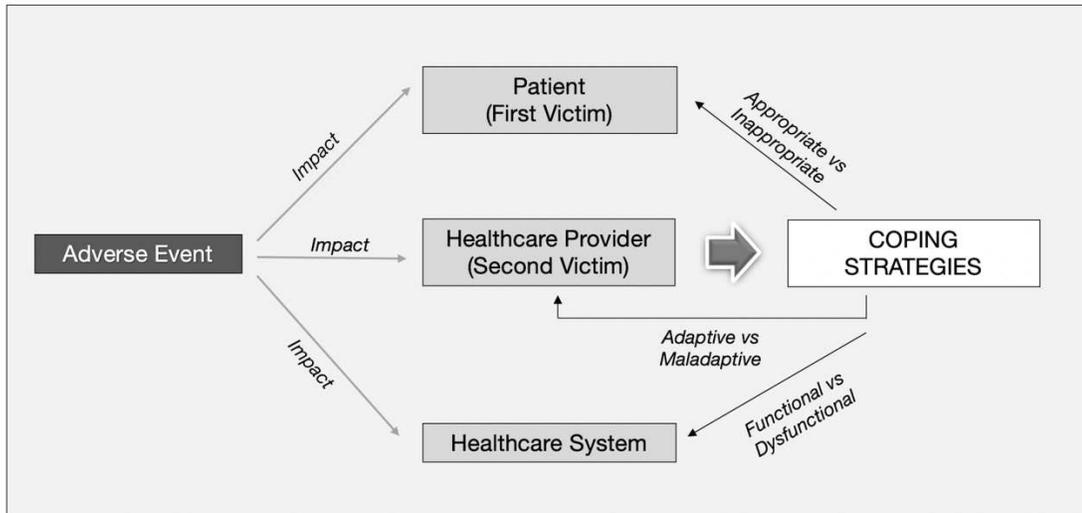


Figure. 1 Second victims’ coping after adverse events and its overall effects on patients, healthcare providers and the healthcare system

For healthcare providers, coping strategies can be considered *adaptive* if they lead to a better psychological adjustment and reduce the stress caused by the medical error, preventing the loss of emotional, cognitive and behavioral functioning. On the contrary, *maladaptive* coping may cause feelings, beliefs and behaviors that negatively influence functioning^{30,59,60}. For the welfare of patients, coping strategies can be considered *appropriate* if they evoke proactive professional skills, attitudes and behaviors which are beneficial for the well-being of the patients and for the therapeutic alliance. *Inappropriate* strategies may lead to more defensive, aggressive, and emotionally detached interactions with patients, weakening the therapeutic alliance and reducing patient satisfaction.

For the healthcare system, coping strategies can be defined as *functional* if they facilitate a reliable and effective performance. Hollnagel and colleagues⁵⁷ argue that promoting system resilience is a key element for ensuring safety. Indeed, the ability of a healthcare organization to provide high reliability under varying conditions is a critical achievement only possible through actively fostering the adaptability and creativity of human performance – a *Safety II*-approach. Accordingly, a coping strategy can also be seen as

functional for the system if it strengthens professionals' resilience. Coping strategies that compromise achievement of quality and safety standards and reduce resilience can be considered *dysfunctional* for the healthcare system.

Although some of the coping strategies identified in our study are classifiable to specific and stable categories (e.g. *Use of alcohol/drugs/medication* can be defined as *maladaptive/inappropriate/dysfunctional* independently from the context), most cannot be categorized without also considering contextual and temporal variables. For example, a coping strategy that in the short term might be adaptive for the second victim can become maladaptive if applied in the long term (e.g. *Distancing*). Similarly, strategies that are functional for the system if flexibly applied, may become dysfunctional and negatively affect the efficiency of the healthcare system if adopted in a rigid and decontextualized way (e.g. *Paying more attention to details*). Table 2 illustrates a critical approach in the assessment of second victims' coping strategies, highlighting the positive and/or negative aspects of the most and least frequent coping strategies from the perspectives of the involved provider, the patient, and the healthcare system.

Table 2. Potential effects of second victims’ coping with adverse events

COPING STRATEGY	SECOND VICTIM		PATIENT		HEALTHCARE SYSTEM	
	ADAPTIVE	MALADAPTIVE	APPROPRIATE	INAPPROPRIATE	FUNCTIONAL	DYSFUNCTIONAL
CHANGING WORK ATTITUDE (↑ task-oriented)	Since the variables of interest retrieved from the primary studies and composing this category* refer to improvements in healthcare providers’ professional attitude and performance (e.g. “ <i>Self-critical of the performance and promising to do things differently next time</i> ”), this coping strategy can be considered as adaptive for the second victim, appropriate for the patient and thus also functional for the quality and safety of the care delivered by the system. However, only in the long term it will be possible to determine if this positive intention to improve the professional performance is followed by concrete actions (e.g. attendance of courses, positive behavioral changes) which would confirm the real proactive and positive nature of this coping strategy.					
FOLLOWING POLICIES AND GUIDELINES MORE ACCURATELY AND CLOSELY (↑ task-oriented)	Increasing the adherence to rules and standardized procedures may help second victims to feel better supported and guided in the decision-making processes as well as in the daily activities.	A too rigid application and an overuse of guidelines and policies due to the fear of future errors may lead in the long term to frustration and additional anxiety related to the loss of autonomy and self-efficacy.	A more conscious and appropriate use of the guidelines (especially if previously ignored or insufficiently considered), taking into account the indications provided in the literature, may increase the quality of care ⁶¹ .	A rigid, decontextualized attitude toward the adoption of guidelines may negatively interfere with the application of a patient-centered approach and could potentially lead to a dehumanized and depersonalized care ⁶¹⁻⁶³ .	Daily clinical practice should be evidence-based and rely on the principles of standardization and reproducibility. A change in the attitude of the healthcare provider previously ignoring or not referring to the guidelines would certainly improve the quality and safety of the service delivered by the system ⁶¹ .	The complexity of the healthcare system cannot be fully addressed and controlled by guidelines and procedures. A rigid application of rules may hamper healthcare providers’ flexibility and capacity to manage the variability and unpredictability of the process of care. These abilities are considered core elements in a <i>Safety-II approach</i> of a resilient system ⁵⁷ . Moreover, a rigid application of guidelines not considering cost effectiveness may reduce the efficiency or waste limited resources of the healthcare system ⁶¹ .
PAYING MORE ATTENTION TO DETAIL (↑ task-oriented)	Paying more attention to detail may help second victims to collect all necessary medical information	By paying too much attention to detail, the complex clinical practice may feel out of one’s control. This may evoke	If applied moderately, this strategy can be considered appropriate since close monitoring of the clinical situation is	An overuse of this strategy may lead to the practice of defensive medicine ²¹ by collecting unnecessary information	Situational awareness (e.g., collecting all necessary information, ensuring an adequate patient monitoring,	Giving excessive attention to detail may prevent from seeing the “bigger picture” of the clinical process ⁶⁵ which is

	about the patient and thus feel better prepared for the complexity of daily clinical practice.	anxiety and insecurity and negatively affect second victims' ability to make appropriate decisions.	essential for anticipating potential changes of patient status and ensuring a proactive and timely management of patient safety and care.	and ordering useless tests which, in turn, can enhance patients' anxiety and increase healthcare costs.	supporting efficient decision making) is recognized as a key "non-technical" skill for improving patient safety and can be thus seen as functional for the healthcare system ⁶⁴ .	essential for teamwork and optimal decision-making based on different perspectives of all involved stakeholders (e.g., healthcare providers, patients, healthcare managers).
ORDERING MORE TESTS (↓ task-oriented)	In terms of stress management, ordering more tests can be considered an adaptive strategy if applied to reduce the uncertainty and the risk of lawsuits in challenging clinical situations ⁶⁶ .	This strategy can turn into maladaptive coping if pervasively applied in all clinical situations aiming to avoid responsibility. In this way, the anxiety cycle is maintained and second victims' self-efficacy reduced.	This strategy can be considered appropriate and lead to better health outcomes ⁵⁵ if based on clinical decision-making that takes into consideration also potential side effects, patients' needs and comfort.	If this strategy is the expression of a defensive attitude based on healthcare providers' needs (e.g., protection from eventual complaints or litigation) rather than on patients' needs and comfort (e.g., unnecessary colonoscopy causing patient's discomfort rather than bringing clinical benefits) ^{21,66} , it has to be considered inappropriate.	This strategy is functional for the system if it is the consequence of a more appropriate application of protocols or clinical guidelines thus improving the quality of the diagnosis and overall of the service offered to patients ⁶¹ .	Ordering unnecessary tests increases healthcare expenses, extends waiting lists and exposes the patient to potential risks. These factors can reduce the efficiency and safety of the healthcare system ⁶⁷ .
CRITICIZING OR LECTURING ONESELF (↑ emotion-oriented)	Self-criticism can be considered adaptive if it helps second victims to recognize their limits and weaknesses and if it fosters the development of efficient ways to prevent the reoccurrence of errors.	This coping strategy can become maladaptive if it is related to a persistent and excessive feeling of guilt and the firm belief of being the only one responsible for the adverse event even if system failures contributed to it ⁶⁸ . Such an attitude may lead to a loss of self-confidence and efficacy.	This strategy can be considered appropriate if it goes along with honestly admitting responsibility which is crucial for a transparent incident disclosure to patients and their families. Such an open communication can help patients and their relatives to understand what happened and re-establish trust in the patient-provider relationship ^{69,70} .	If second victims overly criticize themselves in front of patients, patients may lose trust in healthcare providers' performance and in the healthcare system in general. Some patients may then feel less safe and fearful of potential future errors ⁷¹ . Moreover, healthcare providers, strongly criticizing themselves, may develop insecurities which may impede the therapeutic relationship	This strategy can be seen as functional for the healthcare system if second victims are able to objectively assess their role in the adverse events seeing at the same time the related system failures. Such an approach favors a "Just Culture" ⁷² , in which system failures as well as individual behaviors are recognized as potential contributors to adverse events.	Excessively criticizing oneself may be the result of a blaming culture ⁶⁸ which creates "favorable" conditions for the reoccurrence of the same mistakes. The single healthcare provider is the only one considered guilty, system failures are not taken into account, mistakes are hidden, and attempts to establish reporting and learning cultures are defeated ^{68,73} .

				essential to ensure high levels of safety.		
POSITIVE REAPPRAISAL (↓ emotion-oriented)	Given that the <i>Positive reappraisal</i> of the second victim experience often times favors personal growth and emotional and spiritual development, it is reasonable to consider it as an adaptive, appropriate and functional way of coping with stress ^{29,52} . Similarly, Scott et al. ⁷⁴ addressed the role of <i>Thriving</i> in their six-stages model as a path to successful recovery.					
WISHING THE SITUATION AWAY (↑ avoidance-oriented)	Mentally and emotionally distancing from a stressful situation for a short time can offer relief and help second victims to mitigate negative feelings or catastrophic beliefs. It may also facilitate the development of different perspectives on the causes and consequences related to the adverse event.	The constant and systematic reluctance to remember or discuss the negative experience of the adverse event may inhibit the psychological elaboration of the incident and transform transitory emotional reactions into lasting, clinically relevant psychiatric disorders (e.g., depression, post-traumatic stress disorder) ⁷⁵ .	Emotionally distancing from the incident can reduce the risk of identification with the patient (or the family) thus avoiding intrusive, compulsive, overly involved behaviors during the clinical encounter.	Prolonged negation of the impact of an adverse event inevitably may reduce empathy and cause a detachment in the relationship between patient and healthcare provider. Patients may even be perceived as a threat for healthcare providers' psychological balance which could lead to active or passive aggressive behaviors.	This strategy can be considered functional for the system only if applied to dispel intrusive images, obsessive thoughts, and flashbacks that might disturb or interfere with second victims' daily clinical practice since this kind of interferences could reduce attention and increase the risk of errors or near misses.	In most of the cases, this strategy is not functional for the system, since the healthcare provider should feel responsible during and after an adverse event for the management of the consequences and for the prevention of other errors in the future. Indirectly, if avoidance blocks the emotional elaboration, it may also increase the risk of professional burnout ⁷⁶ whose economical and organizational impact on the system is widely recognized ⁷⁷ .
USE OF ALCOHOL/DRUGS/MEDICATION (↓ avoidance-oriented)	Given that in the included primary studies ^{45,54} , the “use of medication” was described as “problematic” and “self-administered” (and thus, not as therapeutic), this strategy can be seen as much as the use of alcohol and drugs as a maladaptive, inappropriate and dysfunctional response to stress.					

Note.

↑Most frequent; ↓ Least frequent

* Supplemental Data File 5 gives an overview of all grouped variables of interest.

Implications for Clinical Practice and Policy

Our results suggest that the coping strategies used by second victims in the aftermath of an adverse event are part of a complex, multifaceted process that directly affects healthcare providers and indirectly influences patients and healthcare services.

Regarding the role of healthcare organizations, it may be assumed that investing in a systemic approach to risk management⁵⁶⁻⁵⁸, strengthening resilience⁵⁷, promoting a “Just Culture”,⁷² offering training courses that foster the adoption of proactive reactions to work-related stress, and establishing psychological support programs that increase the well-being of second victims and other frontline healthcare personnel could probably encourage the use of adaptive, appropriate and functional coping strategies¹⁹. Such support programs should not only focus on second victims’ psychological and psychosomatic symptoms but should also explicitly address the type of the employed coping strategies and their effects on all involved stakeholders. Nevertheless, more evidence is needed to fully address these aspects.

Limitations and Directions for Future Research

Our results should be interpreted in light of some limitations. Although the quality of the primary studies was satisfactory, our calculations are based only on the self-reported, cross-sectional data extracted from the included studies and are thus likely to be affected by certain biases. For example, participants might have had problems to correctly remember what kind of coping strategies they had used (i.e., recall bias)⁷⁸ or might have had difficulties in recognizing certain behaviors, in particular avoidance behaviors due to low self-awareness and a lack of introspective skills, thus resulting in underreporting. Further, due to the social desirability bias⁷⁹, participants may have avoided reporting strategies commonly seen as inappropriate (e.g. *Use of alcohols/drugs/medication, Trying to hide error/refusing to talk about it*) and reported those that are generally considered socially desirable (e.g. *Apologizing or doing something to make up*). It might be also argued that some coping strategies reported in the primary studies were not the expression of a “real choice” of the healthcare provider but rather mandatory actions. For instance, in some cases,

Disclosing the error with patients might have been required by the healthcare institution thus not representing a personal coping strategy.

Moreover, the included studies differed in terms of medical setting, professions, type of adverse events, and cultural background. We also found for some coping strategies a wide variability in the reported frequency rates of the primary studies. Although we cannot rule out that this variability may have somewhat confounded our analyses, we did not further analyze these differences since most of the I^2 estimates indicated negligible or only moderate statistical heterogeneity across the studies with none suggesting considerable heterogeneity.

Nevertheless, to increase the depth of understanding, future research on these issues is recommended. For instance, regarding the coping strategy *Apologizing or doing something to make up*, a strong increase in the frequency rates of the primary studies (i.e., from 20 %⁵⁵ to 86%⁵³) could be observed. While this finding may be only coincidental, it could also indicate a change in healthcare providers' attitudes towards apologizing and making amends, reflecting the growing efforts in healthcare to be transparent and open with patients and to deal with adverse events promptly and proactively^{69,80,81}. It would be interesting to investigate this apparent trend over time and to correlate it with other trends. Similarly, the underlying reasons for certain outliers in the data, such as the exceptionally high frequency rate of *Better monitoring of the patient/paying better attention to the patient* (i.e., 95%, 95%CI 91-98) reported by Taifoori and Valice⁵³, might be further explored.

In addition, many of the included studies did not record the severity of the adverse events and did not address the potential relationship between the type and outcome of the event (e.g., near miss vs. sentinelevent). Thus, overall, future studies should examine the significant differences in coping strategies across time, cultures, types and outcomes of the incident, professions, and settings of care.

Conclusions

Our meta-analysis adds insight into the coping strategies adopted by healthcare providers involved in adverse events. The results suggest that second victims' coping is primarily task-, emotion- and, to a lesser extent, avoidance-oriented. These coping strategies should be further evaluated considering their positive and negative effects on second victims'

personal and professional well-being, the impact on the relationship with patients and their families and, last but not least, taking into account the overall quality and safety of care delivered by the system.

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7. Patient Safety: a New Basic Science for Professional Education.

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The replica of the translated German version can be found in Appendix E.

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“Patient safety is a core attitude and thus needs to be introduced early and then reinforced throughout postgraduate education and continuing professional development.” (Stefan Lindgren, President of the World Federation for Medical Education)

INTRODUCTION

Beginning in the 1990s, studies of hospital safety and quality from around the world have consistently found problems with patient safety and quality¹. There has been a notable increase in awareness of the problem, with major efforts in the past two decades to improve the safety of medical care. A study conducted for the World Health Organization found that seven types of adverse events cause 43 million injuries a year, making preventable harm the world’s twentieth most common cause of overall morbidity and mortality². Others have suggested the medical errors are even more common³. A chilling statistic from WHO was that in high income countries, on average, one of every ten patients hospitalized suffers a serious, preventable adverse event⁴.

Although patients continue to be harmed by health care, there has been some progress⁵. Since 2000, it has become widely understood and accepted that “it’s the system” – it is the health care system that creates hazards and harm, and that also creates patient safety, rather than individual providers⁶. However, there is a deeply seated, pernicious habit for people, the public and health care managers to blame specific medical errors exclusively on individual health professionals. On the other hand, it is certainly true that individuals are an integral and indispensable component of the health care system. Individuals also act as members of teams, and interact with other parts of the system⁷. Individual must feel they are accountable too. If the balance of accountability swings too far, and we rely entirely on searching for systems solutions, the important process of changing individual behaviors will be lost⁸.

Regardless of whether you take an individual or system perspective on the causation of medical error, there is a need to educate clinicians on how to deliver safer care. We believe that patient safety should be a new basic science for professional education. To accomplish

this, major reforms are needed in health professions education. However, we appreciate that there are challenges associated with incorporating patient safety into education and training.

This special issue on patient safety in medical education in Germany represents an important step to increasing awareness of patient safety as an important element in the training of health professionals. The papers in this issue help to advance the field, in both education and in research on education.

THE PROBLEM

Schools in the health professions, including medicine, nursing, pharmacy, dentistry and others, provide limited education on patient safety. In medicine, the traditional curricular focus is on basic science and medical knowledge. Residency and other post-graduate training add a focus on technical expertise. Other health professions, including nursing, pharmacy and health technology maintain the primary focus on acquiring facts and knowledge. None pay sufficient attention to the key concepts, attitudes and skills necessary to practicing safely and spurring improvements in care.

In addition to the lack of basic knowledge and skills, the prevailing culture and work environment in hospitals and other health care organizations work against many of the prerequisites for safe practice. In many organizations there is a pernicious culture of shame, blame and punishment surrounding medical errors, and a deny-and-defend stance in response to patients and families. A “hidden curriculum” reflecting this culture sabotages attempts at classroom education⁹. Together, these conditions prevent awareness, taking action, and learning from errors.

To address these gaps, health professions schools and training programs will need to refocus their goals, away from the mere acquisition of knowledge and facts. Programs will need to make room in the curriculum for new concepts, attitudes, behaviors and skills, and provide opportunities for trainees to implement them in practice.

EXAMPLES OF EDUCATION

There is accumulating evidence that education can help to improve patient safety and health care quality. Safety curricula are generally popular among trainees and have resulted in increased knowledge of safety and quality improvement (QI) concepts, and led to improvement in care processes¹⁰.

Medical schools are beginning to introduce patient safety training into the undergraduate curriculum^{11,12}. At the Johns Hopkins University in the U.S., a 10-hour curriculum was instituted for first year medical students, and showed improvements in knowledge and attitudes, including future commitment to patient safety¹³. This has been followed by a 3-day curriculum for second year medical students, shortly before they transition from classroom to clinical wards, including lectures and hands-on experiences, which showed advances in knowledge, self-efficacy and systems thinking¹⁴. It is noteworthy that this curriculum consistently receives the highest evaluations from students among all of the special topics taught in the second year.

In the UK, a 5-hour curriculum for senior medical students on understanding error in health care was shown to have improved knowledge¹¹.

Aiming to implement patient safety curricula in the medical education in German-Speaking countries, the committee for Patient Safety and Error Management of the German Association for Medical Education introduced in 2016 a Learning Objective Catalogue addressing patient safety topics and error management in Medical Education. This catalogue serves as basis for a deepened discussion of patient safety issues among medical faculties and as disciplinary and content-related orientation guide for embedding patient safety teaching courses into existing medical curricula^{15,16}.

In practice, studies have found education to benefit patient outcomes. Aiken and colleagues showed that hospitals in the U.S. with higher levels of nursing education had lower patient mortality rates^{17,18}. Berry and colleagues demonstrated that improved safety

culture and teamwork climate were associated with decreases in patient harm and hospital mortality¹⁹.

WHAT SHOULD BE TAUGHT?

The Institute of Medicine's groundbreaking report *To Err Is Human* in 1999⁶ and subsequent publications have influenced recommendations worldwide to promote safer health care. These recommendations have favored competencies over content, with the goal of changing the behavior of health professionals.

Competencies encompass patient safety within the broader domain of practice. In its report *Patient Safety Achieving a New Standard for Care*, the Institute of Medicine identified 5 core competencies which all health professional should be able to demonstrate²⁰. These included the provision of patient-centered care, the ability to work in interdisciplinary teams, employment of evidence-based practices, application of quality improvement concepts, and utilization of informatics.

Several influential groups and authoritative bodies have launched efforts to identify sets of competencies important to promote safer health care practice²⁰⁻²⁵.

The American College of Graduate Medical Education and the American Board of Medical Specialties²² identified competencies within the domains of patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice. These are shown in Table 1.

Table 1. Core Competencies and Criteria for Maintenance of Certification as defined by the American Board of Medical Specialties

Patient care	The ability to provide patient care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health
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Medical knowledge	Demonstration of knowledge of established and evolving biomedical, clinical, epidemiological, and social-behavioral sciences, as well as the application of this knowledge to patient care
Practice-based learning and improvement	Demonstration of the ability to investigate and evaluate the care of one's own patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and life-long learning
Interpersonal and communication skills	Demonstration of interpersonal and communication skills that result in the effective exchange of information and collaboration with patients, their families, and health professionals
Professionalism	Demonstration of a commitment to carrying out professional responsibilities and an adherence to ethical principles
System-based practice	Demonstration of an awareness of and responsiveness to the larger context and system of health care, as well as the ability to call effectively on other resources in the system to provide optimal care

American Board of Medical Specialties: <https://www.abms.org/board-certification/a-trusted-credential-based-on-core-competencies/>

The World Health Organization Patient Safety Programme identified 11 key topics to be covered. This list was initially based on the Australian Patient Safety Education Framework^{26,27}.

The first topic regards the concept and definition of **patient safety** itself. **Human factors** describe the interaction of workers within the work system of health care, and how specific internal factors (knowledge, skills) and external factors (stress, ineffective communication, production pressure) may be associated with medical errors and adverse events. **System** failures and patient harm can result from factors originating from multiple levels within the health care system. These system levels include the patient, task, the individual, the team, tools, management and organization. Communication and **teamwork** involve patients and their carers as well as interdisciplinary collaboration to ensure high quality care. The ability to see systems and failures within them, and to communicate incidents to colleagues are crucial to **learning from errors**. The ability to use **quality improvement**

tools allows closing the loop after these events. **Engaging with patients** and their caregivers is essential to optimizing safety. This includes behaving ethically and appropriately in **managing clinical risk** and being open with patients about medical errors. **Infection control** identifies potential hazards and prevents health care associated infections particularly through the application of universal precautions. **Invasive procedures** are a particularly high-risk part of health care; harm can be reduced through the judicious use of checklists and standard operating procedures. **Medication safety** addresses the ubiquitous risks associated with all of the phases of medication use, particularly for different age groups, high hazard medications and transitions of care.

There is increasing number of patient safety curricula available, and reviews of their successes and challenges^{10,28-34}. The World Health Organization developed a curriculum guide to provide medical students with essential patient safety lessons to allow them to practice safely²⁶. It includes a teacher's guide, and a comprehensive, ready-to-use, topic-based programme with a full set of slides.

Recognizing that other professionals provide the majority of care to people in all countries, the medical student curriculum was followed closely by a more general multi-professional patient safety curriculum guide. This aimed to aid in the implementation of training in inpatient safety, including in the fields of midwifery, nursing and pharmacy, dentistry, and medical technology³⁵.

CHALLENGES TO IMPLEMENTATION

It is sometimes said that the hardest thing to do in academic medicine is to get a new course added to the medical school curriculum. Universities are well known for their professional bureaucracy, and this includes resistance to change. There is a tendency to preserve existing organizational structure, even when it is obvious that it fails to serve institutional goals.

Barriers have been noted to making changes to higher education in general, related to attitudes, existing structures, and resources^{36,37}. Published literature suggests that it can also be challenging to introduce patient safety into health professions schools³⁸.

Human factors barriers to making changes to higher education in general include:

1. Lack of awareness (including lack of interest, engagement, involvement), support, professionalism, policy making and recognition
2. Unsupported structure, conservative disciplinary organization of higher education, inefficient communication, resistance to change, overcrowded curriculum, focus on content-based learning
3. Need for more resources including funding, work pressure and lack of time, lack of access to information, lack of consistent legislation and lack of physical place³⁶

There are specific challenges to incorporating patient safety into health professions education. These include 1) lack of awareness, 2) lack of agreement, including the hidden curriculum, 3) lack of engagement and involvement, 4) lack of leadership, 5) the discipline-based structure of medical science and health care, 6) resistance to change, 7) overcrowded curriculum, 8) historical focus on content-based learning, 9) lack of know-how and support for educators, including funding 10) competing work pressures and lack of time, 12) evidence gaps in best practices.

Lack of awareness and lack of agreement are recognized barriers to physician adherence with guidelines and behavior change³⁹. Course directors are reluctant to accept the need for patient safety science⁴⁰. Many need to be convinced of the importance of this subject in relation to other subjects for students e.g., foundational sciences like anatomy, physiology, and biochemistry.

A hidden curriculum reflecting “real world practice” is ingrained in the culture and behavior of health care organizations. This hidden curriculum perpetuates hierarchies of authority and unprofessional behavior, sabotages teamwork, and reinforces paternalistic attitudes towards patients⁹. Students and trainees witness how their more experienced

colleagues behave, contrary to the lessons they might have been taught in the classroom. These factors contribute to a lack of engagement and involvement by faculty members, which can be exacerbated by the lack of visionary and enabling leadership to advance the patient safety agenda.

The discipline-based structure of medical schools is itself a barrier⁴⁰. Faculty members in individual departments may be reluctant to relinquish space on the curriculum and the status it implies. In a recent personal experience at our own institution, an attempt to teach medical and nursing students together about patient safety was frustrated by conflicting calendars for the respective schools.

Professional schools are already struggling with curricula that are densely packed. There is a limited amount of clinical time, which may reduce the opportunities for students to be exposed to common patient safety issues. Opportunities for interdisciplinary training in practice settings are even more limited⁴¹. In addition, faculty are accustomed to providing content-based rather than competency-based learning. There may be an insufficient number of faculty to teach in this area, and existing faculty may be uncomfortable teaching material outside of their own discipline and expertise⁴².

Thus, top leaders in professional schools and academic medical centers have an important role to play in making successful curricular change. This requires creating a milieu in which change can be accepted and made. Insufficient support in terms of time, financing, and guidance are important barriers to adoption of reforms and their implementation⁴³.

WHAT SHOULD BE DONE

To make changes in curriculum, instill competencies and culture in trainees, and ultimately effect changes in behavior, action will be needed on the part of multiple stakeholders in health professions education and health care organizations.

For an organization embarking on this kind of curricular change, communication and engagement of educators and staff are essential from the start^{44,45}. It is important to let people know the rationale for the proposed changes, and the process of change that will occur. It is crucial to provide professional development opportunities to staff who will be involved. This should include relevant training and activities that will allow them to engage in the change process.

The Lucian Leape Institute of the National Patient Safety Foundation convened an expert group that produced recommendations for improving education in patient safety⁴⁶. Although they were developed in the US for medical school reform, most of these recommendations are widely applicable to the international context and for other professional schools. The recommendations focus first on developing learning cultures that emphasize safety, professionalism, collaboration and transparency. There is an emphasis on promoting interpersonal skills and interdisciplinary teamwork. Resources should be provided to support faculty development of the skills needed to deliver the curricula. Changes should extend to selecting students with the attributes that reflect these new competencies. Patient safety should be conceptualized as a science, and undergraduate professional education should focus on core competencies within the domains identified earlier in this editorial. This learning should extend beyond undergraduate and specialty training, leading to lifelong learning. National accreditation requirements should be aligned with the achievement of these competencies. The impact of this new set of educational priorities should be evaluated, and financial and other incentives should be aligned to support the changes. Many of the recommendations are directed at top university leaders, and at even higher-level external leaders in education ministries and accrediting bodies, as these individuals play important roles in managing change⁴⁷.

There is a variety of tools and strategies that can be deployed. Detailed discussion of these is beyond the scope of this paper. However, these include both high tech and lower tech simulation^{48,49} and also the use of standardized patients. Training in the use of standardized tools to improve teamwork and communication, such as TeamSTEPPS and the

Comprehensive Unit Based Safety Program (CUSP) can be useful to improve knowledge, attitudes, and outcomes⁵⁰⁻⁵².

Traditional role modeling remains crucial as an essential element of teaching. This is particularly important for imparting values and behaviors that support a culture of safety and optimal learning, and to support both the prevention and handling of errors. Partnering whenever possible with patients is also an important part of education⁵³.

There are excellent basic textbooks^{54,55} as well as a growing bank of free on-line resources to provide information, guidance and training in patient safety⁵⁶⁻⁶⁰.

CONCLUSION

It is a worldwide imperative to prepare the health care work force to deliver safer care. We believe that patient safety should be regarded as a new basic science for health professions education. However, the translation of patient safety science into safe practice is also a highly applied activity. Major reforms will be needed to incorporate patient safety into the curricula of professional schools and training programs. These organizations will need to redirect their focus away from the mere acquisition of knowledge to developing competencies and changing behavior.

The new curriculum will need to include competencies related to providing patient-centered care, working in interdisciplinary teams, using evidence-based practices, and applying quality improvement concepts. These competencies involve changing how students see, and changing attitudes and skills. We would like students to be able to see individual safety problems with system lenses, and be able to identify and test potential solutions.

We are aware that there are challenges associated with integrate patient safety into education and training. A major barrier is the prevailing culture of shame, blame, and

denial about medical errors. The hidden curriculum competes with attempts to create a culture of safety and allow optimal learning.

Action will be needed from multiple stakeholders in health professions education and health care organizations. Communication from top leaders and transparency throughout the organization are needed in the entire process. Coordination will also be needed to give students opportunities to practice their new skills in real world settings.

We now have sufficient tools for any organization to make a good start. There is still much to learn, such as effective strategies to educate trainees in multidisciplinary and practice-based settings, and how to adapt materials to fit the local context. Innovations are still needed, and building research and evaluation into early efforts will help us arrive more quickly to the goal of making patients safer.

Competing interests

The authors declare that they have no competing interests.

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8. Discussion and Outlook

SUMMARY OF THE PRINCIPAL FINDINGS

This thesis addresses how patients, patients' caregivers and healthcare providers may be strengthened and supported in care and risk management in order to be acknowledged and valued as resource for a resilient healthcare system. Our research significantly contributes to the current literature on humanization of care, patient involvement and empowerment, the second victim phenomenon, patient safety, and risk management. It enhances our understanding of the interconnectedness of these concepts and is expected to inform policies, clinical practice and medical education.

In the following section, the main findings of each developed project are shortly summarized.

The initial aim of this thesis was to identify the main characteristics of a humanized, relationship-centered care. Systematically reviewing and analyzing the predominantly South American literature on humanization of care, 30 key elements based on the different perspectives of patients, patients' caregivers, and healthcare providers were identified. In particular, empathy and respect towards patients, sufficient human and material resources in healthcare institutions, and a balanced workload for healthcare providers were considered as critical for establishing genuine, mutually beneficial relationships with patients and for providing humanized care.

The second aim of this thesis was to evaluate ways to empower two particularly vulnerable groups of patients (i.e., patients with mental health conditions, patients harmed by adverse events). With respect to the question how the empowerment of patients with mental health conditions may improve risk management, we found, by applying a multi-level codification system, that healthcare providers see patients as crucial partners in risk managements and expect them to play a key role in actively improving safety. The findings of the focus group discussions further suggest that risk management in mental health settings particularly relies on the therapeutic relationship between healthcare providers and patients which should be both empowering and protective.

Regarding the involvement of patients harmed by adverse events in error investigations, we developed a conceptual framework which, based on a literature review, is predicated

on the thoughtful disclosure of adverse events. For each level of the framework (i.e., patient, clinician, and institutional level), we identified barriers to patient participation (e.g., patients' emotional and medical needs, "second victim" burden, existing policies/cultures) and potential strategies to overcome such obstacles (e.g., medical and psychological support systems for patients, easy access to psychological support programs for healthcare providers, implementation of alternative methods for settling claims).

The third aim of this thesis was to investigate the psychological responses and resources (i.e., psychological and psychosomatic symptoms, coping strategies) of healthcare providers to adverse events. The two systematic reviews/meta-analyses demonstrated that the emotional impact of being involved in an adverse event is profound.

Second victims reported a high prevalence and a wide range of symptoms, including troubling memories, anger toward themselves, regret/remorse, distress, and sleeping difficulties. Furthermore, healthcare providers involved in adverse events frequently apply task-oriented (e.g., *Changing work attitude*), emotion-oriented (e.g., *Criticizing or lecturing oneself*) and, to a lesser extent, avoidance-oriented strategies (e.g., *Wishing the situation away*) which may have, depending on the context, positive or negative effects on second victims' personal well-being and professional performance, on the relationship with patients and their caregivers and on the overall quality and safety of care provided by the healthcare system.

Lastly, we outlined ways for promoting a new, blame-free patient safety culture for the next generation of healthcare providers, starting from early medical education and training. Namely, we argued for a new curriculum for professional schools and training programs, enhancing, for instance, patient-centered care, the ability of working in interdisciplinary teams, and promoting evidence-based practices. We also underlined that students should be able to approach and solve individual safety problems applying a systemic approach. Such an innovative medical curriculum may instill a positive safety culture in aspiring healthcare professionals, thus overcoming the prevailing culture of shame, blame, and stigmatization of medical errors.

DISCUSSION

In the recent decades, a considerable literature has grown up around the theme of humanization of care, focusing on theoretical frameworks as well as clinical implications, and connections and overlaps with other theoretical paradigms and clinical models, such as patient-centered and person-focused care, have emerged¹⁻⁶. In our systematic review on humanization of care (see Chapter 2), we aimed to change the approach in the exploration of this topic by selecting only empirical research articles that provided the perspective of the involved stakeholders (i.e., patients, patients' caregivers, healthcare providers) in order to create a common and empirically driven vision for delivering humanized care. Our results highlight the long tradition of South American countries in this field⁷⁻¹⁰ and the existing gaps between the expectations of the protagonists involved in the process of care and routine clinical practice.

The relational aspects of healthcare were the ones most explored and discussed in the included studies. This highlights the need for genuine, authentic relationships among patients, patients' caregivers, and healthcare providers. Such relationships should be based on empathy, transparency, and respect for patient's autonomy, dignity, uniqueness, individuality, and humanity. This evidence broadly supports the work of other authors who previously demonstrated that being empathic¹¹⁻¹³ and transparent¹⁴, treating patient with dignity¹⁵, and engaging patients in their own care considering their preferences¹⁶⁻¹⁸, is linked to improved therapeutic relationships, better patient outcomes and experiences. In the long run, this type of approach can also lead to safer and more cost-effective care¹⁴.

However, in clinical practice, the chance of directly interacting with patients, establishing strong relationships, and thus delivering humanized care is often reduced because of time pressure¹⁹. Other similar barriers identified by our thematic synthesis included fragmented work processes, overwhelming tasks, intense routine, and bureaucratic activities. Further, healthcare systems have been lately affected by staff shortages and scarcity of material resources due to economic imperatives and increasing demands²⁰⁻²². These stressors may lead to burnout, a condition defined by emotional exhaustion, depersonalization and feeling of low professional accomplishment^{23,24}. As Patel et al.²³ point out, healthcare

providers' burnout can negatively affect patient care, potentially evoking a sense of detachment, hostility and cynicism towards patients who are then often "treated as objects rather than human beings"(p.1)²³.

If healthcare institutions provide sufficient human and material resources and adequate working conditions and demonstrate that healthcare providers' well-being is of great importance, healthcare professionals may experience higher job satisfaction, be less susceptible to burnout¹⁹, and deliver better, more humanized care.

Although providing humanized care certainly relies on different factors, by far one of the most important is establishing and strengthening meaningful patient-provider relationships. Investing in these relationships also means to emphasize the role of the involved persons. Following the Safety II approach introduced by Hollnagel, Wears and Braithwaite^{25,26}, it can be argued that empowering patients and their caregivers and supporting healthcare providers in care and risk management represents a way to acknowledge and appreciate these protagonists as beneficial resource for establishing a flexible and resilient healthcare system which delivers high-quality care.

Indeed, the value of involving and empowering patients has been recognized by several researchers, governing bodies and healthcare organizations²⁷⁻³². Nevertheless, empowering patients comes also with challenges^{31,33-36}. This is especially true if highly vulnerable populations are involved in the process of care and safety³⁶. For instance, patients with mental health conditions or patients who were harmed by adverse events might be particularly vulnerable. Since research in this specific area was scarce, two of our studies (see Chapter 3 and 4) concentrated on these two groups of patients.

Our analysis of the focus group discussions revealed that mental health providers consider patients as important partners in the process of risk management who should have a proactive role in enhancing safety. However, the process of empowering patients is seen as highly challenging. Low therapeutic compliance, certain psychopathological conditions (e.g., self harm/suicidal behavior, acute psychotic symptoms), personal aggressions, and a low awareness were viewed as impediments to patient involvement in risk management. Uncertainty pervades also the risk assessment in psychiatry since it depends to a great extent on healthcare providers' subjective perspective. This is partly due to a paucity of

safety practices and clinical protocols tailored to this particular setting^{37,38}. This subjectivity hampers the assessment of mental health providers' objective responsibility in adverse events³⁹. Thus, after an adverse event, particular attention must be paid that mental health providers are not hastily and rashly blamed, and that incident investigations are in line with the concept of just culture, which considers system failures as well as individual behaviors of healthcare providers as potential contributors to adverse events⁴⁰⁻⁴³.

Further, our study suggests that healthcare providers' uncertainty regarding patient involvement partly stems from the difficulty of striking a balance between empowering the patient and ensuring safety. As a side note, this dilemma reminds of healthcare providers' struggle (see Chapter 2) to find a compromise between delivering humanized care and ensuring lifesaving treatment, such as in intensive care situations⁴⁴⁻⁴⁶. Chiovitti's Theory of Protective Empowerment⁴⁷ acknowledges the central role of the therapeutic relationship in encouraging patient autonomy and protecting the patient from harm. This accords with our findings showing that mental health providers place high importance on creating a therapeutic alliance based on trust. Building such a partnership also implies collaborating with the family of the patient, an action which has been strongly recommended by the National Patient Safety Foundation and the Lucian Leape Institute^{30,31}.

Our research highlights that a transparent, respectful, and trustful relationship with patients and their caregivers is crucial not only for humanizing care but also for engaging and empowering patients in care and safety. However, if an adverse event occurs, trust between patients and healthcare providers is often impaired^{48,49} and their relationship is tested. Some authors⁴⁸⁻⁵⁰ suggested that sensible and thoughtful incident investigations involving patients and their caregivers may contribute to their recovery from the event. Indeed, such investigations can help in sharing and processing emotions as well as in reestablishing trust towards healthcare providers. However, actively participating in incident investigations may not be always helpful for patients and caregivers since it may intensify feelings of grief and vulnerability and increase the fear of becoming a victim of future errors^{48,49}. In such case, a patient advocate, representative or a "proxy patient" who has experienced a similar event, may be involved instead⁴⁸.

Despite the importance of this topic and growing emphasis on patient involvement and empowerment^{27,30-32} and transparency¹⁴ in healthcare, there was only little guidance on how to responsibly involve patients in investigations. This led us to review the literature⁴⁸⁻⁵³ and then construct a conceptual framework for approaching patients and patients' caregivers about a potential role in investigating an error made in their care. Our framework argues for a thoughtful adverse event disclosure⁵⁴ before involving the patient. It proposes comprehensive strategies to overcome barriers to patient involvement in incident investigations, which might be related to patient's health and abilities as well as to clinicians' distress and attitude. Organizational, financial, legal aspects, and the safety culture at the institution may also represent obstacles. The proposed approach has also implications for policy, clinical practice, and training which are then discussed further below.

As outlined above, patients and caregivers can add important insights and unique and potentially actionable information to incidents investigations^{53,55,56}, thus representing a strong, valuable resource for a better functioning and more resilient healthcare system. However, it is important to bear in mind that giving patients and caregivers the possibility to actively participate in safety investigations is also the “right thing to do” (p. 8)⁵⁰. As Kok and colleagues argue, patient involvement has both an “epistemological justification” (i.e., recognition of the value of patients' and patient caregivers' perspective and knowledge) and a “moral justification” (i.e., patient involvement as “ethical imperative”) (p. 2)⁵⁰. While the Authors focus only on incident investigations, this reasoning can be transferred also to other fields of patient involvement and empowerment. That is, patients should not only be empowered in care and safety because they are beneficial for the healthcare system but also because they, as humans, should have the space and the means to raise their voice and to actively participate in their own care if they wish to do so.

One of the potential barriers to patient involvement in incident investigation identified in our study was the “second victim burden”. Second victims often suffer from great distress (see Chapter 5) which might prevent them from fully participating in the investigation or supporting their patient through this process. If they do participate, they might be afraid of being blamed and of possible litigations⁴⁸.

We comprehensively assessed the burden of becoming a second victim by performing two systematic reviews/meta-analyses on second victims' emotional distress (see Chapter 5) and coping (see Chapter 6). These were the first meta-analyses so far providing precise estimates of the prevalence of the psychological and psychosomatic symptoms as well as of the frequency of the applied coping strategies. Our findings demonstrate that a large proportion of healthcare providers involved in adverse events is affected by a variety of psychological and psychosomatic symptoms and tries to deal with the impact of these incidents by applying different types of coping strategies (task-, emotion-, and avoidance-oriented).

Although we did not pool the results of the two primary studies reporting prevalence rates of probable posttraumatic stress-disorder (PTSD) due to methodological issues, the overall high prevalence of certain symptoms (i.e., troubling memories, anxiety, depressive symptoms, sleeping problems, loss of confidence, distress) that are frequently linked to posttraumatic stress-disorder^{57,58} was striking. The very high rate of troubling memories (i.e., 81%) among second victims particularly underlines the significant emotional impact of adverse events on this population.

The high rates of guilt, embarrassment, anger at oneself, fear of future errors, frustration and the feeling of inadequacy among second victims (see Chapter 5) should also not be ignored. The presence of these emotions points to an internalized blame culture. Such a culture expects perfection from the healthcare workforce, blames and punishes the individual healthcare provider who is seen as liability to the system and sabotages attempts to implement reporting and learning cultures^{25,40,59}.

Despite this suffering, second victims seem to focus on improving their professional performance, as indicated by the high frequencies of task-oriented strategies, such as *Changing work attitude* and *Following policies and guidelines more accurately and closely*. It emerged that the most common emotion-oriented coping strategies were *Criticizing or lecturing oneself*, *Disclosing the error/talking to/support from medical staff*, and *Apologizing or doing something to make up* and that avoidance-oriented strategies, such as *Trying to hide error/refusing to talk about it* and *Avoidance of patients, procedures, situations*, were the ones least applied. Therefore, it can be assumed that the majority of second victims is inclined to proactively tackle the

challenges that come with adverse events, take personal responsibility, and try to make amends.

Although this attitude can certainly be seen as constructive, the coping strategy *Criticizing and lecturing oneself*, for instance, can become maladaptive, if linked to persistent and excessive feelings of guilt.

Thus, second victims' coping strategies should be interpreted applying a flexible and holistic approach. Aside from few exceptions (e.g., *Use of alcohol/drugs/medication*), most coping strategies cannot be properly categorized as either positive or negative without taking into account contextual and temporal variables (e.g., flexible vs. rigid application, short-term vs. long-term). Further, following a systemic approach³⁹, the quality of coping strategies needs to be evaluated by considering the potential positive and negative effects on second victims themselves (adaptive vs. maladaptive), patients (appropriate vs. inappropriate), and the healthcare system (functional vs. dysfunctional). In regard to healthcare providers, while coping strategies enhancing providers' well-being and alleviating distress can be considered adaptive (e.g., *Problem-solving/concrete action plan*), those negatively affecting emotional, cognitive, and behavioral functioning (e.g., *Being too meticulous*) can be seen as maladaptive⁶⁰⁻⁶². Considering the impact on patients, coping strategies improving patients' welfare and bolstering the therapeutic alliance (e.g., *Paying better attention to the patient*) can be defined as appropriate whereas the strategies decreasing patient satisfaction and eroding this alliance (e.g., *Avoidance of patients, situations, and procedures*) can be categorized as inappropriate. While coping strategies facilitating an effective performance, strengthening the adaptability, creativity, and resilience of human performance (e.g., *Positive reappraisal*), and thus promoting also system resilience²⁵ can be considered functional for the healthcare system, strategies compromising quality and safety (e.g., *Ordering unnecessary, potentially risky tests*) and diminishing healthcare providers' flexibility and resilience (e.g., *Too rigid application of policies and guidelines*) can be characterized as dysfunctional.

Healthcare institutions should create conditions favoring the application of adaptive, appropriate, and functional coping strategies. Indeed, it is crucial to promote a positive safety culture emphasizing fairness, openness, transparency, and learning⁶³ as well as

encouraging a systemic perspective^{39,64}. Thus, healthcare providers will be considered only as the sharp end of any healthcare process, taking into account also latent, systemic conditions that may trigger an adverse event. At the same time, as Braithwaite et al.²⁶ argue, understanding must grow “of how care is delivered so well, so often, under difficult and varying conditions. Healthcare is already far more resilient than we credit it.” (p.3)²⁶, also because healthcare providers are usually highly adaptable to unexpected events²⁵.

IMPLICATIONS FOR POLICY, CLINICAL PRACTICE, AND EDUCATION

Our research suggests that, in order to achieve and sustain a resilient, high-quality healthcare system which empowers patients and caregivers and supports providers, healthcare organizations should strongly invest in humanized, relationship-centered care and adopt a comprehensive approach to risk management by considering systemic elements^{39,65} and by merging the concepts of Safety I and Safety II²⁵.

In particular, the key elements of humanized care proposed earlier suggest several courses of actions for healthcare institutions and providers in order to humanize care, such as establishing meaningful, mutually beneficial relationships with patients and caregivers, ensuring balanced workload for healthcare providers, and providing sufficient human and material resources. Healthcare managers should use these key elements as guidance for launching initiatives that address the various barriers in the process of humanizing care and advance the adoption and use of implementation strategies among the healthcare workforce. Further, clinical practice guidelines for delivering humanized care which take into account relational, organizational, and structural factors should be designed and adapted to different medical settings. Such guidelines should also address other patient-centered or person-focused medical practices closely related to humanized care. For instance, compassionate care^{66,67}, defined as “human response to the vulnerability of others based on caring interpersonal relationships”(p.833)⁶⁶ and narrative medicine⁶⁸⁻⁷¹, described as a medical approach “practiced with narrative skills of recognizing, absorbing, interpreting and being moved by stories of illness”(p. 17)⁶⁸, are widely considered as

beneficial for delivering effective, comprehensive patient care and promoting the patient-provider relationship^{66,68}.

Moreover, patient autonomy, patient involvement as well as shared decision making need to be further promoted in healthcare institutions. As the National Advisory Group on the Safety of Patients in England pointed out, “patient involvement means more than simply engaging people in a discussion about services. Involvement means having the patient voice heard at every level of the service, even when that voice is a whisper” (p.18)⁷². As discussed earlier, patient involvement and empowerment in safety, especially of particularly vulnerable patients (e.g., patients with mental health conditions, patients who were harmed by adverse events) can represent a challenge.

Considering that risk management in mental health care strongly relies on the therapeutic relationship between healthcare providers and patients, it is essential to allocate sufficient human and financial resources to this setting. Furthermore, it is important to provide training opportunities, supervision, and organizational support for healthcare providers who have to find the right balance between empowering the patients and ensuring their safety⁴⁷. Our coding system (see Chapter 3, Figure 1), which was developed to synthesize the focus group content, can help healthcare institutions to identify critical issues regarding patient empowerment in the mental health setting. As depicted in the coding system, critical issues can arise in different areas and categories, such as in *treatment and cure* (e.g., *therapeutic compliance*), *diagnosis and assessment* (e.g., *onset*), *emergency management* (e.g., *self-harm/suicide*), and *comorbidity* (e.g., *drug abuse*). Healthcare organizations should pay attention to specific critical issues like *inappropriate setting and environment*, *patients’ low awareness and reliability*, and *poor teamwork*. Aside from these critical issues, the coding system proposes also several strategies for patient empowerment that are applicable to the same areas (e.g., *treatment and cure*) and categories (e.g., *therapeutic compliance*). Examples for these strategies are *building therapeutic trust/alliance*, *relying on the experience/knowledge of patients*, and *providing information/educate*. These strategies, aligned to safety protocols which are tailored to the specific mental health environment, are expected to serve as valuable complement in the daily clinical practice.

As concerns the participation of patients in incident investigations, our proposed framework might be a useful aid. Striving for a positive safety culture⁶³ should be a priority for healthcare institutions in order to ensure prompt and open adverse event disclosure to patients and caregivers. This is a necessary first step prior to broaching the topic of incident investigation⁵⁴. By being honest and transparent with patients, healthcare providers are also less likely to face malpractice litigation⁷³⁻⁷⁵. Offering training courses in empathic disclosure communication for healthcare providers as well as implementing proactive methods for settling claims (e.g., communication-resolution programs)^{73,74,76} might be effective ways of improving the relation between patients and providers after an adverse event. Importantly, policies encouraging patients and caregivers to take a more active role in the investigation if they wish to do so should be put in place. Further, protocols defining clear strategies to involve all parties in open, transparent discussions need to be established. Instead of only trying to blame an individual (e.g., healthcare provider, patient), such round tables should also work on identifying gaps in the system³⁹. Lastly, healthcare institutions should establish support systems (i.e., medical, psychological, and/or organizational) for both patients and caregivers as well as healthcare providers in the aftermath of the incident and during the entire investigation process.

Indeed, our research on healthcare providers' responses to adverse events underlines the importance of providing support for second victims. Our findings are expected to inform the development of psychological support programs which, tailored to second victims' individual needs, focus not only on psychological and psychosomatic symptoms but also on the applied coping strategies and their effects on all stakeholders. Healthcare managers should ensure that such programs are easily accessible. By improving providers' well-being and encouraging adaptive, appropriate and functional coping strategies, such programs might even have the potential to break the vicious cycle previously mentioned^{77,78}.

Further, it would be beneficial if healthcare providers receive help every time an adverse event occurs, independently from an obvious need for support^{79,80}. The implementation of training courses that enhance the adoption of proactive reactions to work-related stressors (e.g., work overload due to a lack of human and material resources) and unanticipated clinical events may further support healthcare providers. Healthcare

professionals may be then better prepared for responding to stress, less susceptible to burnout and more resilient overall. In case of an adverse event, providers may be more likely to employ coping strategies that have positive effects on themselves, patients' care, and the healthcare system. At the same time, continued efforts by healthcare organizations are necessary to destigmatize mental health issues and the need for psychological help, as several authors have observed⁸⁰⁻⁸².

All these strategies can help create an open, just, and reporting and learning culture in the institution⁶³. By overcoming blame culture⁴⁰ and adopting a systemic^{39,64,65} and a Safety II approach^{25,26}, healthcare providers may not be seen anymore as liability but rather as resource for system flexibility and resilience²⁵.

Broad education can provide a foundation for a safer, more supportive, just, efficient, and resilient healthcare environment. Thus, learning cultures should be fostered and innovative medical curricula developed, implemented, and disseminated, as recommended by the Lucian Leape Institute⁸³. Specific topics that could be discussed in more detail are, for instance, the prevailing culture of blame and stigmatization of medical errors, the experience of being involved in adverse events, the benefits of humanized care, the value of patient's unique perspective, and the delicate balancing act in mental healthcare between patient empowerment and safety, as discussed by Chiovitti⁴⁷.

Instead of only collecting abstract knowledge in classrooms, healthcare professions students should develop early on non-technical competencies⁶³, which can be directly practiced in the medical setting. These include, for example, interpersonal skills⁸³ (e.g., being able to work efficiently in interdisciplinary teams and build trustful relationships with patients and caregivers) as well as the ability to flexibly address individual safety problems. This learning should not stop with the end of medical school or residency but should lead to constant growth and lifelong learning. Multiple stakeholders in professional schools, academic medical centers, and education ministries will need to actively promote and manage these major reforms in medical education⁸⁴ and thus to instill a new type of workplace culture.

Wide-reaching informational campaigns, such as the *WHO World Patient Safety Day*⁸⁵ or the *Patient Empowerment Campaign* organized by the European Patients Forum⁸⁶, can

complement these educational programs by sharing knowledge and increasing public awareness of these issues.

STRENGTHS

The main strengths of this work lay in its innovative, comprehensive approach to the question of how human factors can be fostered in care and risk management in order to be recognized and valued as resource for healthcare system resilience as well as in its ability to provide actionable information for building and sustaining supportive, flexible and thus high-performing healthcare systems. Different methods were carefully selected in order to address individual but related research questions which had not been faced or sufficiently investigated in the past. The following part moves on to describe how this thesis benefited from the key features of some of the chosen techniques.

Performing systematic reviews, we were able to critically evaluate, summarize, and interpret the existing literature focusing on the concept of humanization of care as well as on the emotional distress among second victims and the applied coping strategies. This rigorous approach allowed us to successfully deal with a great amount of complex information and to provide the scientific and healthcare community well-structured syntheses of the existing evidence of the three topics^{87,88}.

To collate the data on the concept of humanization of care, we performed a thematic synthesis⁸⁹. Given the fact that all primary studies had a qualitative or quantitative-qualitative design, we opted for this technique since it is particularly suitable for systematically and transparently synthesizing qualitative data⁸⁹. Furthermore, this method promotes, as highlighted by Thomas and Harden⁸⁹, the generation of “higher order thematic categories” (p.9)⁸⁹. In our project, this advantage helped us to produce the *key elements* and thus to describe the concept of humanization of care.

In order to summarize the findings on second victims’ psychological and psychosomatic symptoms and on coping strategies, we decided to also perform meta-analyses. This gave us the chance to statistically explore and pool the effects from different studies⁸⁸. In fact,

we were able to quantitatively analyze data drawn from a large number of healthcare providers involved in adverse events (i.e., 11,649 and 6,351 reports, respectively) and provide precise estimates of the frequency of second victims' psychological and psychosomatic symptoms and coping strategies.

Finally, performing and analyzing focus group discussions was an adequate starting point for investigating healthcare provider's perspectives on patient empowerment in the mental health setting in regard to risk management. This method is especially appropriate for exploring people's attitudes in healthcare research, as highlighted by Kitzinger⁹⁰. We then selected inductive instead of deductive content analysis because there were no studies which had examined this topic before and in order to reduce researcher subjectivity^{91,92}. The application of this mixed-methods-approach allowed us to gather and systematically analyze plentiful qualitative data⁹¹.

LIMITATIONS

This thesis should be also interpreted in light of certain limitations.

While it aimed to provide a comprehensive vision of the human factor as resource for healthcare resilience, it is worthwhile noting that our investigations have focused so far only on a relatively small part of this broad field of study and offer just potential ways of supporting and empowering patients, patients' caregivers, and healthcare providers involved in the process of care and safety.

In addition, two of the explored topics, namely involving patients in patient safety investigations (see Chapter 4) and incorporating the topic of a positive patient safety culture in medical education and training (see Chapter 7), would have certainly benefited from a more systematic, objective research approach. However, an empirical investigation or a systematic review of the existing literature on these issues were beyond the scope of the respective articles (i.e., review article, guest editorial).

Although the methods applied in our studies showed numerous strengths, as highlighted above, they also suffer from some weaknesses which could have influenced our findings.

Firstly, the intrinsic limitations associated with systematic reviews (see Chapter 2, 5, 6) should be considered. Despite great search efforts of electronic databases and additional literature, we may have nonetheless failed to detect some studies. This may apply in particular to our project about humanization of care since we restricted our search to studies published in English, Italian, or German and searched published and grey literature only in the medical field and not in the fields of humanities, social sciences, and philosophy. Moreover, since we applied relatively few search terms (i.e., “humanization/humanisation of care”, “dehumanization/dehumanization of care”), studies that assessed elements of humanization of care (e.g., liberal visitation policies in pediatric care) or medical practices closely related to humanized care (e.g., narrative medicine, compassionate care) but did not specifically include our search terms could not be detected.

Moreover, shortcomings of the articles included in the systematic reviews and meta-analyses may have influenced our findings to some extent. The qualitative or quantitative-qualitative design and the small sample sizes of the studies focusing on humanization of care limited the generalizability of the findings. However, this was partly compensated by the detailed insight into patients’, caregivers’, and healthcare providers’ perspectives and opinions provided in the selected articles⁹³.

Further, the primary studies included in our two meta-analyses varied in terms of publication year, cultural background, characteristics of the adverse event, healthcare setting, providers’ profession, and instruments used; in some instances, a wide variability in the reported frequency rates became apparent as well. However, since quantitative analyses suggested in most cases negligible or only moderate statistical heterogeneity across studies and never considerable heterogeneity, we decided to not further examine this variability.

Our analyses may have also been affected by some limitations related to the overwhelmingly cross-sectional, retrospective, self-report design of the included studies. Different biases, such as the self-selection⁹⁴, recall⁹⁵, and social desirability bias⁹⁶, may have somehow influenced the results.

Moreover, also the possible role of the sampling bias⁹⁷ should be addressed. Indeed, for the focus group discussions, we recruited only healthcare providers who previously

attended an educational course on risk management. However, we deliberately set this criterion since we considered a common background in risk management a useful prerequisite for guiding participants more easily during the focus group discussions.

Lastly, two of the methods used in our studies (see Chapter 2 and 3, respectively), namely thematic synthesis⁸⁹ and inductive content analysis of focus group discussion⁹¹, have similar weaknesses which may have negatively affected our findings. Indeed, they are prone to subjectivity^{89,91}. To reduce this bias, two researchers performed in both studies all methodological steps independently from each other, then critically discussed their findings, and resolved disagreements by consensus and/or involving a third researcher.

FUTURE RESEARCH DIRECTIONS

Our multi-faceted research on the role of the human factor in care and risk management has thrown light on several new questions which should be further examined.

Although the proposed key elements of humanization can serve as preliminary guidance for providing humanized care, future research should be undertaken to develop a full picture of this concept. Given that our systematic search of the literature just revealed qualitative studies assessing stakeholders' perspectives on humanization of care, further quantitative research may help in establishing a greater degree of data rigidity and replicability and in improving the generalizability of the findings.

Moreover, formalizing a model of humanization of care that adopts a global perspective requires not only international studies but also the examination and quantitative assessment of specific implementation strategies. Additional sub-constructs within the relational, organizational, and structural area should be identified and the links between the model of humanized care and similar medical practices, such as narrative medicine and compassionate care, more closely examined.

Further, healthcare institutions that are planning to establish specific programs to humanize care, as recommended earlier, should first conduct pilot studies to assess feasibility and acceptability. Then, after the implementation of such programs, their

effectiveness and the satisfaction of all stakeholders, but in particular of patients and their caregivers, should be evaluated.

Moreover, there is still room for further progress in determining how patients and caregivers want to be involved in their own care⁹⁸ and safety.

After having investigated healthcare providers' perspectives on the empowerment of patients with mental health illnesses, we plan to conduct focus group discussions with these patients. Using our coding system, we aim to assess if they have a similar understanding of the positive and negative aspects of their empowerment. This methodology would be particularly fitting for exploring this topic since it is associated with direct patient involvement^{90,91,99}. As Moretti et al.⁹¹ underline, it “empowers participants to become active partners in the research process and develop an authentic patient centered approach”(p. 426)⁹¹.

Involving patients harmed by adverse events in patient safety investigations is another aspect requiring further research. In particular, additional empirical studies including patients, patient caregivers, and healthcare providers' voices and assessing the potential positive impact of such an involvement are needed. The deriving evidence could represent a strong argument to provide funds covering additional costs (e.g., support staff for the involved patients and healthcare providers) and would help in promoting patient involvement and empowerment in safety in general.

To examine the question how healthcare providers can be supported in care and risk management, we performed two meta-analyses (see Chapter 5 and 6). These are part of a larger project named *WTHSTAND – Support After Adverse Events*, established at the University of Verona, Italy, in 2016 and expected to be completed in 2023. WTHSTAND is composed of five phases, graphically represented in Figure 1.

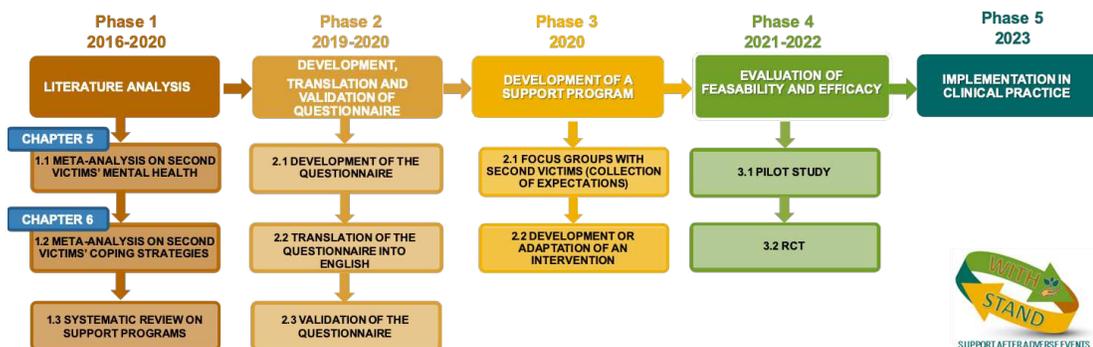


Figure 1. Different phases of WITHSTAND over time (2016-2023)

Since a validated questionnaire focusing not only on second victims' mental health but also on their coping mechanisms is still missing, such an instrument will be also developed and validated within the WITHSTAND project. The self-report items, based on the results of our meta-analyses, retrospectively explore healthcare providers' emotional distress before and after an adverse event and the employed coping strategies. This questionnaire is expected to be used for research purposes and, in particular, as screening tool to identify healthcare providers who may need specific psychological support.

As stated above, healthcare institutions should have psychological support programs for second victims, such as RISE or forYOU in the United States¹⁰⁰⁻¹⁰². We are planning to develop the first Italian program. It will be informed by the findings of our two meta-analyses (see Chapter 5 and 6), by the results of a systematic review on the feasibility and effectiveness of existing support programs as well as by the results of focus group discussions with experts and second victims. Before implementing this intervention in the clinical practice, we will perform a pilot study to assess its acceptability and feasibility. Subsequently, a randomized control trial to evaluate its efficacy will also be conducted.

The studies which were included in our meta-analyses did not assess if healthcare providers had a history of mental disorders. Although our questionnaire will partly address this aspect by asking the participants to recall their emotional distress prior to the adverse event, the applied retrospective approach will leave room for certain biases (e.g., recall bias⁹⁵). Such biases could be overcome by longitudinal studies which could follow a sample

of healthcare providers over the years, record the incidence of adverse events, and evaluate healthcare providers' mental health before and after an incident.

Moreover, since we were only able to pool the prevalence rates of one psychosomatic symptom (i.e., sleeping difficulties) due to methodological issues (i.e., insufficient data and heterogeneous variables of interest), further research is required to better understand prevalence rates of psychosomatic symptoms among second victims.

Furthermore, given that the studies included in our meta-analyses differed in some respects, as noted previously, additional studies should be carried out to investigate if there are significant differences in second victims' psychological and psychosomatic symptoms or coping strategies across time, cultures, types and outcomes of the incidents, professions, and settings of care.

As discussed earlier, reforms in early medical education and training can help creating a more resilient, supportive, and high-quality healthcare system. Establishing such innovative curricula will also provide the spur to further research. Notably, challenges, advantages and the long-term impact of such educational programs will have to be assessed.

CONCLUSIONS

Our findings underline that establishing and strengthening patient-provider relationships, characterized by empathy, transparency, respect, and trust, is the core element of humanized healthcare. Promoting these relationships also implies for healthcare institutions focusing on and caring for the individual persons that are part of this connection. Empowering patients and their caregivers in care and risk management and adequately supporting healthcare providers, in particular in the aftermath of adverse events, represents a promising way to recognize and value these stakeholders as beneficial resource for a flexible, resilient, and thus high-performing healthcare system based on a positive safety culture.

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95. Last JM. *A Dictionary of Epidemiology.* Oxford, UK: Oxford University Press, 2000.
96. Van de Mortel TF. Faking it: social desirability response bias in self-report research. *Aust J Adv Nurs.* 2008;25:40–48.
97. Lavrakas PJ. *Encyclopedia of survey research methods (Vols. 1-0).* Thousand Oaks, CA: Sage Publications, Inc, 2008.
98. Barello S, Graffigna G, Vegni E. Patient engagement as an emerging challenge for healthcare services: mapping the literature. *Nurs Res Pract.* 2012;2012:905934.
99. Bensing J, Dulmen S, de Haes H. Communicatie tussen patiënten en hun hulpverleners. In: Lechner L, Mesters I, Bolman C, editors. *Gezondheidspsychologie bij patiënten.* Assen, The Netherlands: Koninklijke van Gorcum BV/Open Universiteit, 2010. p. 109–34.
100. Edrees H, Connors C, Paine L, et al. Implementing the RISE second victim support programme at the Johns Hopkins Hospital: a case study. *BMJ Open.* 2016;6:e011708.
101. Connors C, Norvell M, Wu AW. *Caregivers in distress: rise peer responder basic training.* Baltimore, MD: The Johns Hopkins University, The Johns Hopkins Hospital, and the Johns Hopkins Health System, 2014.
102. Scott SD, Hirschinger LE, Cox KR, et al. Caring for our own: deploying a systemwide second victim rapid response team. *Jt Comm J Qual Patient Saf.* 2010;36:223–240.

Appendix

APPENDIX A

Supplementary Material of Chapter 2

Humanization of Care: Key Elements Identified by Patients,
Caregivers, and Healthcare Providers. A Systematic Review

Online Resource 1. Number of records retrieved from the databases (without removal of duplicates)

Database	Number of retrieved records*
CINHAL	70
Medline	129
Pubmed	852
PsycInfo	201
Web of Science	422
Total Amount	1,674

* based on the search strategy *humanization of care* OR *humanisation of care* OR *dehumanization of care* OR *dehumanisation of care* applied for each database

Online Resource 2. Additional searches in three databases of gray literature

OpenGrey

Date of search: January 7, 2018

Search terms: *humanization of care, humanisation of care, dehumanization of care, dehumanisation of care*

greylit.org

Date of Search: January 7, 2018

Search terms: *humanization of care, humanisation of care, dehumanization of care, dehumanisation of care*

PsycEXTRA

Date of search: January 7, 2018

Search terms: *humanization of care, humanisation of care, dehumanization of care, dehumanisation of care*

Online Resource 3. List of excluded studies

Study	Reason for exclusion
Alonso JP. Cuidados paliativos: entre la humanización y la medicalización del final de la vida [Palliative care: between humanization and medicalization at the end of life]. <i>Cien Saude Colet.</i> 2013;18:2541-8.	Wrong language: Full-text just available in Spanish.
Araújo FP, Ferreira MA. Representações sociais sobre humanização do cuidado: implicações éticas e morais [Social representations of care humanization in the conception of hospitalized users]. <i>Rev Bras Enferm.</i> 2011;64:287-93.	Wrong language: Full-text just available in Portuguese.
Barbosa IA, Silva MJP. Cuidado humanizado de enfermagem: o agir com respeito em um hospital universitário [Humanization in nursing care: acting with respect in a school hospital]. <i>Rev Bras Enferm.</i> 2007;60:546-51.	Wrong language: Full-text just available in Portuguese.
Buffoli M, Bellini E, Bellagarda A, Di Noia M, Nickolova N, Capolongo S. Listening to people to cure people: the LpCp-tool, an instrument to evaluate hospital humanization. <i>Ann Ig.</i> 2014;26:447-55.	Wrong focus: Investigation of evaluation tools in hospitals.
Buffoli M, Bellini E, Dell'Ovo M, Gola M, Nachiero D, Rebecchi A, Capolongo S. Humanisation and soft qualities in emergency rooms. <i>Ann Ist Super Sanita.</i> 2016. 52:40-7.	Wrong focus: Development of a tool for the examination of humanization and soft qualities
Calne S. Dehumanisation in intensive care. <i>Nursing Times</i> 1994;90:31-3.	Full text not available.
Castro JC, Clapis MJ. Parto humanizado na percepção das enfermeiras obstétricas envolvidas com a assistência ao parto [Humanized birth according to obstetric nurses involved in birth care]. <i>Rev Lat Am Enfermagem.</i> 2005;13:960-67.	Wrong language: Full-text just available in Portuguese.
Chernicharo IM, Freitas FDS, Ferreira MA. Representações sociais da humanização do cuidado na concepção de usuários hospitalizados [Social representations of care humanization in the conception of hospitalized users]. <i>Saúde e Sociedade.</i> 2013;22:830-39.	Wrong language: Full-text just available in Portuguese.
Corbani NMS, Brêtas ACP, Matheus MCC. Humanização do cuidado de enfermagem: o que é isso? [Humanization of nursing care: what is this?]. <i>Rev Bras Enferm.</i> 2009;62:349-54.	Wrong language: Full-text just available in Portuguese.

<p>Dias MAB, Deslandes SF. Expectativas sobre a assistência ao parto de mulheres usuárias de uma maternidade pública do Rio de Janeiro, Brasil: os desafios de uma política pública de humanização da assistência. [Patients' expectations concerning childbirth care at a public maternity hospital in Rio de Janeiro, Brazil: challenges for the humanization of obstetric care]. <i>Cad Saude Publica</i>. 2006;22:2647-55.</p>	<p>Wrong language: Full-text just available in Portuguese.</p>
<p>Duarte MLC, Noro A. Humanização: uma leitura a partir da compreensão dos profissionais da enfermagem [Humanization: a reading from the understanding of nursing professionals]. <i>Revista Gaúcha de Enfermagem</i>. 2010;31: 685-92.</p>	<p>Wrong language: Full-text just available in Portuguese.</p>
<p>França APM, Mendes ARB, Barrias MIF. OC34 Paediatric rehabilitation humanizing nursing care to children and their families. <i>Nurs Child Young People</i>. 2016;28:78.</p>	<p>Full text not available.</p>
<p>Giantaglia FN, Garcia ES, Rocha LC, Costa Godhino MS, Leite EP, Calheiros CA. The care of nurses of an obstetric residence program under the scope of humanization. <i>Journal of Nursing UFPE on line</i>. 2017;11: 1882-91.</p>	<p>Wrong focus: evaluation of nursing care in obstetrics</p>
<p>Gomes AMA, Moura ERF, Nations MK, Alves MSCF. Ethnic evaluation of hospital humanization by the users of the brazilian unified health system and their mediators. <i>Rev Esc Enferm USP</i>. 2008; 42:635-42.</p>	<p>Wrong focus: evaluation of the humanized care provided by a specific hospital.</p>
<p>Heras La Calle G, Oviés ÁA, Tello VG. A plan for improving the humanization of intensive care units. <i>Intensive Care Med</i>. 2017;43:547-9.</p>	<p>Wrong type of article.</p>
<p>Hoga LAK. A dimensão subjetiva do profissional na humanização da assistência à saúde: uma reflexão [The professional subjective dimension in health care humanization: a reflection]. <i>Rev Esc Enferm USP</i>. 2004; 38:13-20.</p>	<p>Wrong language: Full-text just available in Portuguese</p>
<p>Junges JR, Barbiani R, Fernandes RBP, Prudente J, Schaefer R, Kolling V. O discurso dos profissionais sobre a demanda e a humanização [What do professionals have to say about the demand and humanization of health services]. <i>Saúde Soc</i>. 2012;21:686-97.</p>	<p>Wrong language: Full-text just available in Portuguese</p>
<p>Lima TJV, Arcieri RM, Garbin CAS, Moimaz SAS, Saliba O. Humanização na atenção básica de saúde na percepção de idosos [Humanization in primary</p>	<p>Wrong language: Full-text just available in Portuguese</p>

health care from the viewpoint of elderly]. <i>Saúde Soc.</i> 2014;23:265-76.	
Lopes FM, Brito ES. Humanization of physiotherapy care: study with patients post-stay in the intensive care unit. <i>Rev Bras Ter Intensiva.</i> 2009;21:283-91.	Wrong focus: evaluation of humanized physiotherapy care provided by a specific hospital.
Marçal F, Nunes MJ, Pedrosa LAK. O significado da humanização da assistência entre profissionais de enfermagem no contexto da Reforma Psiquiátrica. [The meaning of the humanization of care among nursing professionals in the context of the Psychiatric Reform.] <i>Saúde Coletiva</i> 2010;7:237-40.	Wrong language: Full-text just available in Portuguese
Mongiovi VG, Anjos RCCBL, Soares SBH, Lago-Falcão TM. Reflexões conceituais sobre humanização da saúde: concepção de enfermeiros de Unidades de Terapia Intensiva [Conceptual reflections on health humanization: conception of nurses from Intensive Care Units]. <i>Rev Bras Enferm.</i> 2014; 67:306-11.	Wrong language: Full-text just available in Portuguese
Oliveira NRG, Assis TR, Amaral WND, Falone VE, Salviano LMO. Assistance to Normal Delivery in Two Public Maternities: Perception of the Health Professionals. <i>Rev Bras Ginecol Obstet</i> 2017;39:202-8.	Wrong focus: evaluation of the labor process in two hospitals
Pinho LB, Santos SMA. Dialética do cuidado humanizado na UTI: contradições entre o discurso e a prática profissional do enfermeiro [Dialectics for humanized care in ICUS: contradictions between professional nursing discourse and practice]. <i>Rev Esc Enferm USP.</i> 2008;42:66-72.	Wrong language: Full-text just available in Portuguese
Rolim KMC, Cardoso MVLML. O discurso e a prática do cuidado ao recém-nascido de risco: refletindo sobre a atenção humanizada [Discourse and practice of care to newborns at risk: reflecting about humanized care]. <i>Rev Lat Am Enfermagem.</i> 2006;14:85-92.	Wrong language: Full-text just available in Portuguese
Santos EB, Bevilacqua PD. A integralidade e humanização no atendimento prestado pelos serviços de saúde [Integrity and Humanization in Caregiving by Health Services]. <i>Revista de Atenção Primária a Saúde.</i> 2012;15:220-6.	Wrong language: Full-text just available in Portuguese
Seoane AF, Fortes PAC. Percepção de médicos e enfermeiros de unidades de assistência médica ambulatorial sobre humanização nos serviços de saúde [Physicians and nurses' perception of the	Wrong language: Full-text just available in Portuguese

outpatient medical care regarding humanization in health services]. <i>Saúde Soc.</i> 2014;23:1408-16.	
Silva RMCRA, Oliveira DC, Pereira ER. The discursive production of professionals about humanizing health: singularity, rights and ethics. <i>Rev Lat Am Enfermagem.</i> 2015;23:936-44.	Not sufficient results available (only one short paragraph).
Souza DN, Souza FN. Nursing Teaching Strategies by Encouraging Students' Questioning, Argumentation and Explanation. <i>Rev Esc Enferm USP.</i> 2014;48:155-63.	Wrong focus: Investigation of nursing students' perceptions of regarding anthropology and Sociology of health
Souza TG, Gaíva MA, Modes PS. A humanização do nascimento: percepção dos profissionais de saúde que atuam na atenção ao parto. [The Humanization of birth: how health professionals working in delivery care perceive it]. <i>Revista Gaúcha de Enfermagem</i> 2011;32:479-86.	Wrong language: Full-text just available in Portuguese
Souza KMO, Ferreira SD. Assistência humanizada em UTI neonatal: os sentidos e as limitações identificadas pelos profissionais de saúde [Humanized attention in neonatal intensive-care unit: senses and limitations identified by health professionals]. <i>Cien Saude Colet.</i> 2010;15:471-80.	Wrong language: Full-text just available in Portuguese
Spir EG, Soares AVN, Wei CY, Aragaki IMM, Kurcgant P. A percepção do acompanhante sobre a humanização da assistência em uma unidade neonatal [The companion's perception about the humanization of assistance at a neonatal unit]. <i>Rev Esc Enfermagem USP.</i> 2011;45:1048-54.	Wrong focus: evaluation of humanization of assistance at a specific neonatal unit.
Sueiras P, Romano-Betech V, Vergil-Salgado A, Hoyos A, Quintana-Vargas S, Ruddick W, et al. (2017). Today's medical self and the other: Challenges and evolving solutions for enhanced humanization and quality of care. <i>PloS One</i> 2017;12:e0181514.	Wrong focus: pairing of evidence-based medicine with values-based medicine
Umenai T, Wagner M, Page LA, Page LA, Faundes A, Rattner D, et al. Conference agreement on the definition of humanization and humanized care. <i>Int J Gynecol Obstet.</i> 2001;75:S3-S4.	Wrong type of article.
Vila VS, Rossi LA. [Cultural meaning of humanized care at intensive care units: „lots of words, little action“]. <i>Rev Lat Am Enfermagem.</i> 10:137-44.	Wrong language: Full-text just available in Portuguese

Online Resource 4. Critical appraisal results for included studies using the JBI Critical Appraisal Checklist for Qualitative Research

	1. Congruity between stated philosophical perspective and research methodology	2. Congruity between research methodology and research question or objectives	3. Congruity between research methodology and data collection methods	4. Congruity between research methodology and representation and analysis of data	5. Congruence between the research methodology and the interpretation of results	6. Locating the researchers culturally or theoretically	7. Influence of the researcher on the research, and vice-versa is addressed	8. Representation of participants and their voices	9. Ethical approval by an appropriate body	10. Relationship of conclusions to analysis, or interpretation of the data	Absolute number of criteria met
Backes et al. (2007)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10
Baratto et al. (2016)	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	9
Behruzi et al. (2010)	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	9
Behruzi et al. (2014)	✓	✓	✓	✓	✓	?	✓	✓	✓	✓	9
Brito, Carvalho (2010)	✓	✓	✓	✓	✓	✓	X	?	✓	✓	8
Brophy et al. (2016)	✓	✓	✓	✓	✓	✓	?	✓	✓	✓	9
Calegari et al. (2015)	✓	✓	✓	?	?	✓	X	?	✓	✓	6
Cassiano et al. (2015)	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	9
Chernicharo et al. (2014)	✓	✓	?	?	✓	✓	X	✓	✓	✓	7
Coscrato, Villela Bueno (2015)	✓	✓	✓	?	✓	?	X	✓	✓	✓	7
Evangelista et al. (2016)	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	9
Grisales-Naranjo, Arias-Valencia (2013)	✓	✓	✓	?	?	?	X	✓	✓	✓	6

Marin et al. (2010)	✓	✓	✓	?	?	✓	X	✓	✓	✓	7
Oliveira et al. (2015)	✓	✓	✓	✓	?	✓	X	✓	✓	✓	8
Reis et al. (2013)	✓	✓	✓	?	?	✓	X	✓	✓	✓	7
Santos et al. (2012)	✓	✓	✓	✓	✓	✓	?	✓	✓	✓	9
Silva, Santos, Silva, Reis, Andrade (2015)	✓	✓	✓	✓	?	✓	X	✓	✓	✓	8
Silva, Oliveira, Pereira (2015)	✓	✓	✓	?	?	✓	?	✓	✓	✓	7
Spir et al. (2011)	✓	✓	✓	✓	✓	✓	X	✓	✓	?	8
Versiani et al. (2015)	✓	✓	✓	?	✓	?	X	✓	✓	✓	7

APPENDIX B

Additional File of Chapter 3

Patient empowerment in risk management: a mixed-method study
to explore mental health professionals' perspective

Additional file 1. Sub-categories (strategies and critical issues) divided by thematic area and category

Thematic area ^o (level 2)	Category ^o (level 3)	Strategy		Critical issue	
		Sub-categories (n) (Level 4)		Sub-categories (n) (Level 4)	
Treatment and cure <i>Every comment referring to patient's path of care, either regarding pharmacological treatment or every other therapeutic approach planned for the patient</i>	Therapeutic compliance (256) <i>Every comment referring to psychiatric patient's compliance to his/her therapeutic program, in terms of pharmacological therapy and of any other aspect regarding the management of disability</i>	-	Building therapeutic trust/alliance (34)*	-	Inappropriate setting and environment (9)
		-	Collecting information (6)	-	Patients' low awareness, reliability, accessibility (22)
		-	Handling HPs' emotions (2)	-	Poor teamwork (14)
		-	Handling patients' emotions (1)	-	HPs inadequately trained or inexperienced (8)
		-	Individualized healthcare plan (8)	-	Subjective risk-assessment or unpredictable patients' behaviors (13)
		-	Motivating the patient (11)	-	Impact of risk-management on the process of care/empowerment/autonomy (10)
		-	Promoting collaboration with family (7)	-	Unsupportive/problematic caregivers (14)
		-	Promoting collaboration with other services of the healthcare network (1)	-	Potential threats to the therapeutic process/alliance (13)
		-	Providing information/education (26)	-	Lack of resources and healthcare/social network (2)
		-	Relying on the experience/knowledge of HPs (9)	-	Self-harming patients' attitudes and behaviors (6)
		-	Relying on the experience/knowledge of patients (24)	-	Linguistic and cultural barriers (1)
		-	Team-building (8)	-	Overwhelming and burnout of HPs (2)
		-	Training HPs (5)		
	Therapeutic error (78) <i>Every comment referring to errors in the administration and management of the pharmacological therapy (also known as skill-based or execution errors)</i>	-	Building therapeutic trust/alliance (2)	-	Inappropriate setting and environment (1)
		-	Collecting information (3)	-	Patients' low awareness, reliability, accessibility (4)
		-	Individualized healthcare plan (1)	-	Poor teamwork (8)
		-	Promoting collaboration with family (2)	-	HPs inadequately trained or inexperienced (6)
		-	Providing information/education (12)	-	Subjective risk-assessment or unpredictable patients' behaviors (2)
		-	Relying on the experience/knowledge of HPs (5)	-	Impact of risk-management on the process of care/empowerment/autonomy (3)

		<ul style="list-style-type: none"> - Relying on the experience/knowledge of patients (22) - Team-building (3) 	<ul style="list-style-type: none"> - Potential threats to the therapeutic process/alliance (4)
	<p>Relapse prevention/symptom management (195)</p> <p><i>Every comment referring to the management of patient's chronic symptoms and/or of symptoms' relapse prevention.</i></p> <p><i>The symptoms of acute psychotic states falling into the macro-area "emergency management" are not included.</i></p>	<ul style="list-style-type: none"> - Appropriate setting and environment (10) - Building therapeutic trust/alliance (24) - Collecting information (3) - Handling HPs' emotions (3) - Handling patients' emotions (4) - Individualized healthcare plan (17) - Motivating the patient (4) - Promoting collaboration with family (20) - Providing information/educate (10) - Relying on the experience/knowledge of HPs (6) - Relying on the experience/knowledge of patients (7) - Team-building (5) - Training HPs (1) 	<ul style="list-style-type: none"> - Inappropriate setting and environment (13) - Patients' low awareness, reliability, accessibility (8) - Poor teamwork (8) - HPs inadequately trained or inexperienced (12) - Subjective risk-assessment or unpredictable patients' behaviors (12) - Impact of risk-management on the process of care/empowerment/autonomy (3) - Unsupportive/problematic caregivers (10) - Potential threats to the therapeutic process/alliance (4) - Lack of resources and healthcare/social network (4) - Linguistic and cultural barriers (3) - Being overwhelmed and burnout of HPs (4)
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Diagnosis and assessment</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Every comment referring to the first diagnosis/assessment of the psychiatric patient</p>	<p>Onset (6)</p> <p><i>Every comment referring to the first diagnosis at the onset of the symptoms.</i></p> <p><i>Comments regarding acute psychotic symptoms fall into this area if the main theme is the diagnosis, while they fall into the macro-area "emergency management" and into the micro-area "acute psychotic status" if the main theme is the management of the acute phase.</i></p> <p><i>Comments regarding the management of "chronic" symptoms (i.e., symptoms</i></p>	<ul style="list-style-type: none"> - 	<ul style="list-style-type: none"> - Patients' low awareness, reliability, accessibility (1) - Unsupportive/problematic caregivers (4) - Potential threats to the therapeutic process/alliance (1)

that remain or reappear after the "first diagnosis") fall into the macro-area "treatment and cure" and into the micro-area "relapse prevention/symptom management".

<p>Stigma (7) Every comment referring to stigma usually linked to the first diagnosis and which can lead to "risky" experiences of non-acceptance/denial of the problem that must be appropriately managed to avoid consequences for patient safety</p>	<ul style="list-style-type: none"> - Individualized healthcare plan (2) - Promoting collaboration with family (1) 	<ul style="list-style-type: none"> - HPs inadequately trained or inexperienced (1) - Impact of risk-management on the process of care/empowerment/autonomy (1) - Lack of resources and healthcare/social network (2)
<p>Diagnostic error (7) Every comment referring to diagnostic errors or delays (also known as knowledge-based mistakes or errors based on incorrect reasoning)</p>	<ul style="list-style-type: none"> - Collecting information (1) - Promoting collaboration with other services of the healthcare network (2) - Providing information/education (2) 	<ul style="list-style-type: none"> - Subjective risk-assessment or unpredictable patients' behaviors (1) - Linguistic and cultural barriers (1)
<p>Assessment of social needs (37) Every comment referring to the multi-dimensional evaluation of the psychiatric patient</p>	<ul style="list-style-type: none"> - Building therapeutic trust/alliance (1) - Collecting information (2) - Individualized healthcare plan (4) - Motivating the patient (1) - Promoting collaboration with family (1) - Providing information/education (1) - Relying on the experience/knowledge of HPs (1) - Team-building (1) 	<ul style="list-style-type: none"> - Inappropriate setting and environment (1) - Patients' low awareness, reliability, accessibility (1) - Poor teamwork (2) - HPs inadequately trained or inexperienced (3) - Subjective risk-assessment or unpredictable patients' behaviors (2) - Impact of risk-management on the process of care/empowerment/autonomy (5) - Unsupportive/problematic caregivers (3) - Potential threats to the therapeutic process/alliance (1) - Lack of resources and healthcare/social network (5)

Emergency management
Every comment referring to the diagnosis and assessment of the patient in an acute phase and to the treatment and cure of the patient receiving compulsory medical treatment as well as to the application of restraining and the management of aggression against self and against others

<p>Self-harm/suicide (36) <i>Every comment referring to the management of self-injury or suicidal behavior (including suicidal ideation)</i></p>	<ul style="list-style-type: none"> - Appropriate setting and environment (5) - Building therapeutic trust/alliance (2) - Handling patients' emotions (2) - Promoting collaboration with family (1) - Providing information/educate (2) - Relying on the experience/knowledge of HPs (5) - Relying on the experience/knowledge of patients (1) - Team-building (1) 	<ul style="list-style-type: none"> - Being overwhelmed and burnout of HPs (1) - Inappropriate setting and environment (6) - HPs inadequately trained or inexperienced (1) - Potential threats to the therapeutic process/alliance (2) - Aggressiveness towards HPs (1) - Self-harming patients' attitudes and behaviors (7)
<p>Aggressive Behavior (65) <i>Every comment referring to aggressive behavior towards others (often considered as "states of psychomotor agitation") Aggressive behavior towards others associated with substance abuse or organic states are considered as "delirium" and fall into the macro-area "comorbidity".</i></p>	<ul style="list-style-type: none"> - Appropriate setting and environment (3) - Building therapeutic trust/alliance (4) - Collecting information (1) - Handling patients' emotions (1) - Promoting collaboration with family (2) - Providing information/education (3) - Relying on the experience/knowledge of HPs (2) - Relying on the experience/knowledge of patients (2) - Team-building (3) - Training HPs (2) 	<ul style="list-style-type: none"> - Inappropriate setting and environment (10) - Patients' low awareness, reliability, accessibility (2) - Poor teamwork (1) - HPs inadequately trained or inexperienced (2) - Subjective risk-assessment or unpredictable patients' behaviors (3) - Impact of risk-management on the process of care/empowerment/autonomy (1) - Unsupportive/problematic caregivers (2) - Aggressiveness towards HPs (13) - Linguistic and cultural barriers (7) - Being overwhelmed and burnout of HPs (1)
<p>Involuntary treatment (21) <i>Every comment referring to the management of involuntary treatment, independently of the underlying cause (e.g.,</i></p>	<ul style="list-style-type: none"> - Building therapeutic trust/alliance (3) - Handling patients' emotions (1) - Individualized healthcare plan (1) 	<ul style="list-style-type: none"> - Inappropriate setting and environment (1) - Patients' low awareness, reliability, accessibility (1) - Poor teamwork (1)

<p><i>psychiatric disease, substance addiction, organic delirium)</i></p>	<ul style="list-style-type: none"> - Motivating the patient (1) - Promoting collaboration with other services of the healthcare network (2) - Relying on the experience/knowledge of HPs (1) - Team-building (1) 	<ul style="list-style-type: none"> - Subjective risk-assessment or unpredictable patients' behaviors (1) - Impact of risk-management on the process of care/empowerment/autonomy (7)
<p>Physical/pharmaceutical restraint (12) <i>Every comment referring to both physical and pharmacological restraints, regardless of the underlying cause. The category "compulsory treatment" is used for all comments linked to any treatment "against the will of the patient" and somehow affecting his/ her freedom. The category "restraint" is used whenever the comments refer to the management of restraints as means with specific drawbacks also in the area of patient safety.</i></p>	<ul style="list-style-type: none"> - Handling patients' emotions (1) - Relying on the experience/knowledge of HPs (3) - Team-building (1) 	<ul style="list-style-type: none"> - Patients' low awareness, reliability, accessibility (1) - Impact of risk-management on the process of care/empowerment/autonomy (5) - Unsupportive/problematic caregivers (1)
<p>Acute psychotic status (25) <i>Every comment referring to the management of acute psychotic states linked to a psychiatric diagnosis. If the acute psychotic state is linked to comorbidity (e.g., substance addiction or organic states), then the comment falls into the macro-area "comorbidity". Aspects linked to the first diagnosis (rather than the management) of an acute psychotic state fall into the macro-area "diagnosis and</i></p>	<ul style="list-style-type: none"> - Building therapeutic trust/alliance (3) - Handling patients' emotions (2) - Individualized healthcare plan (1) - Promoting collaboration with family (1) - Providing information/education (2) - Relying on the experience/knowledge of HPs (1) - Relying on the experience/knowledge of patients (2) - Team-building (1) 	<ul style="list-style-type: none"> - Inappropriate setting and environment (1) - Patients' low awareness, reliability, accessibility (2) - Poor teamwork (4) - Subjective risk-assessment or unpredictable patients' behaviors (3) - Impact of risk-management on the process of care/empowerment/autonomy (1) - Lack of resources and healthcare/social network (1)

evaluation” and into the micro-area “onset”.

Comorbidity
Every comment referring to the management of the psychiatric patient who has at the same time a diagnosis of drug abuse or organic comorbidities

Drug abuse (5)
Every comment referring to addiction to or abuse of psychoactive substances (including alcohol addiction and abstinence). Comments regarding acute psychotic states directly linked to substance abuse fall into this category. Comments regarding involuntary treatment and use of restraint for patients with substance abuse fall into the macro-area “Emergency management”.

- **Inappropriate setting and environment (3)**
- **HPs inadequately trained or inexperienced (2)**

Organic conditions (4)
Every comment referring to organic comorbidity (e.g., vascular dementia). Comments regarding acute psychotic states directly linked to comorbidity also fall into this area. Comments regarding involuntary treatment or use of restraint for patients with substance abuse fall into the macro-area “emergency management”.

- Collecting information (1)

- **Patients’ low awareness, reliability, accessibility (1)**
 - **HPs inadequately trained or inexperienced (2)**
-

<p style="text-align: center;">Other <i>Every comment not belonging to any of the above-mentioned categories</i></p>	<p style="text-align: center;">- Other (3)</p>	<p style="text-align: center;">- Other (6)</p>
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^o Coding definitions for Level 2 and 3 are provided.

* The three most frequent strategies and/or critical issues subcategories at Level 4 are highlighted in bold.

APPENDIX C

Supplemental Data Files of Chapter 5

Psychological and Psychosomatic Symptoms of Second Victims of
Adverse Events: a Systematic Review and Meta-Analysis

Supplemental Data File 1. Search strategies and retrieved records from each electronic database

1. PubMed

Date of search: 01/31/2017 Search strategy:

#1 (medical error OR patient safety incident OR adverse event OR near miss OR human error)
#2 (health personnel OR second victim OR health professional OR health care provider)
#3 (psychological impact OR experienc* OR psychological response OR psychological symptom OR feeling OR emotion* OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)

#1 and #2 and #3

n findings: 3,225

2. Cochrane Library

Date of search: 02/01/2017 Search strategy:

#1 “medical error” or “patient safety incident” OR “adverse event” or “near miss” or “human error”
#2 “health personnel” or “second victim” or “health professional” or “health care provider” #3 “psychological impact” or “experienc*” or “psychological response” or “psychological symptom” or “feeling” or “emotion” or “mental health” or “cognit*” or “psychosomatic symptom” or “coping” or “resilience” or “peer support” or “team building”

#4 #1 AND #2 AND #3 *n* findings: 89

3. Web of Science (core collection) search strategy

Date of search: 02/06/2017 Search Strategy:

#1 (medical error OR patient safety incident OR human error OR adverse event)¹
#2 (health personnel OR second victim OR health professional OR health care provider)
#3 (psychological impact OR psychological response OR psychological symptom OR feeling OR emotion OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)

#4 #3 AND #2 AND #1 *n* findings: 1,248

¹ The term “near miss” could not be included due to the error message: *Search Error: Invalid query.*

4. Scopus

Date of search: 02/06/2017 Search Strategy:

((((((medical AND error) OR patient AND safety AND incident) or adverse AND event) OR near AND miss) OR human AND error)) AND (((health AND personnel) OR second AND victim) or health AND professional) OR health AND care AND provider)) AND (((((((((((psychological AND impact) OR experience*) OR psychological AND response) OR psychological AND symptom) OR feeling) OR emotion*) OR mental AND health) OR cognit*) OR psychosomatic AND symptom) OR coping) OR resilience) OR peer AND support) OR team AND building)

n findings: 1,820

5. PsycINFO

Date of search: 02/08/2017 Search strategy:

(medical error OR adverse event OR near miss OR human error) AND (health personnel OR second victim OR health professional OR healthcare provider) AND (psychological impact OR experienc*OR psychological response OR psychological symptom OR feeling OR emotion* OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)

n findings: 419

6. Excerpta Medica Database (EMBASE)

Date of search: 02/08/2017 Search strategy:

#1 (medical error OR patient safety incident OR adverse event OR near miss OR human error)
#2 (health personnel OR second victim OR health professional OR health care provider)
#3 (psychological impact OR experienc* OR psychological response OR psychological symptom OR feeling OR emotion* OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)

#1 and #2 and #3 *n* findings: 212

7. ScienceDirect

Date of search: 02/08/2017

Search strategy:

(medical error OR patient safety incident OR adverse event OR near miss OR human error) AND (health personnel OR second victim OR health professional OR healthcare provider) AND (psychological impact OR experience* OR psychological response OR psychological symptom OR feeling OR emotion* OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)

n findings: 979

8. MEDLINE

Date of search 02/09/2017

Search strategy:

((medical error or patient safety incident or adverse event or near miss or human error) and (health personnel or second victim or health professional or health care provider) and (psychological impact or experience* or psychological response or psychological symptom or feeling or emotion* or mental health or cognit* or psychosomatic symptom or coping or resilience or peer support or team building))

n findings: 122

9. Cumulative Index of Nursing and Allied Health Literature (CINAHL)

Date of search: 02/09/2017

Search strategy:

(medical error OR adverse event OR near miss OR human error) AND (health personnel OR second victim OR health professional OR healthcare provider) AND (psychological impact OR experienc* OR psychological response OR psychological symptom OR feeling OR emotion* OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)

n findings: 235

Supplemental Data File 2. Additional Searches Grey Databases

1. OpenSIGLE database/opengrey.eu
 - Date of the search: 07/11/2017
 - Search strategy: (medical error OR patient safety incident OR adverse event OR near miss OR human error) AND (health personnel OR second victim OR health professional OR health care provider) AND (psychological impact OR experienc* OR psychological response OR psychological symptom OR feeling OR emotion OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)
2. PsycEXTRA
 - Date of the search: 07/14/2017
 - Search strategy: (medical error OR patient safety incident OR adverse event OR near miss OR human error) AND (health personnel OR second victim OR health professional OR health care provider) AND (psychological impact OR experienc* OR psychological response OR psychological symptom OR feeling OR emotion OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)
3. Grey Literature Project (<http://www.greylit.org/home>)
 - Date of the search: 07/14/2017
 - Since the complete search strategy did not reveal any findings, separate searches were conducted for the following search terms: “medical error”, “second victim”, “adverse event”, “patient safety”

Journals (Volumes January 2000 – July 2017)

1. *Journal of the American Medical Association (JAMA)*
2. *JAMA Internal Medicine (formerly Archives of Internal Medicine)*
3. *Annals of Internal Medicine*
4. *BMJ Quality and Safety (formerly Quality in Health Care and Quality & Safety in Health Care)*
5. *Journal of Patient Safety*

Reference lists of reviews

1. Brasaitė I, Kaunonen M, Suominen T. Healthcare professionals' knowledge, attitudes and skills regarding patient safety: a systematic literature review. *Scand J Caring Sci* 2015;29:30- 50.
2. Chan ST, Khong PCB, Wang W. Psychological responses, coping and supporting needs of healthcare professionals as second victims. *Int Nurs Rev* 2017;64:242-62.
3. Coughlan B, Powell D, Higgins MF. The second victim: a review. *Eur J Obstet Gynecol Reprod Biol* 2017;213:11-16.
4. Lewis EJ, Baernholdt M, Hamric AB. Nurses' experience of medical errors: an integrative literature review. *J Nurs Care Qual* 2013;28:153–61.
5. Perez B, Knych SA, Weaver SJ, et al. Understanding the barriers to physician error reporting and disclosure: a systemic approach to a systemic problem. *J Patient Saf* 2014;10:45-51.
6. Sammer CE, Lykens K, Singh KP, et al. What is patient safety culture? A review of the literature. *J Nurs Scholarsh* 2010;42:156-65.

7. Schwappach DL, Boluarte TA. The emotional impact of medical error involvement on physicians: a call for leadership and organizational accountability. *Swiss Med Wkly* 2009;139:9-15.
8. Seys D, Wu AW, Van Gerven E, et al. Health care professionals as second victims after adverse events: a systematic review. *Eval Health Prof* 2013;36:135-62.
9. Seys D, Scott S, Wu A, et al. Supporting involved health care professionals (second victims) following an adverse health event: a literature review. *Int J Nurs Stud* 2013;50:678-87.
10. Sirriyeh R, Lawton R, Gardner P, et al. Coping with medical error: a systematic review of papers to assess the effects of involvement in medical errors on healthcare professionals' psychological well-being. *Qual Saf Health Care* 2010;19:e43.
11. White AA, Waterman AD, McCotter P, et al. Supporting health care workers after medical error: considerations for health care leaders. *JCOM* 2008;15:240-47.
12. Wu AW, Shapiro J, Harrison R, et al. The impact of adverse events on clinicians: what's in a name? *J Patient Saf* Published Online First: November 4, 2017.doi:10.1097/PTS.0000000000000256

Reference lists of books, book chapters, white paper, and consensus statement:

1. Dekker S. Second Victim. Error, Guilt, Trauma and Resilience. Boca Raton, FL: CRC Press, Taylor & Francis Group, 2013.
2. Heyman B, Alasyweski A, Shaw M, et al. Risk, Safety and Clinical Practice. Health care through the lens of risk. Oxford, UK: Oxford University Press, 2010.
3. Hollnagel E, Wears RL, Braithwaite J. From Safety-I to Safety-II: A White Paper. The Resilient Health Care Net: Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia, 2015.
4. Hurwitz B, Sheikh A, eds. Health Care Errors and Patient Safety. West Sussex, UK: BMJ Books, 2009.
5. James JE. Medical Harm: What is it and what is the extent? In: James J, ed. The Health of Populations: Beyond Medicine. Cambridge, MA: Academic Press, 2016:105-31.
6. Powell SK. When things go wrong. responding to adverse events: a consensus statement of the Harvard Hospitals. *Lippincotts Case Manag* 2006;11:193-4.
7. Quick O. Regulating Patient Safety: The End of Professional Dominance? Cambridge, UK: Cambridge University Press, 2017.
8. Vincent C. Patient Safety. Second Edition. West Sussex, UK: BMJ Books, 2010.
9. Vincent C, Amalberti R. Safer Healthcare: Strategies for the Real World. Cham, Switzerland: Springer International Publishing, 2016.
10. Wachter R. Understanding patient safety. New York City: McGraw Hill Professional, 2007.

Supplemental Data File 3. Grouped variables of interest

(listed according to the overall prevalence of the psychological and psychosomatic symptoms)

Troubling memories

- *Troubling memories* (Joesten et al., 2015)
- *Re-experiencing the event* (Wahlberg et al., 2016)
- *Memories of what happened to the patient kept troubling me for a long time after the event* (Schröder et al., 2016)

Anxiety/concern

- *Anxiety* (Cebeci et al., 2015)
- *Generally anxious (eg nervous, panicky or tense)* (Harrison et al., 2014)
- *Deep concern* (Leinweber et al., 2017)

Anger toward oneself

- *Angry at self* (Karga et al., 2011)
- *Self-anger* (Taifoori & Valiee, 2015)
- *Feeling angry at oneself* (Meurier et al., 1997)
- *Feeling angry at oneself* (Wu et al., 1991)
- *Angry with oneself* (Chard, 2010)

Regret/Remorse

- *Remorse* (Hobgood et al., 2005)
- *Fehler bedauert oder bereut* [Engl. *error regretted*] (Cramer et al., 2012)
- *Feeling remorseful* (Wu et al., 1991)

Distress

- *Emotional distress* (Hobgood et al., 2005)
- *Generally distressed (e.g., depressed, upset or angry)* (Harrison et al., 2014)

Fear of future errors

- *Angst, dass mir der Fehler nochmal passiert* [Engl. *fear of repeating the mistake*] (Cramer et al., 2012)
- *Anxiety about future errors* (McLennan et al., 2015)
- *Becoming preoccupied with the possibility of future errors* (Taifoori & Valiee, 2015)
- *Anxiety about the potential for future errors* (Waterman et al., 2007)
- *Anxious about potential for future errors* (Harrison et al., 2014)

Embarrassment

- *Embarrassment* (O'Beirne et al.)
- *Feeling embarrassed* (Karga et al., 2011)
- *Feeling embarrassed* (Taifoori & Valiee, 2015)
- *Feeling embarrassed* (Chard, 2010)

Guilt

- *Guilt* (O'Beirne et al.)
- *Guilt* (Cebeci et al., 2015)
- *Emotions of guilt* (Wahlberg et al., 2016)

- *I will always feel some sort of guilt when thinking about the event* (Schroder et al., 2016)
- *Feeling guilty* (Karga et al., 2011)
- *Feelings of guilt* (Dhillon et al., 2015)
- *Guilt* (Hobgood et al., 2005)
- *Feelings of guilt* (Leinweber et al., 2017)
- *Guilty feelings* (Meurier et al., 1997)
- *Feeling guilty* (Wu et al., 1991)
- *Feeling guilty* (Taifoori & Valice, 2015)
- *Feeling guilty* (Chard, 2010)

Frustration

- *Frustration* (O'Beirne et al., 2012)
- *Frustration* (Hobgood et al., 2005)

Anger

- *Anger* (O'Beirne et al., 2012)
- *Anger* (Hobgood et al., 2005)
- *Anger* (Leinweber et al., 2017)

Fear

- *Fear* (Cebeci et al., 2015)
- *Fear* (Hobgood et al., 2005)
- *Immediate reaction of fear* (Leinweber et al., 2017)

Feeling of inadequacy

- *Fühlte mich 240ncompetent [Engl. I felt incompetent]* (Cramer et al., 2012)
- *Feeling professionally inadequate* (Karga et al., 2011)
- *Feeling inefficient* (Taifoori & Valice, 2015)
- *Feelings of inadequacy* (Meurier et al., 1997)
- *Inadequacy* (Hobgood et al., 2005)
- *Feeling inadequate* (Wu et al., 1991)
- *I felt inadequate* (Chard, 2010)

Reduced job satisfaction

- *Negative impact on job satisfaction* (McLennan et al., 2015)
- *Reduced job satisfaction* (Waterman et al., 2007)
- *Reduced job satisfaction* (Harrison et al., 2014)

Concern regarding colleagues' reactions

- *Feeling fearful of losing their colleagues' trust* (Karga et al., 2011)
- *I worried a lot about what my clinical peers would think about me after the event* (Joesten et al., 2015)
- *I worried a lot about what my clinical peers would think about me after the event* (Schroder et al., 2016)

Symptoms of depression

- *Sadness* (O'Beirne et al., 2012)

- *Feelings of isolation* (Dhillon et al., 2015)
- *Sadness* (Cebeci et al., 2015)
- *Became depressed* (Chard, 2010)
- *Sorrow* (Hobgood et al., 2005)
- *Feeling depressed* (Taifoori & Valice, 2015)

- *Depression* (Shanafelt et al., 2010)
- *Feeling depressed* (Karga et al., 2011)
- *Helplessness* (Leinweber et al., 2017)

Fear of repercussions/official consequences

- *Fearful of repercussions* (Karga et al., 2011)
- *Fear of negative repercussions* (Wu et al., 1999)
- *Fearful of repercussions* (Meurier et al., 1997)
- *Worry about lawsuits* (Joesten et al., 2015)
- *I was fearful of repercussions* (Chard, 2010)
- *I worried about an official complaint (or the possibility of one)* (Schröder et al., 2016)

Sleeping difficulties

- *litt unter Schlafstörungen* [Engl. *suffered from sleeping disturbances*] (Cramer et al., 2012)
- *Difficulty sleeping* (Dhillon et al., 2015)
- *Negative impact on ability to sleep* (McLennan et al., 2015)
- *Sleeping difficulties* (Waterman et al., 2007)
- *Sleep disturbance* (Harrison et al., 2014)

Anger toward others

- *Angry at others* (Karga et al., 2011)
- *Angry with other people* (Chard, 2010)
- *Feeling angry at other people* (Meurier et al., 1997)
- *Feeling angry toward others on the team* (Taifoori & Valice, 2015)

Loss of confidence

- *Loss of self-confidence* (Cebeci et al., 2015)
- *Im Nachhinein unsicher* [Engl. *unconfident afterwards*] (Cramer et al., 2012)
- *Less self-confidence at work* (Taifoori & Valice, 2015)
- *Feeling less confident in my work* (Meurier et al., 1997)
- *I feel less confident in my work* (Chard, 2010)
- *Feeling less confident at work* (Karga et al., 2011)
- *Confidence affected* (Dhillon et al., 2015)
- *Loss of confidence* (Waterman et al., 2007)
- *Negative impact on confidence in ability* (McLennan et al., 2015)
- *Lower professional confidence* (Harrison et al., 2014)

Concern regarding patient's reactions

- *Anxiety about loss of patient's trust* (Cebeci et al., 2015)
- *I feared having to speak to the patient and/or family* (Joesten et al., 2015)

Self-doubts

- *Self-doubt* (O'Beirne et al., 2012)
- *Als Person in Frage gestellt* [Engl. *questioning oneself as person*] (Cramer et al., 2012)

Supplemental Data File 4. Excluded studies

Study	Reason for exclusion
1. Aaraas IJ, Jones B, Gupta TS. [Norwegian and Australian physicians' attitudes to adverse events]. <i>Tidsskr Nor Lægeforen</i> 2005;125:2204-6. Norwegian.	Wrong focus
2. Aasland OG, Førde R. Impact of feeling responsible for adverse events on doctors' personal and professional lives: the importance of being open to criticism from colleagues. <i>Qual Saf Health Care</i> 2005;14:13-7.	Wrong focus
3. Baas MAM, Scheepstra KWF, Stramrood CAI, et al. Work-related adverse events leaving their mark: a cross-sectional study among Dutch gynecologists. <i>BMC Psychiatry</i> 2018;18:73.	Wrong focus
4. Bark P, Vincent C, Olivieri L, et al. Impact of litigation on senior clinicians: implications for risk management. <i>BMJ Qual Saf</i> 1997;6:7-13.	Wrong focus
5. Bell SK, Moorman DW, Delbanco T. Improving the patient, family, and clinician experience after harmful events: the "when things go wrong" curriculum. <i>Acad Med</i> 2010;85:1010-7.	Wrong focus
6. Bognár A, Barach P, Johnson JK, et al. Errors and the burden of errors: attitudes, perceptions, and the culture of safety in pediatric cardiac surgical teams. <i>Ann Thorac Surg</i> 2008;85:1374-81.doi:10.1016/j.athoracsur.2007.11.024	Wrong focus
7. Borrell-Carrió F, Regadera CP, Sala RS, et al. [Clinical error and adverse events: primary care doctors' perception]. <i>Aten Primaria</i> 2006;38:25-32. Spanish.	Wrong focus
8. Burlison JD, Quillivan RR, Scott SD, et al. The effects of the second victim phenomenon on work-related outcomes: connecting self-reported caregiver distress to turnover intentions and absenteeism. <i>J Patient Saf</i> Published Online First: November 2, 2016 2016.	No prevalence of psychological and/or psychosomatic symptoms reported
9. Carrillo I, Ferrús L, Silvestre C, et al. Propuestas para el estudio del fenómeno de las segundas víctimas en España en atención primaria y hospitales. <i>Rev Calid Asist</i> 2016;31Supl.2:3-10. Spanish.	No sufficient information
10. Castel ES, Ginsburg LR, Zaheer S, et al. Understanding nurses' and physicians' fear of repercussions for reporting errors: clinician characteristics, organization demographics, or leadership factors? <i>BMC Health Serv Res</i> 2015;15:326.	Wrong focus
11. Chang Y, Mark B. Effects of learning climate and registered nurse staffing on medication errors. <i>Nurse Res</i> 2011;60:32-9.	Wrong focus

12. Coffey M, Thomas K, Tallett S, et al. Pediatric residents' decision-making around disclosing and reporting adverse events: the importance of social context. <i>Acad Med</i> 2010;85:1619-25.	Wrong focus
13. Corkhill V, Merrick K, Tay J. The impact of SUIs on O&G trainees: a national survey of 'second victims'. Poster presented at: RCOG World Congress 2016; June 20-22, 2016; Birmingham, UK.	No sufficient information
14. Cunningham W. The immediate and long-term impact on New Zealand doctors who receive patient complaints. <i>N Z Med J</i> 2004;117:U972.	Wrong focus
15. Dietz I, Borasio GD, Molnar C, et al. Errors in palliative care: kinds, causes, and consequences: a pilot survey of experiences and attitudes of palliative care professionals. <i>J Palliat Med</i> 2013;16:74-81.	Wrong focus
16. Edrees HH, Paine LA, Feroli ER, et al. Health care workers as second victims of medical errors. <i>Pol Arch Med Wewn</i> 2011;121:101-8.	Wrong focus
17. Engel KG, Rosenthal M, Sutcliffe K. Residents' responses to medical error: coping, learning, and change. <i>Acad Med</i> 2006;81:86-93.	Mismatch with the inclusion criteria
18. Fisseni G, Pentzek M, Abholz HH. Responding to serious medical error in general practice – consequences for the GPs involved: analysis of 75 cases from Germany. <i>Fam Pract</i> 2008;25:9-13.	Wrong focus
19. Gainotti S, Petrini C, Spedicato MR. [A survey on some Italian doctors' opinions about errors in clinical medicine]. <i>Ann Ist Super Sanità</i> 2006;42:348-64. Italian.	No sufficient information
20. Gazoni FM, Amato PE, Malik ZM, et al. The impact of perioperative catastrophes on anesthesiologists: results of a national survey. <i>Anesth Analg</i> 2012 Mar;114:596-603.	No sufficient information
21. Habermann M, Cramer H. [Survey in hospitals. Nursing errors, error culture and error management.] <i>Pflege Z</i> 2010;63:552-5. German.	Full-text not available
22. Han K, Bohnen, JD, Peponis T, et al. The Surgeon as the second victim? Results of the Boston intraoperative adverse events surgeons' attitude (BISA) study. <i>J Am Coll Surg</i> 2017;224:1048-1056.doi:10.1016/j.jamcollsurg.2016.12.039	Mixed population
23. Harrison R, Lawton R, Perlo J, et al. Emotion and coping in the aftermath of medical error: a cross-country exploration. <i>J Patient Saf</i> 2015;11:28-35.	No prevalence of psychological and/or psychosomatic symptoms reported
24. Hayashino Y, Utsugi-Ozaki M, Feldman MD, et al. Hope modified the association between distress and incidence of self-perceived medical errors among practicing physicians: prospective cohort study. <i>PLoS ONE</i> 2012;7:e35585.	Wrong focus

25. Heard GC, Sanderson PM, Thomas RD. Barriers to adverse event and error reporting in anesthesia. <i>Anesth Analg</i> 2012;114:604-14.	Wrong focus
26. Heard GC, Thomas RD, Sanderson PM. In the aftermath: attitudes of anesthesiologists to supportive strategies after an unexpected intraoperative patient death. <i>Anesth Analg</i> 2016;122:1614-24.	Wrong focus
27. Hu YY, Fix ML, Hevelone ND, et al. Physicians' needs in coping with emotional stressors: the case for peer support. <i>Arch Surg</i> 2012;147:212-7.	Wrong focus
28. Hwang JI, Park HA. Nurses' perception of ethical climate, medical error experience and intent-to-leave. <i>Nurs Ethics</i> 2014;21:28-42.	Wrong focus
29. Hwang JI, Park HA. Relationships between evidence-based practice, quality improvement and clinical error experience of nurses in Korean hospitals. <i>J Nurs Manag</i> 2015;23:651-60.	Wrong focus
30. Jones JH, Treiber L. When the 5 rights go wrong: medication errors from the nursing perspective. <i>J Nurs Care Qual</i> 2010;25:240-7.	Mismatch with the inclusion criteria
31. Kaldjian LC, Forman-Hoffman VL, Jones EW, et al. Do faculty and resident physicians discuss their medical errors? <i>J Med Ethics</i> 2008;34:717-22.	Wrong focus
32. Kaldjian LC, Jones EW, Wu BJ, et al. Reporting medical errors to improve patient safety: a survey of physicians in teaching hospitals. <i>Arch Intern Med</i> 2008;168:40-6.	Wrong focus
33. Kershaw K. Adverse clinical incidents: support for midwives. <i>RCM Midwives</i> 2007;10:462-5.	Wrong focus
34. Kozłowska K, Nunn K, Cousens P. Adverse experiences in psychiatric training. Part 2. <i>Aust N Z J Psychiatry</i> 1997;31:641-52.	Wrong focus
35. Lander LI, Connor JA, Shah RK, et al. Otolaryngologists' responses to errors and adverse events. <i>Laryngoscope</i> 2006;116:1114-20.	No sufficient information
36. Lewis EJ, Baernholdt MB, Yan G, et al. Relationship of adverse events and support to RN burnout. <i>J Nurs Care Qual</i> 2015;30:144-52.	Mixed population
37. Li Y, Cao F, Cao D, et al. Nursing students' post-traumatic growth, emotional intelligence and psychological resilience. <i>J Psychiatr Ment Health Nurs</i> 2015;22:326-32.	Wrong focus
38. Mahjoub M, Bouafia N, Cheikh AB, et al. [Patient safety culture based on a non-punitive response to error and freedom of expression of healthcare professionals]. <i>Santé Publique</i> 2016;5:641-6. French.	Wrong focus

39. Martinez W, Lehmann LS. The “hidden curriculum” and residents’ attitudes about medical error disclosure: comparison of surgical and nonsurgical residents. <i>J Am Coll Surg</i> 2013;217:1145-50.	Wrong focus
40. Meurier CE, Vincent CA, Parmar DG. Nurses’ responses to severity dependent errors: a study of the causal attributions made by nurses following an error. <i>J Adv Nurs</i> 1998;27:349-54.	Wrong focus
41. Mira JJ, Carrillo I, Lorenzo S, et al. The aftermath of adverse events in Spanish primary care and hospital health professionals. <i>BMC Health Serv Res</i> 2015;15:151.	Mixed population
42. Mizrahi T. Managing medical mistakes: ideology, insularity and accountability among internists-in-training. <i>Soc Sci Med</i> 1984;19:135-46.	Mismatch with the inclusion criteria
43. Mrayyan MT, Shishani K, Al-Faouri I. Rate, causes and reporting medication errors in Jordan: nurses’ perspectives. <i>J Nurs Manag</i> 2007;15:659-70.	Wrong focus
44. Muller D, Ornstein K. Perceptions of and attitudes towards medical errors among medical trainees. <i>Med Educ</i> 2007;41:645-52.	Wrong focus
45. Nielsen KJ, Pedersen AH, Rasmussen K, et al. Work-related stressors and occurrence of adverse events in an ED. <i>Am J Emerg Med</i> 2013;31:504-8.	Wrong focus
46. Oshikoya KA, Oreagba IA, Ogunleye OO, et al. Medication administration errors among paediatric nurses in Lagos public hospitals: an opinion survey. <i>Int J Risk Saf Med</i> 2013;25:67-78.	Wrong focus
47. Panella M, Rinaldi C, Leigh F, et al. The determinants of defensive medicine in Italian hospitals: the impact of being a second victim. <i>Rev Calid Asist</i> 2016;31Suppl2:20-5.	Wrong focus
48. Paulsen PME, Brattebø G. Medisinstudentar og legar sine haldningar til medisinske feil og pasientskade. <i>Tidsskr Nor Lægeforen</i> 2006;126:2129-32. Norwegian.	Wrong focus
49. Petrova E. Nurses’ perceptions of medication errors in Malta. <i>Nurs Stand</i> 2010;24:41-8.	Wrong focus
50. Pratt SD, Jachna BR. Care of the clinician after an adverse event. <i>Int J Obstet Anesth</i> 2015;24:54-63.	Mismatch with the inclusion criteria
51. Pronovost PJ, Bienvenu OJ. A piece of my mind. From shame to guilt to love. <i>JAMA</i> 2015;314:2507-8.	Mismatch with the inclusion criteria
52. Quillivan RR, Burlison JD, Browne EK, et al. Patient safety culture and the second victim phenomenon: connecting culture to staff distress in nurses. <i>Jt Comm J Qual Patient Saf</i> 2016;42:377-86.	Wrong focus

53. Ramirez AJ, Graham J, Richards MA, et al. Burnout and psychiatric disorder among cancer clinicians. <i>Br J Cancer</i> 1995;71:1263-9.	Wrong focus
54. Raymond CB, Woloschuk DM, Honcharik N. Attitudes and behaviours of hospital pharmacy staff toward near misses. <i>Healthc Q</i> 2011;14:48-56.	Wrong focus
55. Rinaldi C, Leigheb F, Vanhaecht K, et al. Becoming a “second victim” in health care: pathway of recovery after adverse event. <i>Rev Calid Asist</i> 2016;31Suppl2:11-19.	Mismatch with the inclusion criteria
56. Rivera EY, Lee C, Bernstein PS, et al. “Second victim” experiences in obstetrics and Gynecology [339] [abstract]. <i>Obstet Gynecol</i> 2015; 125:107S.	No sufficient information
57. Robertson JH, Thomason AM. An exploration of the effects of clinical negligence litigation on the practice of midwives in England: a phenomenological study. <i>Midwifery</i> 2016;33:55-63.	Mismatch with the inclusion criteria
58. Santos AE, Padilha KG. [Medication adverse events in emergency department: nurse’s professional conduct and personal feelings]. <i>Rev Bras Enferm</i> 2005;58:429-33. Portuguese.	Wrong focus
59. Schelbred AB, Nord R. Nurses’ experiences of drug administration errors. <i>J Adv Nurs</i> 2007;60:317-24.	Mismatch with the inclusion criteria
60. Schröder K, Larsen PV, Jørgensen JS, et al. Psychosocial health and well-being among obstetricians and midwives involved in traumatic childbirth. <i>Midwifery</i> 2016;41:45-53.	No sufficient information
61. Scott SD, Hirschinger LE, Cox KR, et al. Caring for our own: deploying a systemwide second victim rapid response team. <i>Jt Comm J Qual Patient Saf</i> 2010;36:233-40.	Wrong focus
62. Stangierski A, Warmuz-Stangierska I, Ruchala M, et al. Medical errors – not only patients’ problem. <i>Arch Med Sci</i> 2012;8:569-74.	Wrong focus
63. Taylor D, Hassan MA, Luterman A, et al. Unexpected intraoperative patient death: the imperatives of family-and surgeon-centered care. <i>Arch Surg</i> 2008;143:87-92.	Mismatch with the inclusion criteria
64. Teng CI, Chang SS, Hsu KH. Emotional stability of nurses: impact on patient safety. <i>J Adv Nurs</i> 2009; 65:2088-96.	Wrong focus
65. Theorell T. [Many physicians feel distressed after committing Medical errors. Two thirds worried about committing new errors, according to a North American survey]. <i>Lakartidningen</i> 2008;105:610-1. Swedish.	Full-text not available

66. Tipton DJ, Giannetti VJ, Kristofik JM. Managing the aftermath of medication errors: managed care's role. <i>J Am Pharm Assoc</i> 2003;43:622-8.	Mismatch with the inclusion criteria
67. Torppa MA, Kuikka L, Nevalainen M, et al. Emotionally exhausting factors in general practitioners' work. <i>Scand J Prim Health Care</i> 2015;33:178-83.	Wrong focus
68. Ugur E, Kara S, Yildirim S, et al. Medical errors and patient safety in the operating room. <i>J Pak Med Assoc</i> 2016;66:593-7.	Wrong focus
69. Van Gerven E, Seys D, Panella M, et al. Involvement of health-care professionals in an adverse event: the role of management in supporting their workforce. <i>Pol Arch Med Wewn</i> 2014;124:313-20.	Wrong focus
70. Van Gerven E, Bruyneel L, Panella M, et al. Psychological impact and recovery after involvement in a patient safety incident: a repeated measures analysis. <i>BMJ Open</i> 2016;6:e011403.	No prevalence of psychological and/or psychosomatic symptoms reported
71. Van Gerven E, Vander Elst T, Vandebroek S, et al. Increased risk of burnout for physicians and nurses involved in a patient safety incident. <i>Med Care</i> 2016;54:937-43.	Wrong focus
72. Varughese E, Janda M, Obermair A. Can the use of quality assurance tools reduce the impact of surgical complications on the well-being of obstetricians and gynaecologists in Australia and New Zealand. <i>Aust N Z J Obstet Gynaecol</i> 2014;54:30-5.	Wrong focus
73. Venus E, Galam E, Aubert JP, et al. Medical errors reported by French general practitioners in training: results of a survey and individual interviews. <i>BMJ Qual Saf</i> 2012;21:279-86.	Mismatch with the inclusion criteria
74. Vohra PD, Johnson JK, Daugherty CK, et al. Housestaff and medical student attitudes toward medical errors and adverse events. <i>Jt Common J Qual Patient Saf</i> 2007;33:493-501.	Wrong focus
75. Wahlberg A, Andreen Sachs M, Bergh Johannesson K, et al. Self-reported exposure to severe events on the labour ward among Swedish midwives and obstetricians: a cross-sectional retrospective study. <i>Int J Nurs Stud</i> 2017;65:8-16.	Wrong focus
76. West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. <i>JAMA</i> 2006;296:1071-8.	No sufficient information
77. White AA, Gallagher TH, Krauss MJ, et al. The attitudes and experiences of trainees regarding disclosing medical errors to patients. <i>Acad Med</i> 2008;83:250-6.	Wrong focus

78. Wolf ZR, Serembus JF, Smetzer J, et al. Responses and concerns of healthcare providers to medication errors. <i>Clin Nurse Spec</i> 2000;14:278-87.	Wrong focus
79. Wu AW, Folkman S, McPhee, SJ, et al. Do house officers learn from their mistakes? <i>Qual Saf Health Care</i> 2003;12:221-8.	Reprint of the paper published in JAMA, 1991, Volume 265, pages 2089-94.
80. Wurst FM, Kunz I, Skipper G, et al. The therapist's reaction to a patient's suicide: results of a survey and implications for health care professionals' well-being. <i>Crisis</i> 2011;32:99-105.	No sufficient information

Supplemental Data File 5. Critical appraisal results for the included studies using the JBI Critical Appraisal Checklist for Prevalence Studies

	1. Appropriate sample frame to address target population	2. Appropriate way of recruitment	3. Adequate sample size	4. Description of study subjects and setting in detail	5. Data Analysis with sufficient coverage of the identified sample	6. Use of valid methods for identifying the condition	7. Measurement of condition in standard, reliable way	8. Appropriate statistical analysis	9. Adequate response rate or, if not, appropriate management of low response rate	Absolute number of criteria met
Cebeci et al. (2015)	✓	✓	?	✗	✓	✗	✓	✓	✓	6
Chard (2010)	✓	✓	✓	✓	✓	✓	✓	✓	?	8
Cramer et al. (2012)	✓	✓	✓	✓	✓	✗	✓	✓	✓	8
Dhillon et al. (2015)	✓	✓	?	✓	✓	✗	✓	✓	?	6
Harrison et al. (2014)	✓	✓	✓	✓	✓	?	✓	✓	✓	8
Hobgood et al. (2005)	✓	✗	?	✓	✓	✗	✓	✓	✓	6
Joesten et al. (2015)	✓	✗	?	?	✓	✗	✓	✓	✓	5
Karga et al. (2011)	✓	✓	✓	✓	✓	✓	✓	✗	✓	8
Leinweber et al. (2017)	✓	✓	✓	✓	✓	✓	✓	✗	✗	7
McLennan et al. (2015)	✓	✓	?	✗	✓	?	✓	✓	✓	6
Meurier et al. (1997)	✓	?	?	✗	✓	✓	✓	✓	✓	6
O'Beirne et al. (2012)	✓	✓	?	✓	✓	?	✓	✗	NA*	5

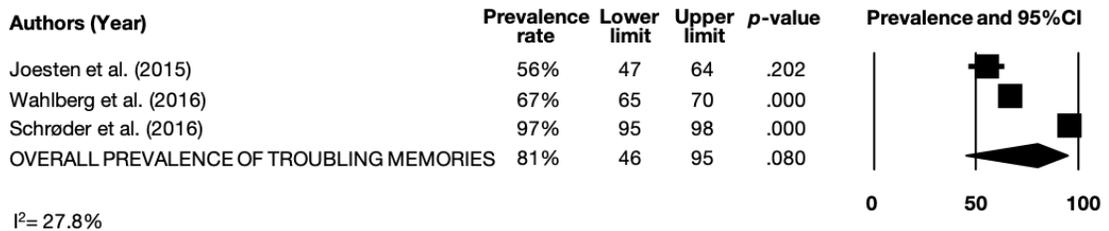
Schröder et al. (2016)	✓	✓	✓	✓	✓	?	✓	✓	✓	8
Shanafelt et al. (2010)	✓	✓	✓	✓	✓	✓	✓	✓	?	8
Taifoori & Valiee (2015)	✓	✓	✓	✓	✓	?	✓	✓	✓	8
Wahlberg et al. (2016)	✓	✓	✓	X	✓	✓	✓	✓	✓	8
Waterman et al. (2007)	✓	✓	✓	✓	✓	X	✓	X	X	6
Wu et al. (1991)	✓	✓	?	✓	✓	✓	✓	✓	✓	8

✓ = Yes; X = No; ? = Unsure; NA = Not applicable

* This item is not applicable in this case because patient safety incident reports had been collected over three years.

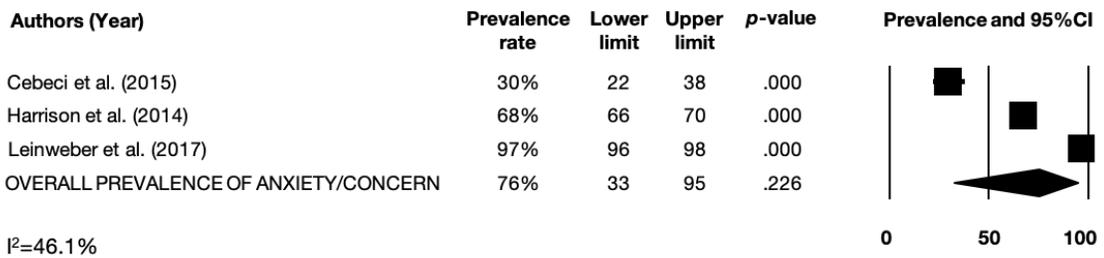
Supplemental Data File 6. Forest plots of all performed meta-analyses

TROUBLING MEMORIES



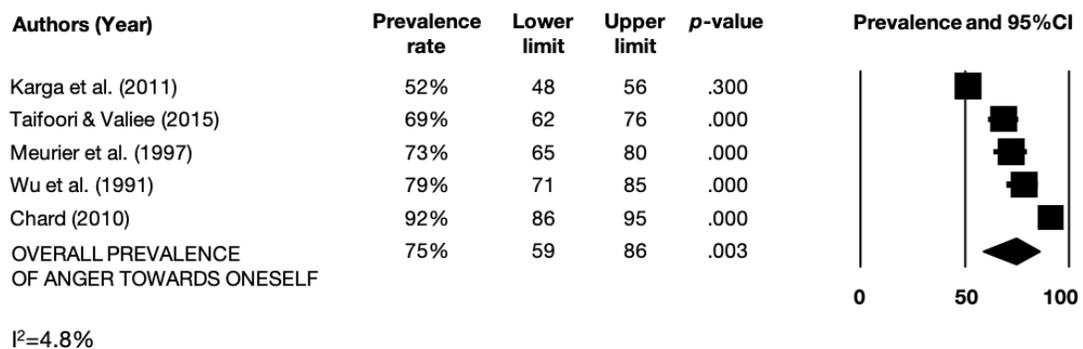
Meta Analysis

ANXIETY/CONCERN



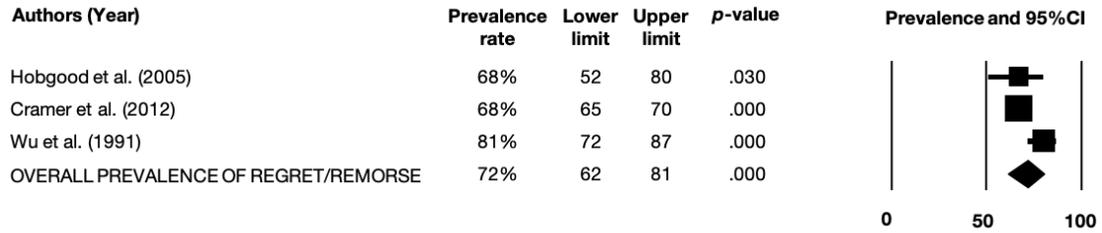
Meta Analysis

ANGER TOWARDS ONESELF



Meta Analysis

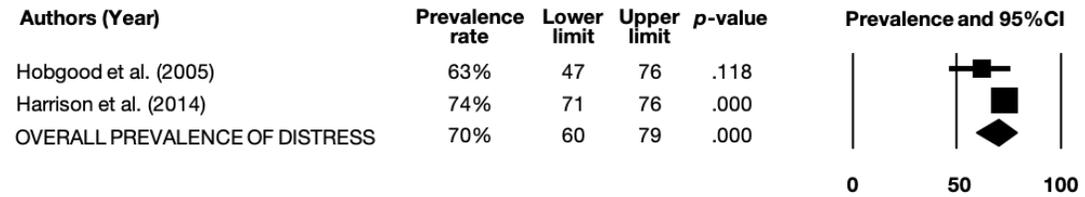
REGRET/REMORSE



$I^2=0\%$

Meta Analysis

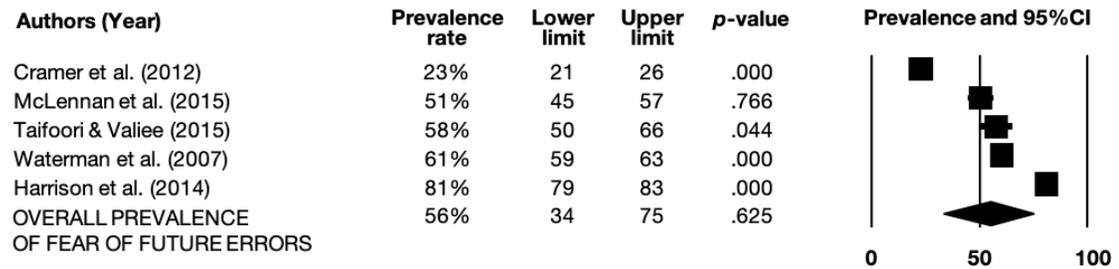
DISTRESS



$I^2=0\%$

Meta Analysis

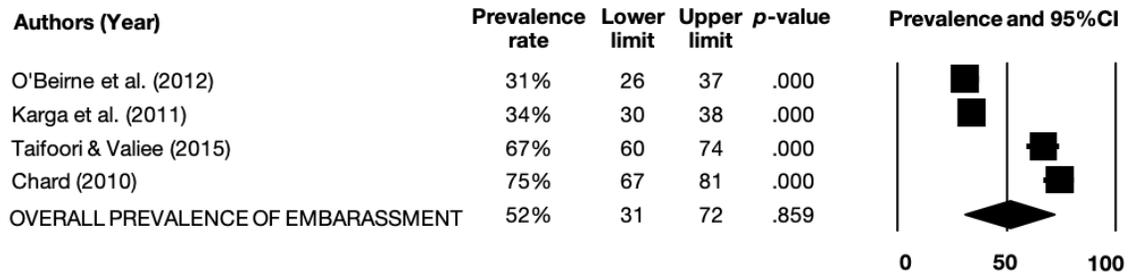
FEAR OF FUTURE ERRORS



$I^2=0\%$

Meta Analysis

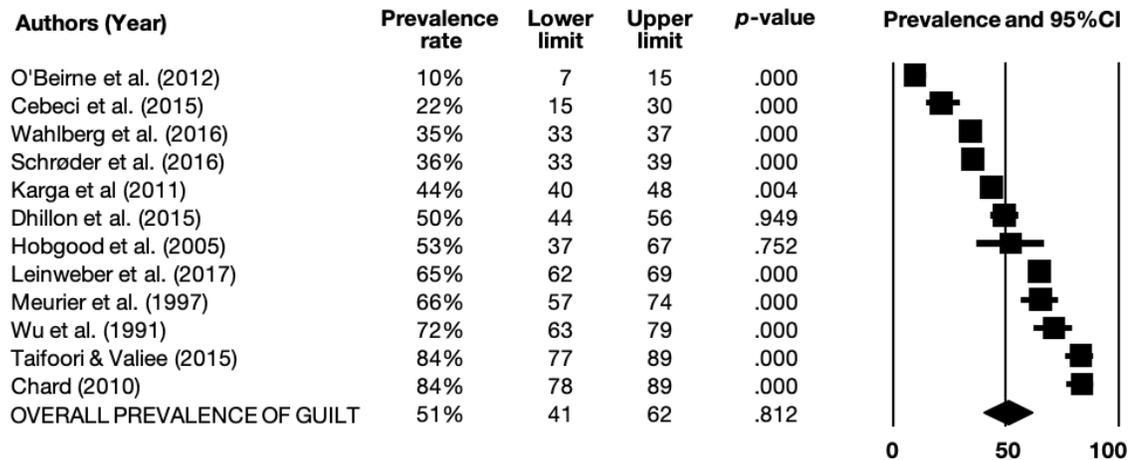
EMBARASSMENT



$I^2=13.6\%$

Meta Analysis

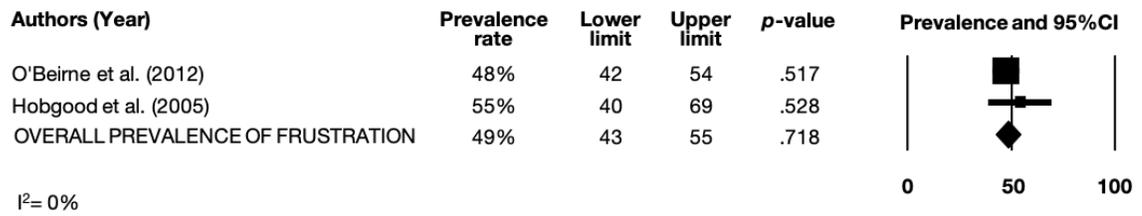
GUILT



$I^2=53.1\%$

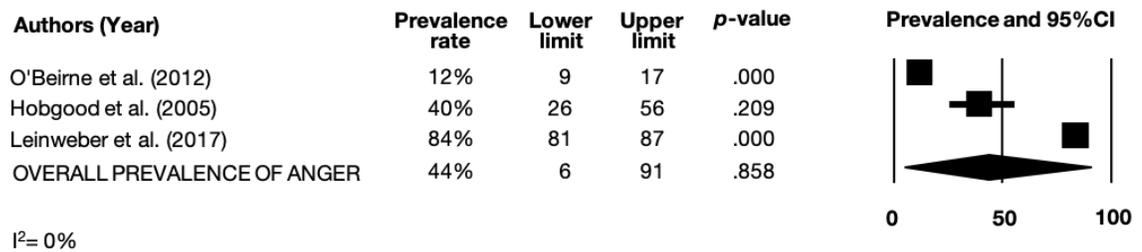
Meta Analysis

FRUSTRATION



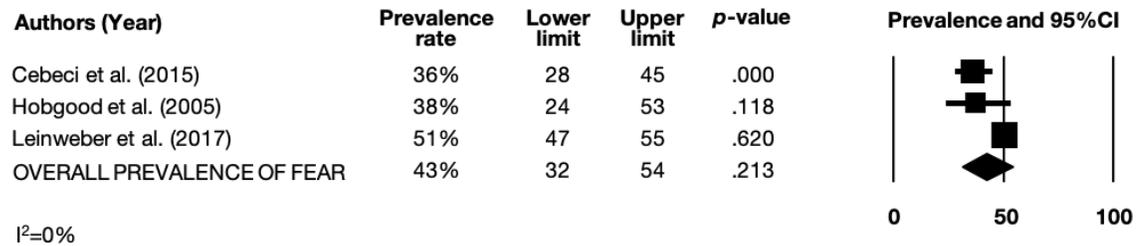
Meta Analysis

ANGER



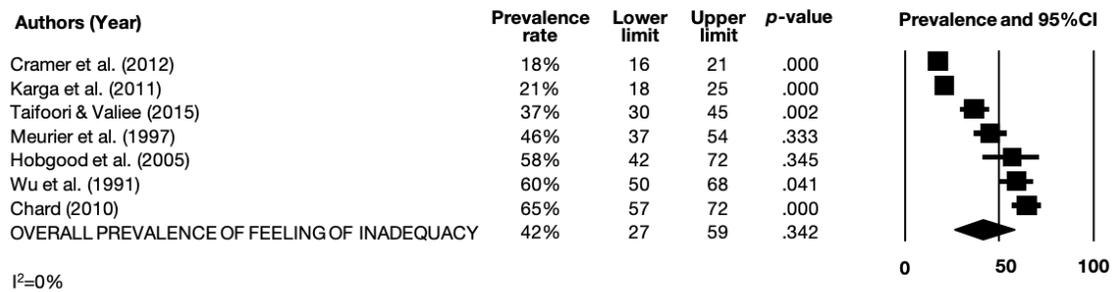
Meta Analysis

FEAR



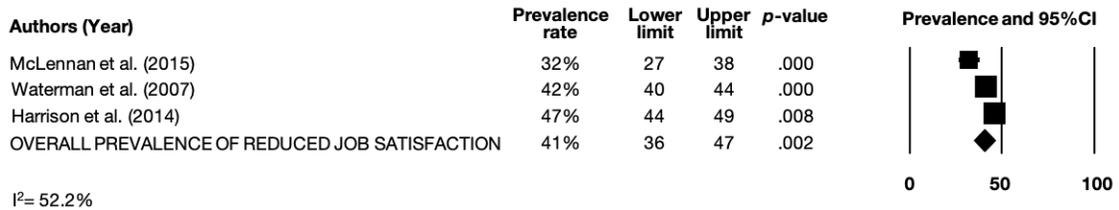
Meta Analysis

FEELING OF INADEQUACY



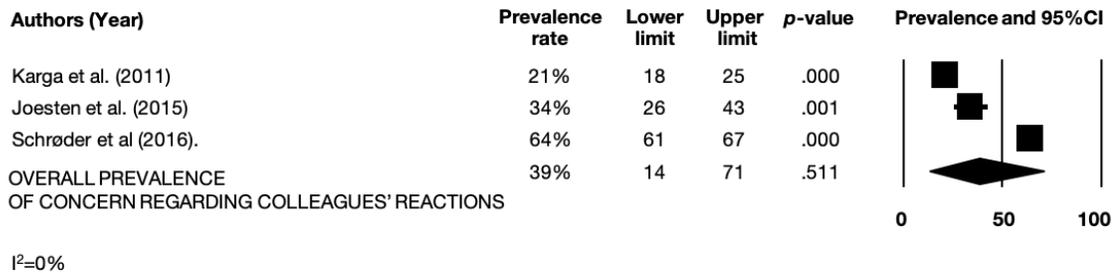
Meta Analysis

REDUCED JOB SATISFACTION



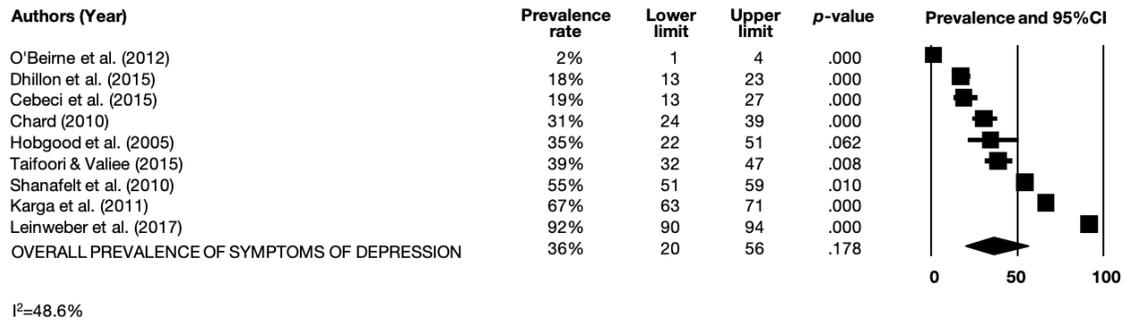
Meta Analysis

CONCERN REGARDING COLLEAGUES' REACTIONS



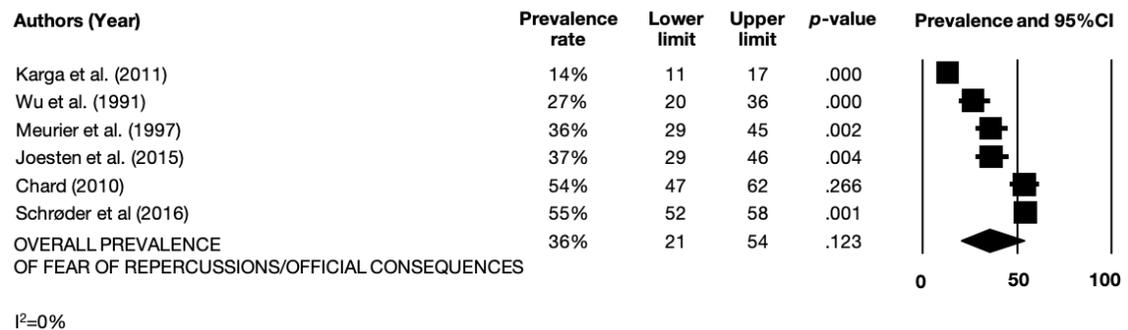
Meta Analysis

SYMPTOMS OF DEPRESSION



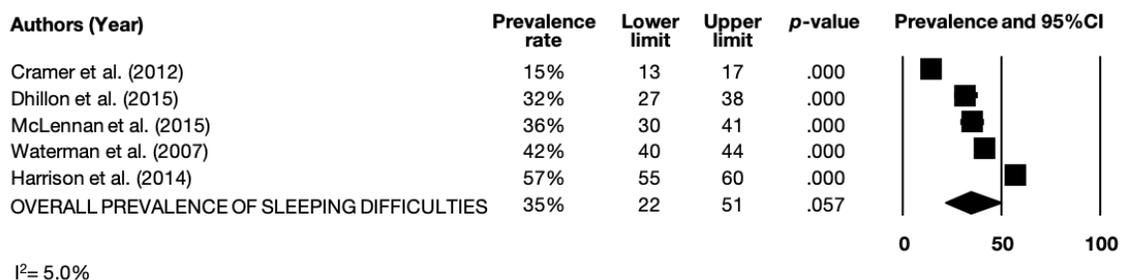
Meta Analysis

FEARS OF REPERCUSSIONS/OFFICIAL CONSEQUENCES



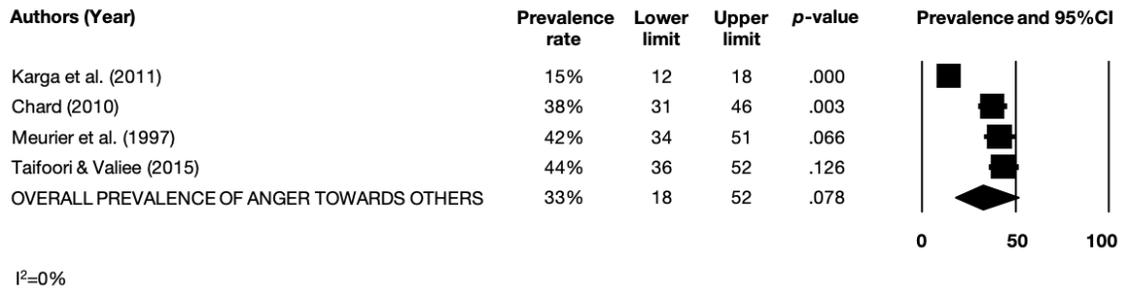
Meta Analysis

SLEEPING DIFFICULTIES



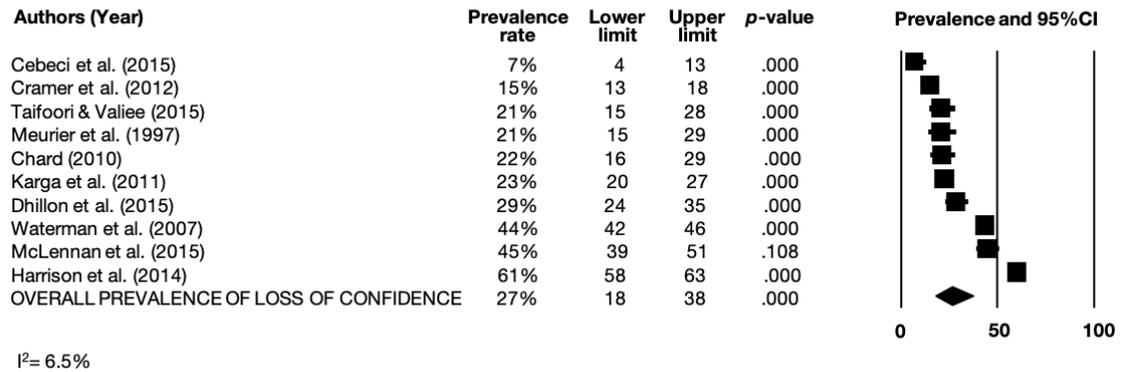
Meta Analysis

ANGER TOWARDS OTHERS



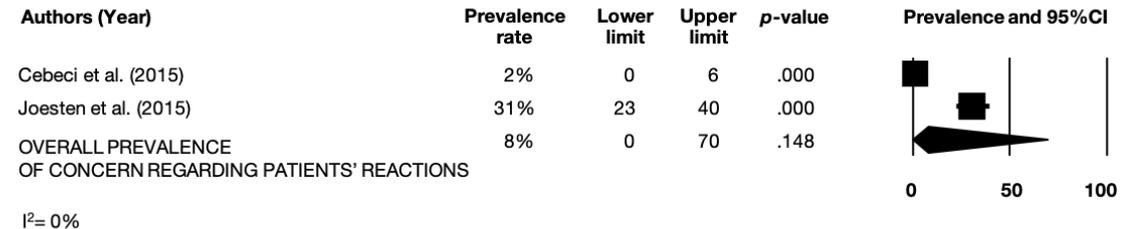
Meta Analysis

LOSS OF CONFIDENCE



Meta Analysis

CONCERN REGARDING PATIENTS' REACTIONS



Meta Analysis

SELF-DOUBTS

Authors (Year)	Prevalence rate	Lower limit	Upper limit	p-value	Prevalence and 95%CI
O'Beirne et al. (2012)	3%	2	7	.000	
Cramer et al. (2012)	9%	7	10	.000	
OVERALL PREVALENCE OF SELF-DOUBTS	6%	2	14	.000	

$I^2 = 0\%$

0 50 100

Meta Analysis

Supplemental Data File 7. Prevalence rates of ungrouped variables of interest

Cebeci et al. (2015)

- *panic/worries* (10%*, 13/124)

Chard (2010)

- *I felt devastated that I may have have hurt someone* (76%; 118/158)

Cramer et al. (2012)

- *aufgeregt, gestresst oder geärgert* [Engl. *being nervous, stressed, or angry*] (52.6%; 579/1,100)
- *schämte mich oder fühlte mich schuldig* [Engl. *I was embarrassed or I felt guilty*] (34.2%, n=376/1,100)

Dhillon et al. (2015)

- *Difficulty concentrating* (16%; 40/245)
- *Change in appetite* (9.0%; 22/245)

Harrison et al. (2014)

- *Negative towards yourself (eg, shame, guilt or feeling incompetent)* (27.3%; 399/1,463)

Joesten et al. (2015)

- *There were times when I felt less able to work safely and effectively because of what happened.* (28.4%; 34/120)
- *I found it difficult to continue to practice effectively after the event* (27.5%; 33/120)
- *I had extreme anxiety about disclosing it to the patient and/or family* (27.5%; 33/120)

Karga et al. (2011)

- *fearful of patient's clinical course* (36.0%; 192/536**)

Leinweber et al. (2017)

- *powerlessness* (82%; 563/687**)
- *feeling horrified* (75%; 515/687**)
- *prevalence of probable PTSD* (17%; 95% CI 14.2 to 20.0; 102/601)

O'Beirne et al. (2012)

- *blame* (5.5%; 13/238**)
- *relief* (3.8%; 9/238**)
- *shame* (2.9%; 6/238**)

Schröder et al. (2016)

- *In the beginning I felt guilty that things turned out the way they did* (49.7%; 507/1,021)

Taifoori & Valiee (2015)

- *Being upset about having harmed the patient* (85.6 %; 131/153)
- *Fear of others' reactions* (47.1%, 72/153)
- *Nonchalant and dispassionate* (10.5 %, 16/153)
- *Self-criticism and self-blame* (71.2%; 109/153)

Wahlberg et al. (2016)

- *Probable symptoms of PTSD* (15%; 95% CI 13 to 17; 244/1,628**)
- *Symptoms of probable PTSD* (5% 95% CI 4 to 7; 81/1,628**)
- *Emotions of intense fear, helplessness or panic (A2:1 criterion)* (43%; 700/1,628**)
- *Threat to professional role/identity (A2:2 criterion)* (19.8%; 323/1,628***)
- *at least one symptom of avoidance or numbing (C criterion)* (36.7%; 598/1,628***)
- *one or more symptoms of arousal (D criterion)* (57.6%; 937/1,628***)

* we converted the absolute frequency into the percentage

** we converted the percentage into the absolute frequency

*** we summed up the percentages reported for obstetricians and midwives and then converted the overall percentage into the absolute frequency

APPENDIX D

Supplemental Data Files of Chapter 6

Dealing with Adverse Events: a Meta-analysis on Second Victims'
Coping Strategies

Supplemental Data File 1. Search strategies and retrieved records from each electronic database

1. PubMed

Date of search: 10/19/2018

Search strategy:

#1 (medical error OR patient safety incident OR adverse event OR near miss OR human error)

#2 (health personnel OR second victim OR health professional OR health care provider)

#3 (psychological impact OR experienc* OR psychological response OR psychological symptom OR feeling OR emotion* OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)

#1 and #2 and #3

n findings: 3,678

2. Cochrane Library

Date of search: 10/19/2018

Search strategy:

#1 “medical error” or “patient safety incident” OR “adverse event” or “near miss” or “human error”

#2 “health personnel” or “second victim” or “health professional” or “health care provider”

#3 “psychological impact” or “experienc*” or “psychological response” or “psychological symptom” or “feeling” or “emotion” or “mental health” or “cognit*” or “psychosomatic symptom” or “coping” or “resilience” or “peer support” or “team building”

#4 #1 AND #2 AND #3

n findings: 93

3. Web of Science (core collection) search strategy

Date of search: 10/19/2018

Search Strategy:

#1 (medical error OR patient safety incident OR human error OR adverse event)¹

#2 (health personnel OR second victim OR health professional OR health care provider)

#3 (psychological impact OR psychological response OR psychological symptom OR feeling OR emotion OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)

#4 #3 AND #2 AND #1

¹The term near miss” could not be included due to the error message:
Search Error: Invalid query.

n findings: 1,362

4. Scopus

Date of search: 10/19/2018

Search Strategy:

(((((medical AND error) OR patient AND safety AND incident) or adverse AND event) OR near AND miss) OR human AND error)) AND (((health AND personnel) OR second AND victim) or health AND professional) OR health AND care AND provider)) AND (((((((((((psychological AND impact) OR experience*) OR psychological AND response) OR psychological AND symptom) OR feeling) OR emotion*) OR mental AND health) OR cognit*) OR psychosomatic AND symptom) OR coping) OR resilience) OR peer AND support) OR team AND building)

n findings: 2,220

5. PsycINFO

Date of search: 10/19/2018

Search strategy:

(medical error OR adverse event OR near miss OR human error) AND (health personnel OR second victim OR health professional OR healthcare provider) AND (psychological impact OR experienc* OR psychological response OR psychological symptom OR feeling OR emotion* OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)

n findings: 465

6. Excerpta Medica Database (EMBASE)

Date of search: 10/19/2018

Search strategy:

#1 (medical error OR patient safety incident OR adverse event OR near miss OR human error)

#2 (health personnel OR second victim OR health professional OR health care provider)

#3 (psychological impact OR experienc* OR psychological response OR psychological symptom OR feeling OR emotion* OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)

#1 and #2 and #3

n findings: 217

7. ScienceDirect

Date of search: 10/19/2018

Search strategy:

("medical error" OR "patient safety incident" OR "adverse event" OR "near miss" OR "human error") AND ("health personnel" OR "second victim" OR "health professional" OR "healthcare provider") AND ("psychological impact" OR "experienc*" OR "psychological response" OR "psychological symptom" OR "feeling" OR "emotion*" OR "mental health" OR "cognit*" OR "psychosomatic symptom" OR "coping" OR "resilience" OR "peer support" OR "team building")

n findings: 3,372

8. MEDLINE

Date of search: 10/19/2018

Search strategy:

((medical error or patient safety incident or adverse event or near miss or human error) and (health personnel or second victim or health professional or health care provider) and (psychological impact or experience* or psychological response or psychological symptom or feeling or emotion* or mental health or cognit* or psychosomatic symptom or coping or resilience or peer support or team building))

n findings: 316

9. Cumulative Index of Nursing and Allied Health Literature (CINAHL)

Date of search: 10/19/2018

Search strategy:

(medical error OR adverse event OR near miss OR human error) AND (health personnel OR second victim OR health professional OR healthcare provider) AND (psychological impact OR experienc* OR psychological response OR psychological symptom OR feeling OR emotion* OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)

n findings: 369

Supplemental Data File 2. Additional searches

1. OpenSIGLE database/opengrey.eu

- Date of the search: 10/10/2018
- Search strategy: (medical error OR patient safety incident OR adverse event OR near miss OR human error) AND (health personnel OR second victim OR health professional OR health care provider) AND (psychological impact OR experienc* OR psychological response OR psychological symptom OR feeling OR emotion OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)

2. PsycEXTRA

- Date of the search: 10/10/2018
- Search strategy: (medical error OR patient safety incident OR adverse event OR near miss OR human error) AND (health personnel OR second victim OR health professional OR health care provider) AND (psychological impact OR experienc* OR psychological response OR psychological symptom OR feeling OR emotion OR mental health OR cognit* OR psychosomatic symptom OR coping OR resilience OR peer support OR team building)

3. Grey Literature Project (<http://www.greylit.org/home>)

- Date of the search: 10/10/2018
- Since the complete search strategy did not reveal any findings, separate searches were conducted for the following search terms: “medical error”, “second victim”, “adverse event”, “patient safety”

Journals (Volumes January 2000 – October 2018)

1. *Journal of the American Medical Association (JAMA)*
2. *JAMA Internal Medicine (formerly Archives of Internal Medicine)*
3. *Annals of Internal Medicine*
4. *BMJ Quality and Safety (formerly Quality in Health Care and Quality & Safety in Health Care)*
5. *Journal of Patient Safety*

Reference lists of reviews

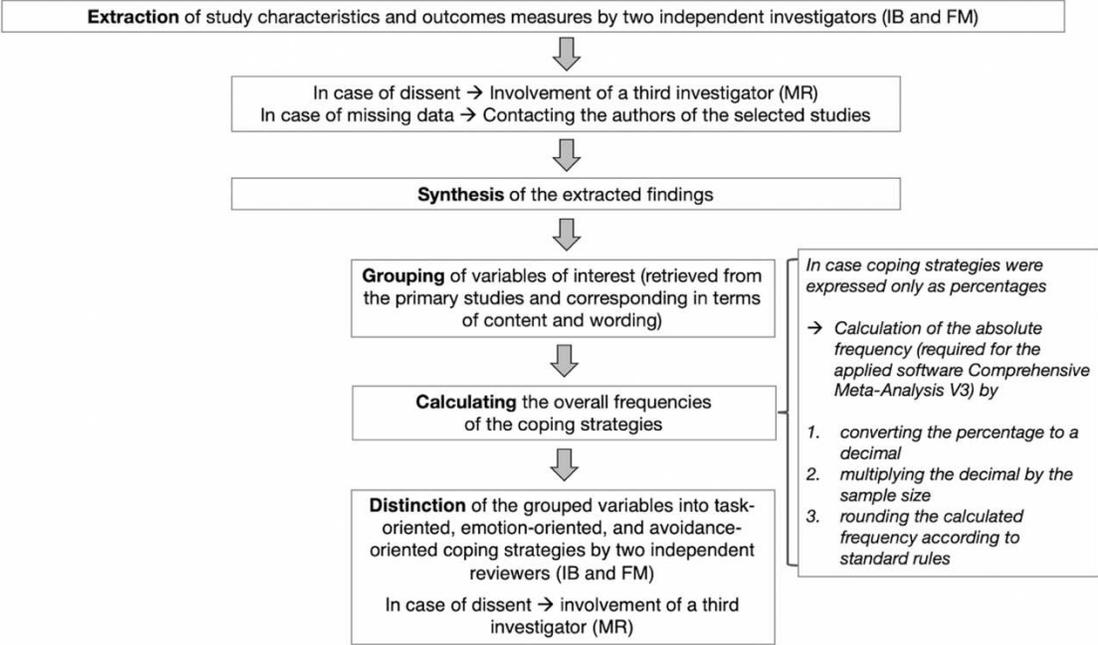
1. Brasaitė I, Kaunonen M, Suominen T. Healthcare professionals' knowledge, attitudes and skills regarding patient safety: a systematic literature review. *Scand J Caring Sci.* 2015;29:30- 50.
2. Cabilan CJ, Kynoch K. Experiences of and support for nurses as second victims of adverse nursing errors: a qualitative systematic review. *JBI Database System Rev Implement Rep.* 2017;15:2333-2364.
3. Chan ST, Khong PCB, Wang W. Psychological responses, coping and supporting needs of healthcare professionals as second victims. *Int Nurs Rev.* 2017;64:242-262.
4. Coughlan B, Powell D, Higgins MF. The second victim: a review. *Eur J Obstet Gynecol Reprod Biol.* 2017;213:11-16.

5. Lewis EJ, Baernholdt M, Hamric AB. Nurses' experience of medical errors: an integrative literature review. *J Nurs Care Qual.* 2013;28:153–161.
6. Perez B, Knych SA, Weaver SJ, et al. Understanding the barriers to physician error reporting and disclosure: a systemic approach to a systemic problem. *J Patient Saf.* 2014;10:45-51.
7. Sammer CE, Lykens K, Singh KP, et al. What is patient safety culture? A review of the literature. *J Nurs Scholarsh.* 2010;42:156-165.
8. Schwappach DL, Boluarte TA. The emotional impact of medical error involvement on physicians: a call for leadership and organizational accountability. *Swiss Med Wkly.* 2009;139:9-15.
9. Seys D, Wu AW, Van Gerven E, et al. Health care professionals as second victims after adverse events: a systematic review. *Eval Health Prof.* 2013;36:135-162.
10. Seys D, Scott S, Wu A, et al. Supporting involved health care professionals (second victims) following an adverse health event: a literature review. *Int J Nurs Stud.* 2013;50:678-687.
11. Sirriyeh R, Lawton R, Gardner P, et al. Coping with medical error: a systematic review of papers to assess the effects of involvement in medical errors on healthcare professionals' psychological well-being. *Qual Saf Health Care.* 2010;19:e43.
12. White AA, Waterman AD, McCotter P, et al. Supporting health care workers after medical error: considerations for health care leaders. *JCOM.* 2008;15:240-247.
13. Wu AW, Shapiro J, Harrison R, et al. The impact of adverse events on clinicians: what's in a name? *J Patient Saf.* Published Online First: November 4, 2017.doi:10.1097/PTS.0000000000000256

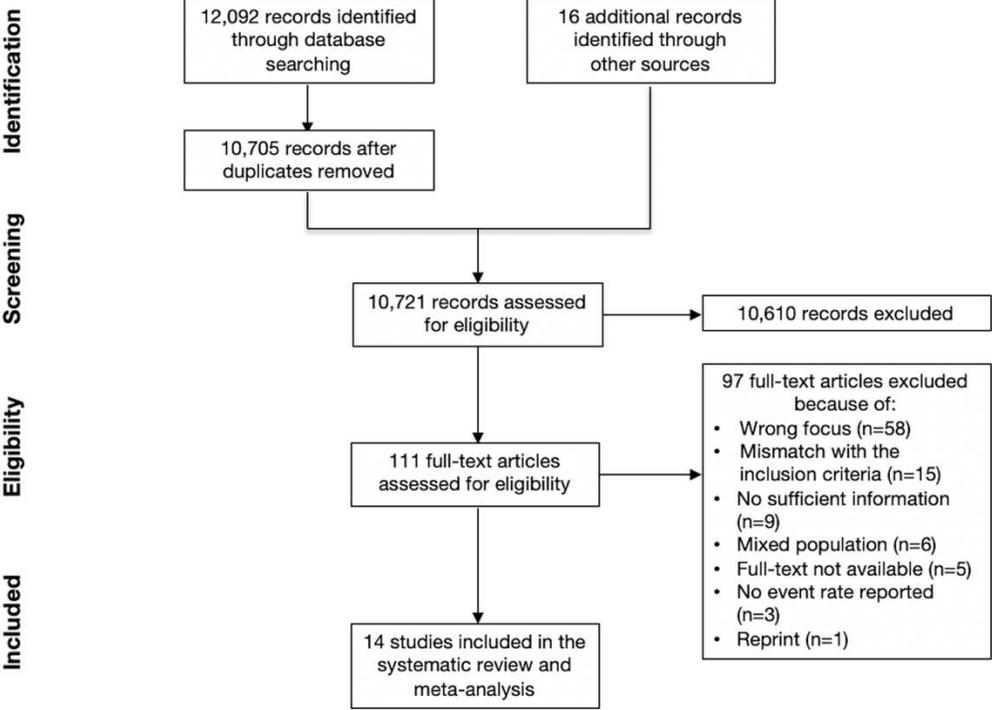
Reference lists of books, book chapters, white paper, and consensus statement:

1. Dekker S. *Second Victim. Error, Guilt, Trauma and Resilience.* Boca Raton, FL: CRC Press, Taylor & Francis Group; 2013.
2. Heyman B, Alasyweski A, Shaw M, et al. *Risk, Safety and Clinical Practice. Health care through the lens of risk.* Oxford, UK: Oxford University Press; 2010.
3. Hollnagel E, Wears RL, Braithwaite J. *From Safety-I to Safety-II: A White Paper.* The Resilient Health Care Net: Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia, 2015.
4. Hurwitz B, Sheikh A, eds. *Health Care Errors and Patient Safety.* West Sussex, UK: BMJ Books; 2009.
5. James JE. Medical Harm: What is it and what is the extent? In: James J, ed. *The Health of Populations: Beyond Medicine.* Cambridge, MA: Academic Press; 2016:105-131.
6. Powell SK. When things go wrong: responding to adverse events: a consensus statement of the Harvard Hospitals. *Lippincott's Case Manag.* 2006;11:193-4.
7. Quick O. *Regulating Patient Safety: The End of Professional Dominance?* Cambridge, UK: Cambridge University Press; 2017.
8. Vincent C. *Patient Safety. Second Edition.* West Sussex, UK: BMJ Books; 2010.
9. Vincent C, Amalberti R. *Safer Healthcare: Strategies for the Real World.* Cham, Switzerland: Springer International Publishing; 2016.
10. Wachter R. *Understanding patient safety.* New York City: McGraw Hill Professional; 2007.

Supplemental Data File 3. Methodological steps of data extraction and synthesis



Supplemental Data File 4. Prima Flow Diagram



Supplemental Data File 5. Excluded studies

Study	Reason for exclusion
1. Aaraas IJ, Jones B, Gupta TS. [Norwegian and Australian physicians' attitudes to adverse events]. <i>Tidsskr Nor Lægeforen</i> . 2005;125:2204–2206. Norwegian.	Wrong focus
2. Aasland OG, Førde R. Impact of feeling responsible for adverse events on doctors' personal and professional lives: the importance of being open to criticism from colleagues. <i>Qual Saf Health Care</i> . 2005;14:13–17.	Wrong focus
3. Baas MAM, Scheepstra KWF, Stramrood CAI, et al. Work-related adverse events leaving their mark: a cross-sectional study among Dutch gynecologists. <i>BMC Psychiatry</i> . 2018;18:73.	Wrong focus
4. Bark P, Vincent C, Olivieri L, et al. Impact of litigation on senior clinicians: implications for risk management. <i>BMJ Qual Saf</i> . 1997;6:7–13.	Wrong focus
5. Bell SK, Moorman DW, Delbanco T. Improving the patient, family, and clinician experience after harmful events: the "when things go wrong" curriculum. <i>Acad Med</i> . 2010;85:1010–1017.	Wrong focus
6. Bognár A, Barach P, Johnson JK, et al. Errors and the burden of errors: attitudes, perceptions, and the culture of safety in pediatric cardiac surgical teams. <i>Ann Thorac Surg</i> . 2008;85:1374–1381.	Wrong focus
7. Borrell-Carrió F, Regadera CP, Sala RS, et al. [Clinical error and adverse events: primary care doctors' perception]. <i>Aten Primaria</i> . 2006;38:25–32. Spanish.	Wrong focus
8. Burlison JD, Quillivan RR, Scott SD, et al. The effects of the second victim phenomenon on work-related outcomes: connecting self-reported caregiver distress to turnover intentions and absenteeism. <i>J Patient Saf</i> . Published Online First: November 2, 2016. doi:10.1097/PTS.0000000000000301	No frequency of coping strategies reported
9. Carrillo I, Ferrús L, Silvestre C, et al. Propuestas para el estudio del fenómeno de las segundas víctimas en España en atención primaria y hospitales. <i>Rev Calid Asist</i> . 2016;31Supl.2:3–10. Spanish.	No sufficient information
10. Castel ES, Ginsburg LR, Zaheer S, et al. Understanding nurses' and physicians' fear of repercussions for reporting errors: clinician characteristics, organization demographics, or leadership factors? <i>BMC Health Serv Res</i> . 2015;15:326.	Wrong focus
11. Cebeci F, Karazeybek E, Sucu G, et al. Nursing students' medication errors and their opinions on the reasons of errors: a cross-sectional survey. <i>J Pak Med Assoc</i> . 2015;65:457–462.	Wrong focus

12. Chang Y, Mark B. Effects of learning climate and registered nurse staffing on medication errors. <i>Nurse Res.</i> 2011;60:32–39.	Wrong focus
13. Coffey M, Thomas K, Tallett S, et al. Pediatric residents' decision-making around disclosing and reporting adverse events: the importance of social context. <i>Acad Med.</i> 2010;85:1619–1625.	Wrong focus
14. Corkhill V, Merrick K, Tay J. The impact of SUIs on O&G trainees: a national survey of 'second victims'. Poster presented at: RCOG World Congress 2016; June 20-22, 2016; Birmingham, UK.	No sufficient information
15. Cullati S, Cheval B, Schmidt RE, Agoritsas T, Chopard P, Courvoisier DS. Self-Rated Health and Sick Leave among Nurses and Physicians: The Role of Regret and Coping Strategies in Difficult Care-Related Situations. <i>Front Psychol.</i> 2017;8:623.	Wrong focus
16. Cunningham W. The immediate and long-term impact on New Zealand doctors who receive patient complaints. <i>N Z Med J.</i> 2004;117:U972.	Wrong focus
17. Dietz I, Borasio GD, Molnar C, et al. Errors in palliative care: kinds, causes, and consequences: a pilot survey of experiences and attitudes of palliative care professionals. <i>J Palliat Med.</i> 2013;16:74–81.	Wrong focus
18. Edrees HH, Paine LA, Feroli ER, et al. Health care workers as second victims of medical errors. <i>Pol Arch Med Wewn.</i> 2011;121:101–108.	Wrong focus
19. Engel KG, Rosenthal M, Sutcliffe K. Residents' responses to medical error: coping, learning, and change. <i>Acad Med.</i> 2006;81:86–93.	Mismatch with the inclusion criteria
20. Fisseni G, Pentzek M, Abholz HH. Responding to serious medical error in general practice – consequences for the GPs involved: analysis of 75 cases from Germany. <i>Fam Pract.</i> 2008;25:9–13.	Wrong focus
21. Gainotti S, Petrini C, Spedicato MR. [A survey on some Italian doctors' opinions about errors in clinical medicine]. <i>Ann Ist Super Sanità.</i> 2006;42:348–364. Italian.	No sufficient information
22. Gómez-Durán E, Vizcaíno-Rakosnik M, Martín-Fumadó C, et al. Physicians as second victims after a malpractice claim: an important issue in need of attention. <i>J Healthc Qual Res.</i> 2018;33:284-289.	Full-text not available
23. Habermann M, Cramer H. [Survey in hospitals. Nursing errors, error culture and error management.] <i>Pflege Z.</i> 2010;63:552–555.	Full-text not available
24. Han K, Bohnen, JD, Peponis T, et al. The Surgeon as the second victim? Results of the Boston intraoperative adverse events surgeons' attitude (BISA) study. <i>J Am Coll Surg.</i> 2017;224:1048–1056.	Mixed population

25. Harrison R, Lawton R, Perlo J, et al. Emotion and coping in the aftermath of medical error: a cross-country exploration. <i>J Patient Saf.</i> 2015;11:28–35.	No frequency of coping strategies reported
26. Hayashino Y, Utsugi-Ozaki M, Feldman MD, et al. Hope modified the association between distress and incidence of self-perceived medical errors among practicing physicians: prospective cohort study. <i>PLoS ONE.</i> 2012;7:e35585.	Wrong focus
27. Heard GC, Sanderson PM, Thomas RD. Barriers to adverse event and error reporting in anesthesia. <i>Anesth Analg.</i> 2012;114:604–614.	Wrong focus
28. Heard GC, Thomas RD, Sanderson PM. In the aftermath: attitudes of anesthesiologists to supportive strategies after an unexpected intraoperative patient death. <i>Anesth Analg.</i> 2016;122:1614–1624.	Wrong focus
29. Hu YY, Fix ML, Hevelone ND, et al. Physicians' needs in coping with emotional stressors: the case for peer support. <i>Arch Surg.</i> 2012;147:212–217.	Wrong focus
30. Hwang JI, Park HA. Nurses' perception of ethical climate, medical error experience and intent-to-leave. <i>Nurs Ethics.</i> 2014;21:28–42.	Wrong focus
31. Hwang JI, Park HA. Relationships between evidence-based practice, quality improvement and clinical error experience of nurses in Korean hospitals. <i>J Nurs Manag.</i> 2015;23:651–660.	Wrong focus
32. Jones JH, Treiber L. When the 5 rights go wrong: medication errors from the nursing perspective. <i>J Nurs Care Qual.</i> 2010;25:240–247.	Mismatch with the inclusion criteria
33. Kaldjian LC, Forman-Hoffman VL, Jones EW, et al. Do faculty and resident physicians discuss their medical errors? <i>J Med Ethics.</i> 2008;34:717–722.	Wrong focus
34. Kaldjian LC, Jones EW, Wu BJ, et al. Reporting medical errors to improve patient safety: a survey of physicians in teaching hospitals. <i>Arch Intern Med.</i> 2008;168:40–46.	Wrong focus
35. Kershaw K. Adverse clinical incidents: support for midwives. <i>RCM Midwives.</i> 2007;10:462–465.	Wrong focus
36. Kozłowska K, Nunn K, Cousens P. Adverse experiences in psychiatric training. Part 2. <i>Aust N Z J Psychiatry.</i> 1997;31:641–652.	Wrong focus
37. Lander LI, Connor JA, Shah RK, et al. Otolaryngologists' responses to errors and adverse events. <i>Laryngoscope.</i> 2006;116:1114–1120.	No sufficient information

38. Leinweber J, Creedy DK, Rowe H, et al. Responses to birth trauma and prevalence of posttraumatic stress among Australian midwives. <i>Women Birth</i> . 2017;30:40–45.	Wrong focus
39. Lewis EJ, Baernholdt MB, Yan G, et al. Relationship of adverse events and support to RN burnout. <i>J Nurs Care Qual</i> . 2015;30:144–152.	Mixed population
40. Lipitz-Snyderman A, Kale M, Robbins L, et al. Peers without fears? Barriers to effective communication among primary care physicians and oncologists about diagnostic delays in cancer. <i>BMJ Qual Saf</i> . 2017; 26:892-898.	Mismatch with the inclusion criteria
41. Li Y, Cao F, Cao D, et al. Nursing students' post-traumatic growth, emotional intelligence and psychological resilience. <i>J Psychiatr Ment Health Nurs</i> . 2015;22:326–332.	Wrong focus
42. Mahjoub M, Bouafia N, Cheikh AB, et al.[Patient safety culture based on a non-punitive response to error and freedom of expression of healthcare professionals]. <i>Santé Publique</i> . 2016;5:641–646. French.	Wrong focus
43. Martinez W, Lehmann LS. The “hidden curriculum” and residents' attitudes about medical error disclosure: comparison of surgical and nonsurgical residents. <i>J Am Coll Surg</i> . 2013;217:1145–1150.	Wrong focus
44. McLennan SR, Engel-Glatzer S, Meyer AH, et al. The impact of medical errors on Swiss anaesthesiologists: a cross-sectional survey. <i>Acta Anaesthesiol Scand</i> . 2015;59:990–998.	Wrong focus
45. Meurier CE, Vincent CA, Parmar DG. Nurses' responses to severity dependent errors: a study of the causal attributions made by nurses following an error. <i>J Adv Nurs</i> . 1998;27:349–354.	Wrong focus
46. Mira JJ, Carrillo I, Lorenzo S, et al. The aftermath of adverse events in Spanish primary care and hospital health professionals. <i>BMC Health Serv Res</i> . 2015;15:151.	Mixed population
47. Mizrahi T. Managing medical mistakes: ideology, insularity and accountability among internists-in-training. <i>Soc Sci Med</i> . 1984;19:135–146.	Mismatch with the inclusion criteria
48. Mrayyan MT, Shishani K, Al-Faouri I. Rate, causes and reporting medication errors in Jordan: nurses' perspectives. <i>J Nurs Manag</i> . 2007;15:659–670.	Wrong focus
49. Muller D, Ornstein K. Perceptions of and attitudes towards medical errors among medical trainees. <i>Med Educ</i> . 2007;41:645–652.	Wrong focus
50. Nayar RC, Pandit RV, Gopinath KS. The second victim: ignored in the Indian perspective. <i>Indian J Surg Oncol</i> . 2017;9:114-115.	Mismatch with inclusion criteria

51. Nielsen KJ, Pedersen AH, Rasmussen K, et al. Work-related stressors and occurrence of adverse events in an ED. <i>Am J Emerg Med.</i> 2013;31:504–508.	Wrong focus
52. O’Beirne M, Sterling P, Palacios-Derflingher L, et al. Emotional impact of patient safety incidents on family physicians and their office staff. <i>J Am Board Fam Med.</i> 2012;25:177–183.	Mixed population
53. Oshikoya KA, Oreagba IA, Ogunleye OO, et al. Medication administration errors among paediatric nurses in Lagos public hospitals: an opinion survey. <i>Int J Risk Saf Med.</i> 2013;25:67–78.	Wrong focus
54. Panella M, Rinaldi C, Leigh F, et al. The determinants of defensive medicine in Italian hospitals: the impact of being a second victim. <i>Rev Calid Asist.</i> 2016;31Suppl2:20–25.	Wrong focus
55. Paulsen PME, Brattebø G. Medisinstudentar og legar sine haldningar til medisinske feil og pasientskade. <i>Tidsskr Nor Lægeforen.</i> 2006;126:2129–132. Norwegian.	Wrong focus
56. Petrova E. Nurses’ perceptions of medication errors in Malta. <i>Nurs Stand.</i> 2010;24:41–48.	Wrong focus
57. Pratt SD, Jachna BR. Care of the clinician after an adverse event. <i>Int J Obstet Anesth.</i> 2015;24:54–63.	Mismatch with the inclusion criteria
58. Pronovost PJ, Bienvenu OJ. A piece of my mind. From shame to guilt to love. <i>JAMA.</i> 2015;314:2507–2508.	Mismatch with the inclusion criteria
59. Quillivan RR, Burlison JD, Browne EK, et al. Patient safety culture and the second victim phenomenon: connecting culture to staff distress in nurses. <i>Jt Comm J Qual Patient Saf.</i> 2016;42:377–386.	Wrong focus
60. Ramirez AJ, Graham J, Richards MA, et al. Burnout and psychiatric disorder among cancer clinicians. <i>Br J Cancer.</i> 1995;71:1263–1269.	Wrong focus
61. Raymond CB, Woloschuk DM, Honcharik N. Attitudes and behaviours of hospital pharmacy staff toward near misses. <i>Healthc Q.</i> 2011;14:48–56.	Wrong focus
62. Rinaldi C, Leigh F, Vanhaecht K, et al. Becoming a “second victim” in health care: pathway of recovery after adverse event. <i>Rev Calid Asist.</i> 2016;31Suppl2:11–19.	Mismatch with the inclusion criteria
63. Rivera EY, Lee C, Bernstein PS, et al. “Second victim” experiences in obstetrics and Gynecology [339] [abstract]. <i>Obstet Gynecol.</i> 2015; 125:107S.	No sufficient information
64. Robertson JH, Thomason AM. An exploration of the effects of clinical negligence litigation on the practice of midwives in England: a phenomenological study. <i>Midwifery.</i> 2016;33:55–63.	Mismatch with the inclusion criteria

65. Rodriguez J, Scott DS. When Clinicians drop out and start over after adverse events. <i>Jt Comm J Qual Patient Saf.</i> 2018; 44:137-145.	Mixed population
66. Santos AE, Padilha KG. [Medication adverse events in emergency department: nurse's professional conduct and personal feelings]. <i>Rev Bras Enferm.</i> 2005;58:429–433. Portuguese.	Wrong focus
67. Schelbred AB, Nord R. Nurses' experiences of drug administration errors. <i>J Adv Nurs.</i> 2007;60:317–324.	Mismatch with the inclusion criteria
68. Schiess C, Schwappach D. Healthcare professionals as second victims of adverse events. <i>Internistische Praxis.</i> 2018; 58:647-657. Mediengruppe Oberfranken Fachverlage.	Full-text not available.
69. Schröder K, Larsen PV, Jørgensen JS, et al. Psychosocial health and well-being among obstetricians and midwives involved in traumatic childbirth. <i>Midwifery.</i> 2016;41:45–53.	No sufficient information
70. Schröder K, Edrees HH, Christensen RD, et al. Second victims in the labor ward: Are Danish midwives and obstetricians getting the support they need? <i>Int J Qual Health Care.</i> 2018. doi:10.1093/intqhc/mzy219. [Epub ahead of print]	No sufficient information
71. Scott SD, Hirschinger LE, Cox KR, et al. Caring for our own: deploying a systemwide second victim rapid response team. <i>Jt Comm J Qual Patient Saf.</i> 2010;36:233–240.	Wrong focus
72. Shanafelt TD, Balch CM, Bechamps G, et al. Burnout and medical errors among American surgeons. <i>Ann Surg.</i> 2010;251:995–1000.	Wrong focus
73. Stangierski A, Warmuz-Stangierska I, Ruchala M, et al. Medical errors – not only patients' problem. <i>Arch Med Sci.</i> 2012;8:569–574.	Wrong focus
74. Taylor D, Hassan MA, Luterman A, et al. Unexpected intraoperative patient death: the imperatives of family-and surgeon-centered care. <i>Arch Surg.</i> 2008;143:87–92.	Mismatch with the inclusion criteria
75. Teng CI, Chang SS, Hsu KH. Emotional stability of nurses: impact on patient safety. <i>J Adv Nurs.</i> 2009; 65:2088–2096.	Wrong focus
76. Theorell T. [Many physicians feel distressed after committing Medical errors. Two thirds worried about committing new errors, according to a North American survey]. <i>Lakartidningen.</i> 2008;105:610–1. Swedish.	Full-text not available
77. Tipton DJ, Giannetti VJ, Kristofik JM. Managing the aftermath of medication errors: managed care's role. <i>J Am Pharm Assoc.</i> 2003;43:622–628.	Mismatch with the inclusion criteria
78. Torppa MA, Kuikka L, Nevalainen M, et al. Emotionally exhausting factors in general practitioners' work. <i>Scand J Prim Health Care.</i> 2015;33:178–183.	Wrong focus

79. Tsiga E, Panagopoulou E, Montgomery A. Examining the link between burnout and medical error: a checklist approach. <i>Burnout Research</i> . 2017; 6:1-8.	Wrong focus
80. Treiber L, Jones J. After the medication error: recent nursing graduates' reflections on adequacy of education. <i>J Nurs Educ Pract</i> . 2018; 57:275-280.	Full-text not available
81. Treiber LA, Jones JH. Making an infusion error: the second victims of infusion therapy-related medication errors. <i>J Infus Nurs</i> . 2018;41:156-163.	Mismatch with the inclusion criteria
82. Ugur E, Kara S, Yildirim S, et al. Medical errors and patient safety in the operating room. <i>J Pak Med Assoc</i> . 2016;66:593-597.	Wrong focus
83. Van Gerven E, Seys D, Panella M, et al. Involvement of health-care professionals in an adverse event: the role of management in supporting their workforce. <i>Pol Arch Med Wewn</i> . 2014;124:313-320.	Wrong focus
84. Van Gerven E, Bruyneel L, Panella M, et al. Psychological impact and recovery after involvement in a patient safety incident: a repeated measures analysis. <i>BMJ Open</i> . 2016;6:e011403.	No frequency of coping strategies reported
85. Varughese E, Janda M, Obermair A. Can the use of quality assurance tools reduce the impact of surgical complications on the well-being of obstetricians and gynaecologists in Australia and New Zealand. <i>Aust N Z J Obstet Gynaecol</i> . 2014;54:30-35.	Wrong focus
86. Venus E, Galam E, Aubert JP, et al. Medical errors reported by French general practitioners in training: results of a survey and individual interviews. <i>BMJ Qual Saf</i> . 2012;21:279-286.	Mismatch with the inclusion criteria
87. Vohra PD, Johnson JK, Daugherty CK, et al. Housestaff and medical student attitudes toward medical errors and adverse events. <i>Jt Common J Qual Patient Saf</i> . 2007;33:493-501.	Wrong focus
88. Wahlberg A, Andreen Sachs M, Johannesson K, et al. Post-traumatic stress symptoms in Swedish obstetricians and midwives after severe obstetric events: a cross-sectional retrospective survey. <i>BJOG</i> . 2017;124:1264-1271.	Mixed population
89. Wahlberg A, Andreen Sachs M, Bergh Johannesson K, et al. Self-reported exposure to severe events on the labour ward among Swedish midwives and obstetricians: a cross-sectional retrospective study. <i>Int J Nurs Stud</i> . 2017;65:8-16.	Wrong focus
90. Waterman AD, Garbutt J, Hazel E, et al. The emotional impact of medical errors on practicing physicians in the United States and Canada. <i>Jt Comm J Qual Patient Saf</i> . 2007;33:467-476.	Wrong focus

91. West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. <i>JAMA</i> . 2006;296:1071–1078.	No sufficient information
92. White AA, Gallagher TH, Krauss MJ, et al. The attitudes and experiences of trainees regarding disclosing medical errors to patients. <i>Acad Med</i> . 2008;83:250–256.	Wrong focus
93. Winning AM, Merandi JM, Lewe D, et al. The emotional impact of errors or adverse events on healthcare providers in the NICU: The protective role of coworker support. <i>J Adv Nurs</i> . 2018;74:172-180.	Wrong focus
94. Wolf ZR, Serembus JF, Smetzer J, et al. Responses and concerns of healthcare providers to medication errors. <i>Clin Nurse Spec</i> . 2000;14:278-287.	Wrong focus
95. Wu AW, Folkman S, McPhee, SJ, et al. Do house officers learn from their mistakes? <i>Qual Saf Health Care</i> . 2003;12:221–228.	Reprint of the paper published in JAMA, 1991, Volume 265, pages 2089–94.
96. Wurst FM, Kunz I, Skipper G, et al. The therapist’s reaction to a patient’s suicide: results of a survey and implications for health care professionals’ well-being. <i>Crisis</i> . 2011;32:99–105.	No sufficient information
97. Xiang D, Linos D. Supporting the patient through supporting the surgeon involved in an adverse event and/or medical litigation. <i>Surgery</i> . 2018;164:176-177.	Mismatch with the inclusion criteria

Supplemental Data File 6.

Critical appraisal results for the included studies using the JBI Critical Appraisal Checklist for Prevalence Studies

	1. Appropriate sample frame to address target population	2. Appropriate way of sampling	3. Adequate sample size	4. Description of study subjects and setting in detail	5. Data Analysis with sufficient coverage of the identified sample	6. Use of valid methods for identifying the condition	7. Measurement of condition in standard, reliable way	8. Appropriate statistical analysis	9. Adequate response rate or, if not, appropriate management of low response rate	Absolute number of criteria met
Chard (2010)	✓	✓	✓	✓	✓	✓	✓	✓	?	8
Cramer, Foraita, Habermann (2012)	✓	✓	✓	✓	✓	?	✓	✓	✓	8
Dhillon, Russell, Stiegler (2015)	✓	✓	?	✓	✓	✗	✓	✓	?	6
Gazoni, Amato, Malik, et al. (2012)	✓	✓	✓	✓	✓	?	✓	✗	✓	7
Harrison, Lawton, Stewart (2014)	✓	✓	✓	✓	✓	?	✓	✓	✓	8
Hobgood, Hevia, Tamayo-Sarver, et al. (2005)	✓	✗	?	✓	✓	?	✓	✗	✓	5
Joesten, Cipparrone, Okuno-Jones, et al. (2015)	✓	✗	?	?	✓	?	✓	✓	✓	5
Karga, Kiekkas, Aretha, et al. (2011)	✓	✓	✓	✓	✓	✓	✓	✓	✓	9
Meurier, Vincent, Parmar (1997)	✓	?	?	✗	✓	✓	✓	✓	✓	6
Nevalainen, Kuikka, Pitkälä (2014)	✓	✗	?	✓	✓	?	✓	✓	✓	6

Schroder, Jørgensen, Lamont, et al. (2016)	✓	✓	✓	✓	✓	?	✓	✓	✓	8
Taifoori, Valice (2015)	✓	✓	✓	✓	✓	?	✓	✓	✓	8
Van Gerven, Elst, Vandenbroeck, et al. 2016	✓	X	✓	✓	✓	?	✓	✓	X	6
Wu, Folkman, McPhee, et al. (1991)	✓	✓	?	✓	✓	✓	✓	✓	✓	8

✓ = Yes; X = No; ? = Unsure

Supplemental Data File 7. Characteristics of included studies

Authors	Year	Country	Study design	Setting	Sample size of healthcare providers involved in an adverse event	Adverse event (type, severity, outcomes)	Coping strategies (number of participants applying the respective coping strategy)
Chard	2010	USA	Cross-sectional study design applying descriptive and inferential statistics; paper-and-pencil, self-report "Perioperative Nurse Questionnaire" (developed by the author, closed-ended questions)	Perioperative nursing	158	Intraoperative nursing errors (e.g., unclear about surgical site, break in sterile technique)	<ul style="list-style-type: none"> - Changing work attitude (n=146) - Following policies and guidelines more accurately and closely (n=119) - Paying more attention to detail (n=156) - Problem-solving/ concrete action plan (n=143) - Criticizing or lecturing oneself (n=133) - Better monitoring of the patient/ paying better attention to the patient (n=96) - Apologizing or doing something to make up (n=96) - Disclosing the error/ talking to/ support from (unspecified) person (n=101) - Seeking (more) advice from colleagues and senior staff (n=93) - Emotional self-control (n=131) - Wishing the situation away (n=67) - Working more slowly and carefully (n=101) - Disclosing the error to/ talking to/ support from friends/ partner/ family (n=38) - Trusting others less (n=83) - Distancing (n=61) - Trying to hide error/ refusing to talk about it (n=42) - Avoidance of patients, procedures, situations (n=15) - Turnover intentions (n=25)
Cramer, Foraita, Habenmann	2012	Germany	Cross-sectional study design applying descriptive and inferential statistics; paper-and-pencil, self-report questionnaire	Inpatient care (also pediatric and geriatric care) (not further specified)	1,100	Nursing errors (not further specified)	<ul style="list-style-type: none"> - Positive reappraisal (n=268)

			(developed by the research team, closed-ended and open-ended questions)				
Dhillon, Russell, Stiegler	2015	USA	Cross-sectional study design applying descriptive and inferential statistics; web-based, self-report questionnaire (developed by the research team, closed-ended and open-ended questions)	Anesthesiology	245	Perioperative errors (e.g., drug error) resulting in, for example, venous air embolism, anoxic brain injury, anaphylaxis or death	<ul style="list-style-type: none"> - <i>Disclosing the error to/ talking to/ support from medical staff (n=144)</i> - <i>Disclosing the error and talking to the patient and the family (n=125)</i> - <i>Use of alcohol/ drugs/ medication (n=13)</i>
Gazoni Amato, Malik, et al.	2012	USA	Cross-sectional study design applying descriptive statistics; paper-and-pencil, self-report questionnaire (developed by the research team, closed-ended and open-ended questions)	Anesthesiology	570	Perioperative catastrophe, resulting in, for example, serious injury or even death	<ul style="list-style-type: none"> - <i>Disclosing the error to/ talking to/ support from medical staff (n=535)</i> - <i>Disclosing the error to/ talking to/ support from friends/ partner/ family (n=410)</i> - <i>Turnover intentions (n=68)</i> - <i>Use of alcohol/ drugs/ medication (n=28)</i>
Harrison, Lawton, Stewart	2014	UK	Cross-sectional study design applying descriptive statistics; web-based, self-report questionnaire (modified version of the questionnaire used by Waterman <i>et al.</i> , closed-ended questions)	Internal medicine	1,463	Adverse events (not further specified) with serious or minor patient harm; Near misses with potential for serious or minor patient harm)	<ul style="list-style-type: none"> - <i>Changing work attitude (n=1179)</i> - <i>Positive reappraisal (n=110)</i>
Hobgood, Helvia, Tamayo-Sarver, et al.	2005	USA	Cross-sectional study design, applying descriptive and inferential statistics;	Emergency care	40	Medication errors, diagnostic errors, evaluation and treatment errors, procedural errors, communication errors,	<ul style="list-style-type: none"> - <i>Changing work attitude (n=36)</i> - <i>Paying more attention to detail (n=32)</i> - <i>Disclosing the error to/ talking to/ support from medical staff (n=27)</i>

			paper-and-pencil, self-report questionnaire (developed by the research team, closed-ended and open-ended questions)			leading to adverse outcomes, such as physical discomfort, increased length of stay, clinical deterioration or even death.	<ul style="list-style-type: none"> - <i>Disclosing the error/talking to/support from (unspecified) person (n=33)</i> - <i>Personally confirming data (n=20)</i> - <i>Seeking (more) advice from colleagues and senior staff (n=14)</i> - <i>Disclosing the error to/talking to/support from friends/partner/family (n=19)</i> - <i>Trusting others less (n=12)</i> - <i>Disclosing the error and talking to the patient and the family (n=10)</i> - <i>Reading more (n=11)</i> - <i>Changing one's data organization (n=4)</i> - <i>Ordering more tests (n=5)</i> - <i>Trying to hide error/refusing to talk about it (n=2)</i> - <i>Avoidance of patients, procedures, situations (n=2)</i>
Joesten, Cipparrone, Okuno-Jones, et al.	2015	USA	Cross-sectional study design applying descriptive statistics; web-based, modified version of the self-report "Medically Induced Trauma Support Services Staff Support Survey" (closed-ended questions)	Inpatient care (also pediatric care)	120	Adverse events (not further specified) leading to negative patient outcomes	<ul style="list-style-type: none"> - <i>Disclosing the error to/talking to/support from medical staff (n=77)</i> - <i>Disclosing the error to/talking to/support from friends/partner/family (n=68)</i> - <i>Disclosing the error and talking to the patient and the family (n=53)</i> - <i>Turnover intentions (n=24)</i>
Karga, Kiekkas, Aretha, et al.	2011	Greece	Cross-sectional study design applying descriptive and inferential statistics; paper-and-pencil, self-report questionnaire (modified version of the questionnaire by Wu et al.[53] and Meurier et al.,[48] respectively; closed-ended and open-ended questions)	Different hospital departments (e.g., Hemodialysis, surgery, intensive care)	536	Medication errors, errors linked to haemodialysis practices, surgical practices, or other tasks (e.g., documentation and blood transfusion), error severity was perceived as high, medium, low or none; adverse outcomes included need for additional therapeutic interventions and monitoring and patient death.	<ul style="list-style-type: none"> - <i>Paying more attention to detail (n=367)</i> - <i>Problem-solving/ concrete action plan (n=319)</i> - <i>Disclosing the error to/talking to/support from medical staff (n=271)</i> - <i>Better monitoring of the patient/ paying better attention to the patient (n=271)</i> - <i>Apologizing or doing something to make up (n=435)</i> - <i>Disclosing the error/talking to/support from (unspecified) person (n=390)</i> - <i>Seeking (more) advice from colleagues and senior staff (n=258)</i> - <i>Emotional self-control (n=248)</i> - <i>Trusting others less (n=192)</i> - <i>Reading more (n=146)</i> - <i>Distancing (n=120)</i>

							<ul style="list-style-type: none"> - <i>Trying to hide error/refusing to talk about it (n=133)</i> - <i>Avoidance of patients, procedures, situations (n=165)</i> - <i>Turnover intentions (n=20)</i>
Meurier, Vincent, Parmar	1997	UK	Cross-sectional study design applying descriptive and inferential statistics; paper-and-pencil, self-report questionnaire (modified version of the questionnaire by Wu et al.,[53] closed-ended and open-ended questions)	Different hospital departments (not further specified)	129	Errors related to communication, assessment, planning, intervention and evaluation with no consequences, mild, moderate or severe effects	<ul style="list-style-type: none"> - <i>Paying more attention to detail (n=108)</i> - <i>Problem-solving/ concrete action plan (n=80)</i> - <i>Disclosing the error to/ talking to/ support from medical staff (n=85)</i> - <i>Better monitoring of the patient/ paying better attention to the patient (n=68)</i> - <i>Apologizing or doing something to make up (n=87)</i> - <i>Disclosing the error/ talking to/ support from (unspecified) person (n=32)</i> - <i>Seeking (more) advice from colleagues and senior staff (n=64)</i> - <i>Emotional self-control (n=248)</i> - <i>Wishing the situation away (n=50)</i> - <i>Disclosing the error/ talking to/ support from friends/ partner/ family (n=30)</i> - <i>Trusting others less (n=43)</i> - <i>Disclosing the error and talking to the patient and the family (n=30)</i> - <i>Distancing (n=20)</i> - <i>Trying to hide error/refusing to talk about it (n=24)</i>
Nevalainen, Kuikka, Pitkälä	2014	Finland	Cross-sectional study design applying descriptive and inferential statistics; web-based, self-report questionnaire (developed by the research team; closed-ended questions)	General medicine	165	Not specified.	<ul style="list-style-type: none"> - <i>Disclosing the error to/ talking to/ support from medical staff (n=107)</i> - <i>Disclosing the error and talking to the patient and the family (n=107)</i> - <i>Trying to hide error/refusing to talk about it (n=7)</i>
Schröder, Jørgensen, Lamont, et al.	2016	Denmark	Cross-sectional mixed-method study design applying descriptive statistics; Self-report questionnaire with	Midwifery, Obstetrics	1,027*	Traumatic childbirth with fatal outcome, severe or permanent injuries for infant or mother	<ul style="list-style-type: none"> - <i>Positive reappraisal (n=404)</i> - <i>Turnover intentions (n=234)</i>

			closed-ended questions & semi-structured interviews, (developed by the research team)				
Taifoori & Valiee	2015	Iran	Cross-sectional study design applying descriptive statistics; paper-and-pencil, self-report questionnaire ("Perioperative Nurse Questionnaire", closed-ended questions)	Perioperative nursing	153	Perioperative errors (e.g., Not following sterile technique, incorrect counts of surgical gauze, incorrect counts of surgical tools, leaving a foreign body in the patient)	<ul style="list-style-type: none"> - Changing work attitude (n=149) - Following policies and guidelines more accurately and closely (n=146) - Paying more attention to detail (n=150) - Problem-solving/ concrete action plan (n=133) - Better monitoring of the patient/ paying better attention to the patient (n=146) - Apologizing or doing something to make up (n=131) - Disclosing the error/ talking to/ support from (unspecified) person (n=114) - Seeking (more) advice from colleagues and senior staff (n=140) - Wishing the situation away (n=122) - Working more slowly and carefully (n=66) - Disclosing the error to/ talking to/ support from friends/ partner/ family (n=98) - Trusting others less (n=48) - Distancing (n=59) - Trying to hide error/ refusing to talk about it (n=59) - Avoidance of patients, procedures, situations (n=54) - Turnover intentions (n=32)
Van Gerven, Elst, Vandenbroeck, et al.	2016	Belgium	Cross-sectional study design applying descriptive and inferential statistics; different self-report questionnaires (validated scales, such as the "Utrechtse Burnout Schaal",[54] and scales developed by the research team; closed-ended and open-ended questions)	Inpatient care (acute and psychiatric care; not further specified)	531	Severity of the adverse events (not further specified) resulting in no harm, temporary or permanent harm or even death.	<ul style="list-style-type: none"> - Use of alcohol/ drugs/ medication (n=107)

Wu, Folkman, McPhee, et al.	1991	USA	Cross-sectional study design applying descriptive and inferential statistics; paper-and-pencil, self-report questionnaire (developed by the research team, closed-ended and open-ended questions)	Internal medicine	114	Errors in diagnosis, evaluation and treatment, prescribing and dosing, procedural complications, faulty communication with overwhelmingly serious adverse outcomes (e.g., delayed treatment, stroke, amputation, respiratory failure, death)	<ul style="list-style-type: none"> - <i>Changing work attitude (n=86)</i> - <i>Paying more attention to detail (n=93)</i> - <i>Criticizing or lecturing oneself (n=70)</i> - <i>Disclosing the error to/ talking to/ support from medical staff (n=100)</i> - <i>Apologizing or doing something to make up (n=23)</i> - <i>Disclosing the error/ talking to/ support from (unspecified) person (n=66)</i> - <i>Personally confirming data (n=82)</i> - <i>Seeking (more) advice from colleagues and senior staff (n=71)</i> - <i>Trusting others less (n=56)</i> - <i>Disclosing the error and talking to the patient and the family (n=27)</i> - <i>Reading more (n=62)</i> - <i>Changing one's data organization (n=59)</i> - <i>Ordering more tests (n=29)</i> - <i>Trying to hide error/ refusing to talk about it (n=15)</i> - <i>Avoidance of patients, procedures, situations (n=7)</i>
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Notes. *We used for the meta-analyses slightly varying sample sizes according to the respective variable of interest (n₁= 1019, n₂=1022, n₃=1024)

Supplemental Data File 8. Grouped variables of interest

(listed according to the overall frequency of the applied coping strategies)

Changing work attitude

- *I promised to do things differently next time* (Chard, 2010)
- *Determined to improve (eg feeling determined, resourceful or strong)* (Harrison, Lawton, Stewart, 2014)
- *Self-critical of the performance and promising to do things differently next time* (Hobgood, Hevia, Tamayo-Sarver, et al. 2005)
- *Making the decision to do better next time* (Taifoori & Valice, 2015)
- *Promising to do things differently next time* (Wu, Folkman, McPhee, et al., 2003)

Following policies and guidelines more accurately and closely

- *I follow policies and procedures more closely* (Chard, 2010)
- *Following guidelines and procedures more accurately* (Taifoori & Valice, 2015)

Paying more attention to detail

- *I pay more attention to detail* (Chard, 2010)
- *Pay more attention to details* (Hobgood, Hevia, Tamayo-Sarver, et al. 2005)
- *Paying more attention to detail* (Karga, Kiekkas, Aretha, et al., 2011)
- *Paying more attention to detail* (Meurier, Vincent, Parmar, 1997)
- *Paying more attention to detail* (Taifoori & Valice, 2015)
- *Pay more attention to detail* (Wu, Folkman, McPhee, et al., 2003)

Problem-solving/concrete action plan

- *I made a plan of action and followed it* (Chard, 2010)
- *Planful problem solving* (Karga, Kiekkas, Aretha, et al., 2011)
- *Taking steps to make oneself less liable to make errors* (Meurier, Vincent, Parmar, 1997)
- *Creating a new plan and following it next time* (Taifoori & Valice, 2015)

Criticizing or lecturing oneself

- *I criticized or lectured myself* (Chard, 2010)
- *Criticizing or lecturing oneself* (Wu, Folkman, McPhee, et al., 2003)

Disclosing the error to/talking to/support from medical staff

- *Talking with colleagues* (Dhillon, Russell, Stiegler, 2015)
- *Anesthesia personnel as source of postevent support* (Gazoni, Amato, Malik, et al., 2012)
- *Disclosure to attending responsible for patient* (Hobgood, Hevia, Tamayo-Sarver, et al. 2005)
- *My clinical colleagues provided meaningful and sustained support after the event* (Joesten, Cipparrone, Okuno-Jones, et al., 2015)
- *Support from senior staff* (Karga, Kiekkas, Aretha, et al., 2011)
- *Discuss error with colleagues* (Meurier, Vincent, Parmar, 1997)
- *Has told the supervisor/a colleague* (Nevalainen, Kuikka, Pitkälä, 2014)

- *Discussed the mistake with another physician who was not in a supervisory capacity* (Wu, Folkman, McPhee, et al., 2003)

Better monitoring of the patient/paying better attention to the patient

- *I keep better documentation on the patients* (Chard, 2010)
- *Devote more observation on patients* (Karga, Kiekkas, Aretha, et al., 2011)
- *Keeping better records on patients* (Meurier, Vincent, Parmar, 1997)
- *Listening to patients more carefully* (Taifoori & Valiee, 2015)

Apologizing or doing something to make up

- *Apologized or did something to make up* (Chard, 2010)
- *Accepting responsibility* (Karga, Kiekkas, Aretha, et al., 2011)
- *Accepting responsibility* (Meurier, Vincent, Parmar, 1997)
- *Apologizing* (Taifoori & Valiee, 2015)
- *Apologizing or doing something to make up* (Wu, Folkman, McPhee, et al., 2003)

Disclosing the error/talking to/support from (unspecified) person

- *I talked to someone about how I was feeling* (Chard, 2010)
- *Disclosure to anyone* (Hobgood, Hevia, Tamayo-Sarver, et al. 2005)
- *Seeking social support* (Karga, Kiekkas, Aretha, et al., 2011)
- *Talked to someone about how I was feeling* (Meurier, Vincent, Parmar, 1997)
- *Talking with others about one's feelings* (Taifoori & Valiee, 2015)
- *Talking to a non-medical person about the mistake* (Wu, Folkman, McPhee, et al., 2003)

Personally confirming data

- *Personally confirm data* (Hobgood, Hevia, Tamayo-Sarver, et al. 2005)
- *Personally confirm data* (Wu, Folkman, McPhee, et al., 2003)

Seeking (more) advice from colleagues and senior staff

- *I am more likely to seek advice* (Chard, 2010)
- *Seeking more advice from senior staff* (Hobgood, Hevia, Tamayo-Sarver, et al. 2005)
- *Asking colleagues what they would have done in a similar situation* (Karga, Kiekkas, Aretha, et al., 2011)
- *Asking colleagues what they would have done in a similar situation* (Meurier, Vincent, Parmar, 1997)
- *Asking colleagues about their actions in the same situation* (Taifoori & Valiee, 2015)
- *Seek more advice* (Wu, Folkman, McPhee, et al., 2003)

Emotional self-control

- *I tried to keep my feelings from interfering with other things too much* (Chard, 2010)
- *Emotional self-control* (Karga, Kiekkas, Aretha, et al., 2011)
- *I tried to keep feelings to self* (Meurier, Vincent, Parmar, 1997)

Wishing the situation away

- *I wished the situation would go away or somehow be over* (Chard, 2010)
- *Wishing the whole thing would go away* (Meurier, Vincent, Parmar, 1997)
- *Hoping for the elimination of a situation or for it to not occur again* (Taifoori & Valiee, 2015)

Working more slowly and carefully

- *I slow down more* (Chard, 2010)
- *Working more slowly and carefully* (Taifoori & Valiee, 2015)

Disclosing the error to/talking to/support from friends/partner/family

- *I asked a relative or friend I respected for advice* (Chard, 2010)
- *Spouse, family, or friends as source of postevent support* (Gazoni, Amato, Malik, et al., 2012)
- *Disclosure to friend or spouse* (Hobgood, Hevia, Tamayo-Sarver, et al. 2005)
- *My family and friends were the mainstay of my support after the event* (Joesten, Cipparrone, Okuno-Jones, et al. 2015)
- *Discussed the error with spouse or significant other* (Meurier, Vincent, Parmar, 1997)
- *Requesting support or advice from a friend* (Taifoori & Valiee, 2015)

Trusting others less

- *I am less trusting of others' capability* (Chard, 2010)
- *Trust others' judgement less* (Hobgood, Hevia, Tamayo-Sarver, et al. 2005)
- *Trust others less* (Karga, Kiekkas, Aretha, et al., 2011)
- *Being less trusting of other people* (Meurier, Vincent, Parmar, 1997)
- *Less trust in others' capabilities* (Taifoori & Valiee, 2015)
- *Trust others' judgment less* (Wu, Folkman, McPhee, et al., 2003)

Disclosing the error and talking to the patient and the family

- *Disclosure to family* (anesthesiologist) (Dhillon, Russell, Stiegler, 2015)
- *Disclosure to patient or patient's family* (Hobgood, Hevia, Tamayo-Sarver, et al. 2005)
- *I had the opportunity to speak with the patient and/or family.* (Joesten, Cipparrone, Okuno-Jones, et al. 2015)
- *Patients or their relatives were told about the error* (Meurier, Vincent, Parmar, 1997)
- *Told the patient and explained* (Nevalainen, Kuikka, Pitkälä, 2014)
- *Told the patient or family* (Wu, Folkman, McPhee, et al., 2003)

Reading more

- *Read more* (Hobgood, Hevia, Tamayo-Sarver, et al. 2005)
- *Read for covering knowledge deficiencies* (Karga, Kiekkas, Aretha, et al., 2011)
- *Read* (Wu, Folkman, McPhee, et al., 2003)

Distancing

- *I didn't let it get to me, I refused to think about it too much* (Chard, 2010)
- *Distancing* (Karga, Kiekkas, Aretha, et al., 2011)

- *Went on as if nothing happened* (Meurier, Vincent, Parmar, 1997)
- *Trying to forget the whole incidence* (Taifoori & Valiee, 2015)

Changing one's data organization

- *Have changed my organization of data* (Hobgood, Hevia, Tamayo-Sarver, et al. 2005)
- *Change organization of data* (Wu, Folkman, McPhee, et al., 2003)

Positive reappraisal

- *Persönlich gewachsen* [engl.: *personally grown*] (Cramer, Foraita, Habermann, 2012)
- *More confident in your abilities* (eg feeling effective, efficient or competent) (Harrison, Lawton, Stewart, 2014)
- *The event gave rise to personal development opportunities of an emotional and/or spiritual character.* (Schröder, Jørgensen, Lamont, et al., 2016)

Ordering more tests

- *Order more tests* (Hobgood, Hevia, Tamayo-Sarver, et al., 2005)
- *Order more tests* (Wu, Folkman, McPhee, et al., 2003)

Trying to hide error/refusing to talk about it

- *I kept others from knowing how bad things were* (Chard, 2010)
- *Keep error to myself more often* (Hobgood, Hevia, Tamayo-Sarver, et al., 2005)
- *More likely to not discuss error* (Karga, Kiekkas, Aretha, et al., 2011)
- *Refusing to talk about it* (Meurier, Vincent, Parmar, 1997)
- *Has tried to hide an error* (Nevalainen, Kuikka, Pitkälä, 2014)
- *Trying to keep others from realizing the magnitude of the error or results* (Taifoori & Valiee, 2015)
- *Keep mistakes to self* (Wu, Folkman, McPhee, et al., 2003)

Avoidance of patients, procedures, situations

- *I try to avoid similar patients or procedures or both* (Chard, 2010)
- *Avoid similar patients* (Hobgood, Hevia, Tamayo-Sarver, et al., 2005)
- *Escape-avoidance* (Karga, Kiekkas, Aretha, et al., 2011)
- *Avoiding similar patients, procedures or both* (Taifoori & Valiee, 2015)
- *Avoid similar patients* (Wu, Folkman, McPhee, et al., 2003)

Turnover intentions

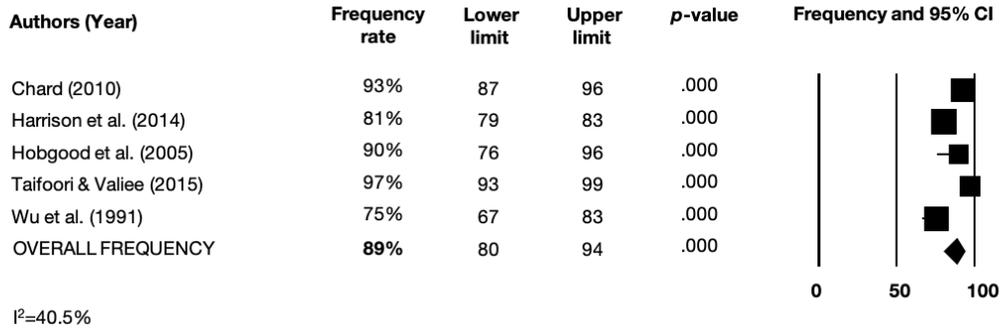
- *I thought about leaving nursing.* (Chard, 2010)
- *Considered a career change after the event* (Gazoni, Amato, Malik, et al., 2012)
- *I seriously considered moving to another institution because of the event or what happened afterwards* (Joesten, Cipparrone, Okuno-Jones, et al., 2015)
- *Considered leaving profession* (Karga, Kiekkas, Aretha, et al., 2011)
- *I considered leaving my profession because of the event* (Schröder, Jørgensen, Lamont, et al., 2016)
- *Thinking about leaving the job* (Taifoori & Valiee, 2005)

Use of alcohol/drugs/medication

- *Alcohol/self-medication* (Dhillon, Russell, Stiegler, 2015)
- *Use of drugs or alcohol* (Gazoni, Amato, Malik, et al., 2012)
- *Problematic medication use* (Van Gerven, Else, Vandenbroeck, et al. 2016)

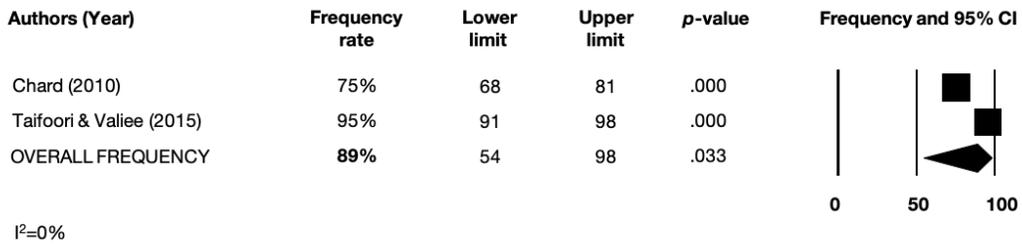
Supplemental Data File 9. Forest Plots of all performed meta-analyses

CHANGING WORK ATTITUDE



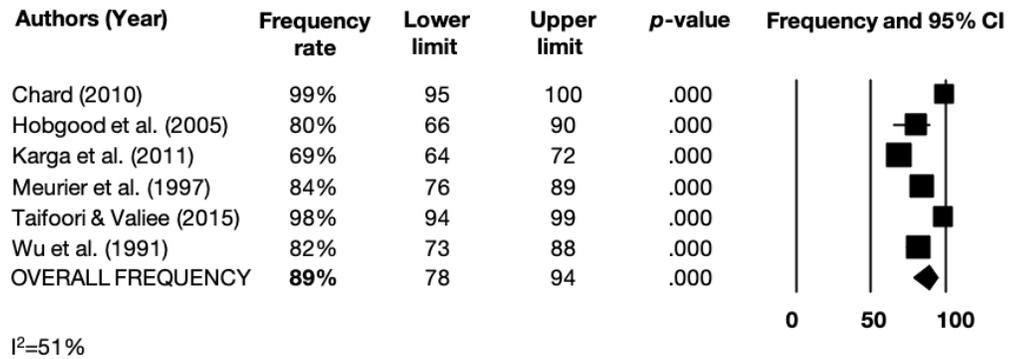
Meta Analysis

FOLLOWING POLICIES AND GUIDELINES MORE ACCURATELY AND CLOSELY



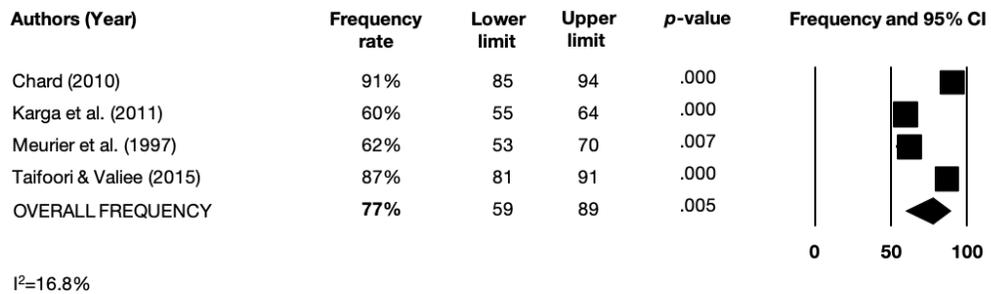
Meta Analysis

PAYING MORE ATTENTION TO DETAIL



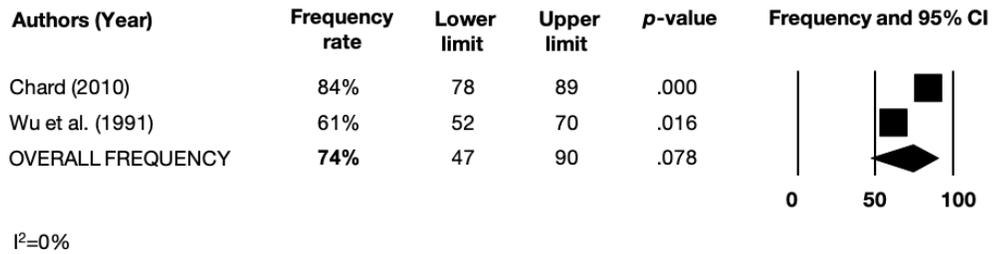
Meta Analysis

PROBLEM-SOLVING/CONCRETE ACTION PLAN



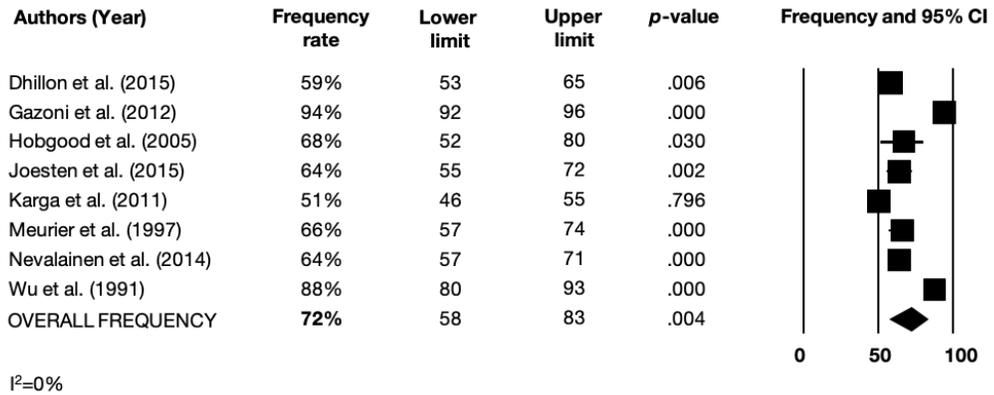
Meta Analysis

CRITIZING OR LECTURING ONESELF



Meta Analysis

DISCLOSING THE ERROR TO/TALKING TO/SUPPORT FROM MEDICAL STAFF



Meta Analysis

BETTER MONITORING OF THE PATIENT/ PAYING BETTER ATTENTION TO THE PATIENT

Authors (Year)	Frequency rate	Lower limit	Upper limit	p-value	Frequency and 95% CI
Chard (2010)	61%	53	68	.007	
Karga et al. (2011)	51%	46	55	.796	
Meurier et al. (1997)	53%	44	61	.538	
Taifoori & Valiee (2015)	95%	91	98	.000	
OVERALL FREQUENCY	69%	52	82	.034	

$I^2=69.8\%$

Meta Analysis

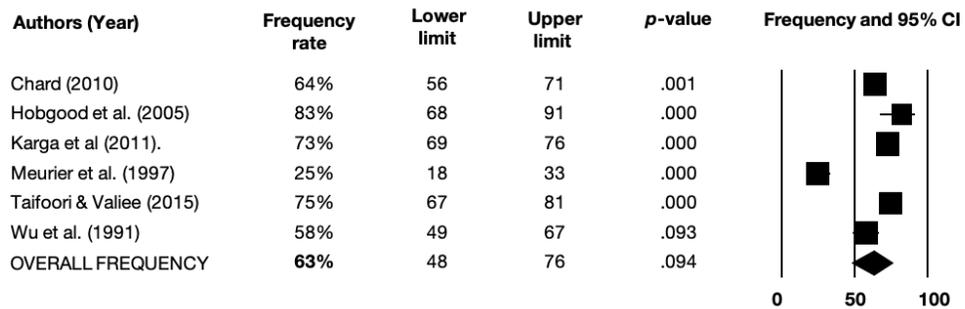
APOLOGIZING OR DOING SOMETHING TO MAKE UP

Authors (Year)	Frequency rate	Lower limit	Upper limit	p-value	Frequency and 95% CI
Chard (2010)	61%	53	68	.007	
Karga et al. (2011)	81%	78	84	.000	
Meurier et al. (1997)	67%	59	75	.000	
Taifoori & Valiee (2015)	86%	79	90	.000	
Wu et al. (1991)	20%	14	29	.000	
OVERALL FREQUENCY	65%	43	82	.189	

$I^2=27.5\%$

Meta Analysis

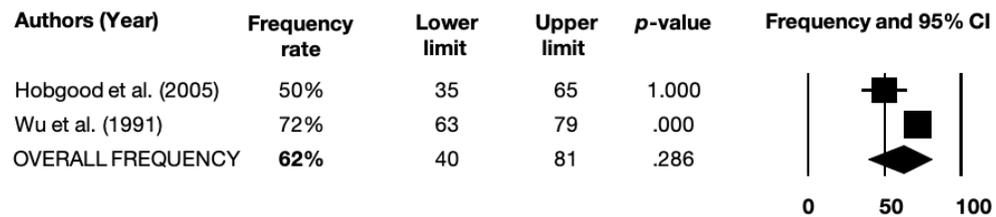
DISCLOSING THE ERROR/TALKING TO/SUPPORT FROM (UNSPECIFIED) PERSON



$I^2=25.1\%$

Meta Analysis

PERSONALLY CONFIRMING DATA



$I^2=0\%$

Meta Analysis

SEEKING (MORE) ADVICE FROM COLLEAGUES AND SENIOR STAFF

Authors (Year)	Frequency rate	Lower limit	Upper limit	p-value	Frequency and 95% CI
Chard (2010)	59%	51	66	.027	
Hobgood et al. (2005)	35%	22	51	.062	
Karga et al. (2011)	48%	44	52	.388	
Meurier et al. (1997)	50%	41	58	.930	
Taifoori & Valiee (2015)	92%	86	95	.000	
Wu et al. (1991)	62%	53	71	.009	
OVERALL FREQUENCY	60%	46	72	.148	

$I^2=52.1\%$

Meta Analysis

EMOTIONAL SELF-CONTROL

Authors (Year)	Frequency rate	Lower limit	Upper limit	p-value	Frequency and 95% CI
Chard (2010)	83%	76	88	.000	
Karga et al. (2011)	46%	42	51	.084	
Meurier et al. (1997)	33%	25	41	.000	
OVERALL FREQUENCY	56%	30	79	.684	

$I^2=36.4\%$

Meta Analysis

WISHING THE SITUATION AWAY

Authors (Year)	Frequency rate	Lower limit	Upper limit	p-value	Frequency and 95% CI
Chard (2010)	42%	35	50	.057	
Meurier et al. (1997)	39%	31	47	.011	
Taifoori & Valiee (2015)	80%	73	85	.000	
OVERALL FREQUENCY	55%	29	78	.719	

$I^2=11.6\%$

Meta Analysis

WORKING MORE SLOWLY AND CAREFULLY

Authors (Year)	Frequency rate	Lower limit	Upper limit	p-value	Frequency and 95% CI
Chard (2010)	64%	56	71	.001	
Taifoori & Valiee (2015)	43%	36	51	.091	
OVERALL FREQUENCY	54%	34	73	.728	

$I^2=0\%$

Meta Analysis

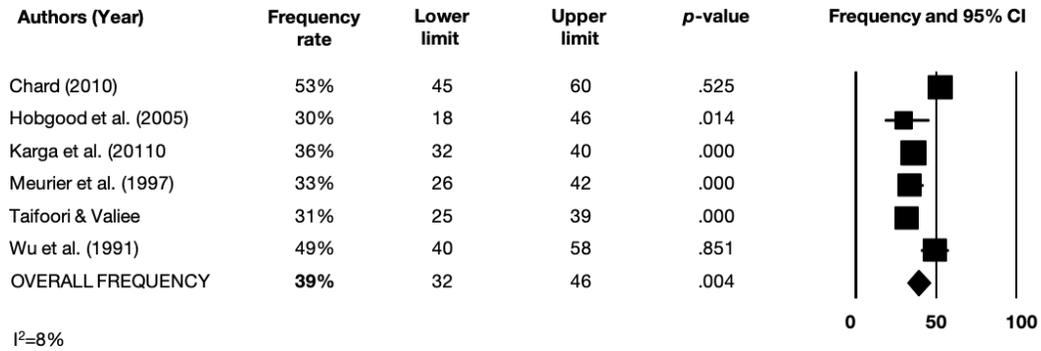
DISCLOSING THE ERROR TO/TALKING TO/SUPPORT FROM FRIENDS/PARTNER/FAMILY

Authors (Year)	Frequency rate	Lower limit	Upper limit	p-value	Frequency and 95% CI
Chard (2010)	24%	18	31	.000	
Gazoni et al. (2012)	72%	68	76	.000	
Hobgood et al. (2005)	48%	33	63	.752	
Joesten et al. (2015)	57%	48	65	.145	
Meurier et al. (1997)	23%	17	31	.000	
Taifoori & Valiee (2015)	64%	56	71	.001	
OVERALL FREQUENCY	47%	29	66	.799	

$I^2=0\%$

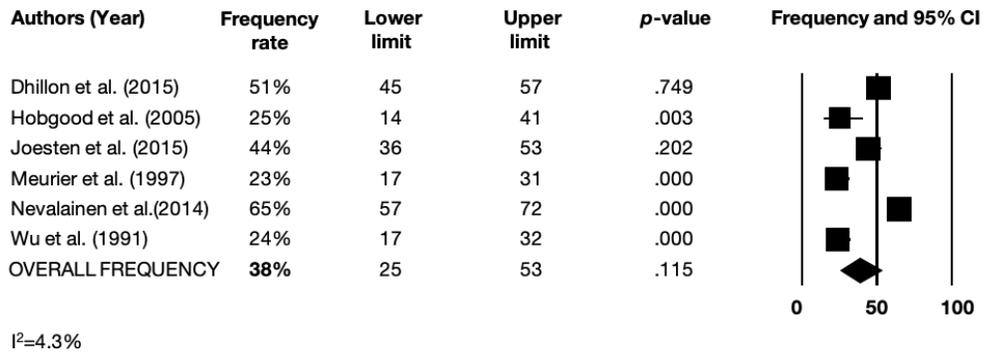
Meta Analysis

TRUSTING OTHERS LESS



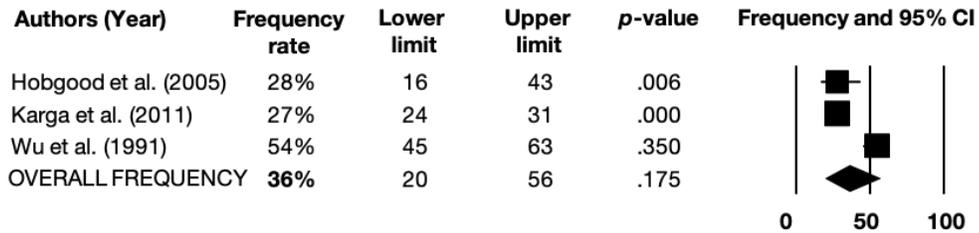
Meta Analysis

DISCLOSING THE ERROR AND TALKING TO THE PATIENT AND THE FAMILY



Meta Analysis

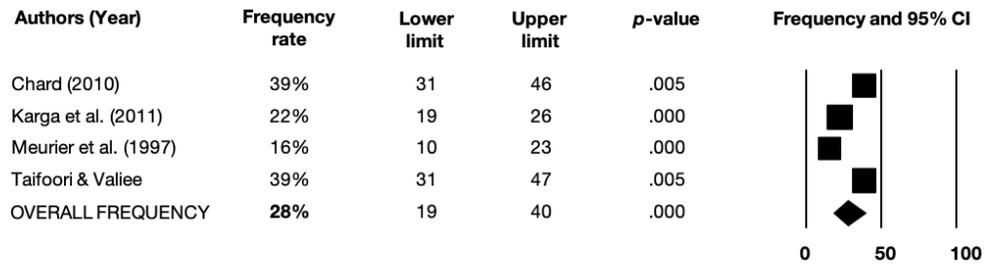
READING MORE



$I^2=0\%$

Meta Analysis

DISTANCING



$I^2=18\%$

Meta Analysis

CHANGING ONE'S DATA ORGANIZATION

Authors (Year)	Frequency rate	Lower limit	Upper limit	p-value	Frequency and 95% CI
Hobgood et al. (2005)	10%	3	24	.000	
Wu et al. (1991)	52%	43	61	.708	
OVERALL FREQUENCY	27%	4	77	.372	

I²=0%

Meta Analysis

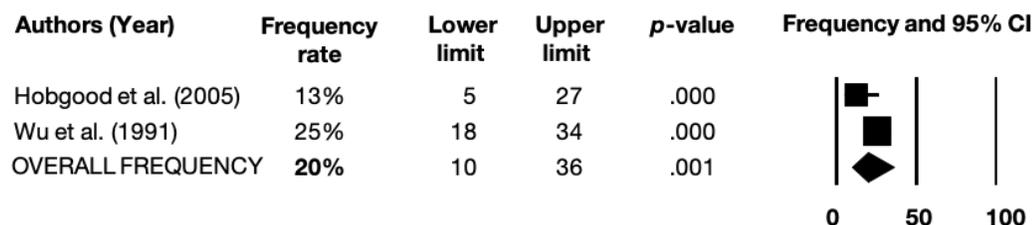
POSITIVE REAPPRAISAL

Authors (Year)	Frequency rate	Lower limit	Upper limit	p-value	Frequency and 95% CI
Cramer et al. (2012)	24%	22	27	.000	
Harrison et al. (2014)	8%	6	9	.000	
Schröder et al. (2016)	40%	37	43	.000	
OVERALL FREQUENCY	21%	8	43	.014	

I²=19.3%

Meta Analysis

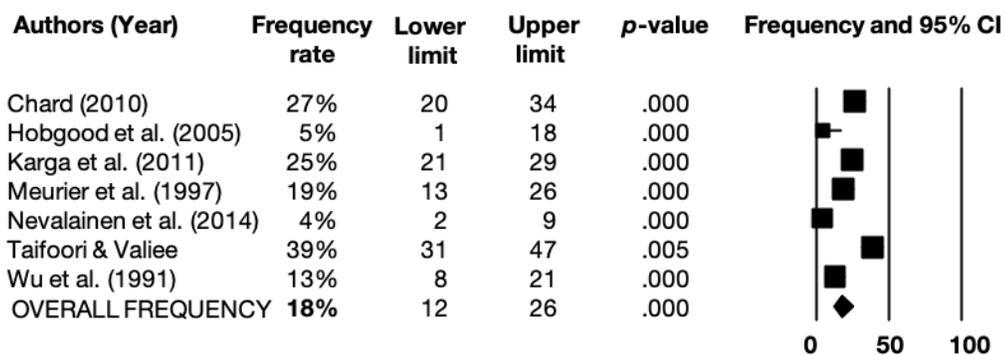
ORDERING MORE TESTS



$I^2=0\%$

Meta Analysis

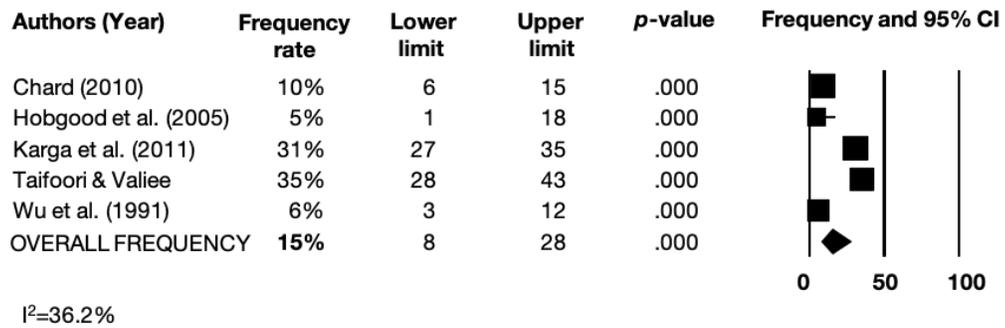
TRYING TO HIDE THE ERROR/REFUSING TO TALK ABOUT IT



$I^2=48\%$

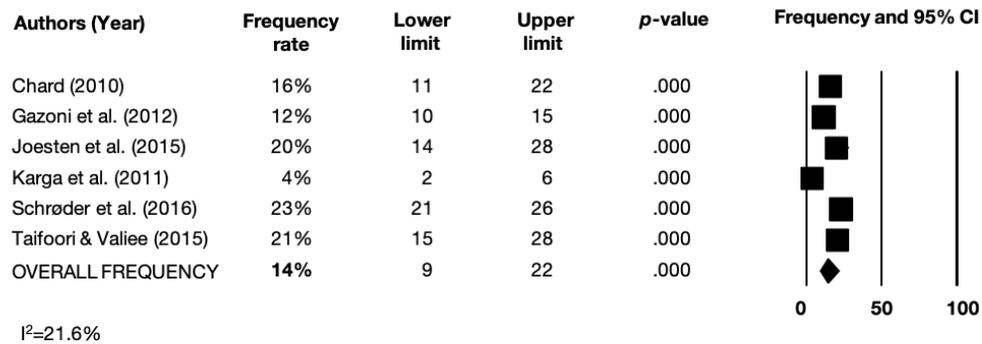
Meta Analysis

AVOIDANCE OF PATIENTS, PROCEDURES, SITUATIONS



Meta Analysis

TURNOVER INTENTIONS



Meta Analysis

USE OF ALCOHOL/DRUGS/MEDICATION

Authors (Year)	Frequency rate	Lower limit	Upper limit	p-value	Frequency and 95% CI
Dhillon et al. (2015)	5%	3	9	.000	
Gazoni et al. (2012)	5%	3	7	.000	
Van Gerven et al. (2016)	20%	17	24	.000	
OVERALL FREQUENCY	8%	3	23	.000	

$I^2=0\%$

Meta Analysis

APPENDIX E

Translated German version of the replica of the paper presented in
Chapter 7: *Patientensicherheit: Eine neue Grundlagenwissenschaft
für die berufliche Ausbildung*

EINLEITUNG

“Die Patientensicherheit ist eine Grundhaltung und muss daher frühzeitig eingeführt und dann während der postgradualen Ausbildung und der beruflichen Weiterbildung gestärkt werden” (Stefan Lindgren, Präsident der *World Federation for Medical Education*)

Seit den 1990er Jahren haben Studien zur Sicherheit und Qualität von Krankenhäusern auf der ganzen Welt immer wieder Probleme im Bereich der Patientensicherheit und -qualität festgestellt¹. Das Problembewusstsein ist deutlich gestiegen. So wurden in den letzten zwei Jahrzehnten große Anstrengungen unternommen, um die Sicherheit der medizinischen Versorgung zu verbessern. Eine für die Weltgesundheitsorganisation (WHO) durchgeführte Studie ergab, dass sieben Arten von unerwünschten medizinischen Zwischenfällen jährlich 43 Millionen Verletzungen verursachen, vermeidbare Schäden, welche die zwanzig häufigste Ursache für die weltweite Morbidität und Mortalität ausmachen². Andere Studien gehen davon aus, dass medizinische Fehler sogar noch häufiger sind³. Eine beunruhigende Statistik der WHO zeigte auf, dass in Ländern mit hohem Einkommen durchschnittlich jeder zehnte Krankenhauspatient in ein schwerwiegendes, vermeidbares unerwünschtes Ereignis involviert ist⁴.

Obwohl Patientinnen und Patienten weiterhin durch die Gesundheitsfürsorge geschädigt werden, wurden dennoch einige Fortschritte erzielt⁵. Seit 2000 ist allgemein bekannt und akzeptiert, dass „es das System ist“. Es ist hauptsächlich das Gesundheitssystem, welches Gefahren und Schäden verursacht, aber auch Patientensicherheit schaffen kann und nicht etwa einzelne Personen aus dem Gesundheitswesen⁶. Verantwortliche im Gesundheitswesen sowie der Öffentlichkeit neigen allerdings dazu, spezifische medizinische Fehler ausschließlich den einzelnen medizinischen Fachkräften zuzuschreiben. Andererseits muss natürlich eingeräumt werden, dass Einzelpersonen einen integralen und unverzichtbaren Bestandteil des Gesundheitssystems darstellen, als Mitglieder von Teams fungieren und mit anderen Teilen des Gesundheitssystems interagieren⁷. Auch der oder die Einzelne muss sich also verantwortlich fühlen. Wenn man sich nämlich einzig auf die Suche nach Systemlösungen konzentriert, geht dies zu Lasten des wichtigen Prozesses, in dem individuelle Verhaltensweisen verändert werden⁸.

Unabhängig davon, ob man eine individuelle oder systembezogene Perspektive auf die Ursachen von medizinischen Fehlern einnimmt, ist es notwendig, das klinische Personal darin zu schulen, wie eine sicherere Behandlung gewährleistet werden kann. Wir glauben, dass die Patientensicherheit eine neue Grundlagenwissenschaft für die medizinische Ausbildung darstellen sollte. Um dies zu erreichen, sind umfassende Reformen in der Ausbildung zu Gesundheitsberufen erforderlich. Wir sind uns jedoch bewusst, dass die Integration des Themas Patientensicherheit in Ausbildung und Training mit Herausforderungen verbunden ist.

Das Erscheinen dieser Sonderausgabe zur Patientensicherheit in der medizinischen Ausbildung in Deutschland ist ein wichtiger Schritt, um das Bewusstsein für die Bedeutung der Patientensicherheit zu schärfen. Die Beiträge in dieser Ausgabe sollen dabei helfen, dieses Feld in Forschung und Lehre voranzubringen.

DAS PROBLEM

Fachbereiche im Gesundheitswesen, wie etwa Medizin, Krankenpflege, Pharmazie, Zahnmedizin und andere, bieten nur eine eingeschränkte Schulung in Patientensicherheit. In der Medizin liegt der traditionelle Schwerpunkt des Lehrplans auf der Grundlagenwissenschaft und medizinischem Wissen. Die Ausbildung zum Facharzt/zur Fachärztin und andere postgraduale Schulungen haben zudem die technische Expertise im Blick. Andere Gesundheitsberufe, einschließlich

Krankenpflege, Pharmazie und Gesundheitstechnologie, behalten den Erwerb von Fakten und Wissen als Schwerpunkt bei. Dabei werden den Schlüsselkonzepten, Einstellungen und Fertigkeiten, die erforderlich sind, um sicher zu praktizieren und Verbesserungen in der medizinischen Versorgung zu erreichen, nicht genügend Aufmerksamkeit geschenkt.

Zusätzlich zum Mangel an grundlegenden Kenntnissen und Fertigkeiten beeinträchtigen die vorherrschende Kultur und das Arbeitsumfeld in Krankenhäusern und anderen Gesundheitsorganisationen die Bedingungen für eine sichere Praxis. In vielen Organisationen herrscht eine schädliche Kultur aus Scham, Schuldzuschreibung und Bestrafung im Zusammenhang mit medizinischen Fehlern sowie eine Haltung des Leugnens und der Rechtfertigung gegenüber Patienten und Patientinnen und ihren Familien. Ein Lehrplan, der diese Kultur unterschwellig widerspiegelt, gewissermaßen ein *heimlicher Lehrplan*, sabotiert entsprechende Versuche der Unterrichtsausbildung⁹. Zusammengenommen beeinträchtigen diese Bedingungen das Problembewusstsein, das Ergreifen von Maßnahmen und das Lernen aus Fehlern.

Um diese Lücken zu schließen, müssen die Schulen und Ausbildungsprogramme der Gesundheitsberufe ihre Ziele neu ausrichten, wobei sie sich nicht ausschließlich auf den Erwerb von Wissen und Fakten konzentrieren dürfen. Die Programme müssen im Lehrplan Raum für neue Konzepte, Einstellungen, Verhaltensweisen und Fähigkeiten schaffen und den Auszubildenden die Möglichkeit geben, sie entsprechend in die Praxis umzusetzen.

AUSBILDUNGSMODELLE

Es gibt immer mehr Anhaltspunkte dafür, dass eine angemessene Schulung zur Verbesserung der Patientensicherheit und der Qualität der medizinischen Versorgung beitragen kann. Lehrpläne zur Patientensicherheit sind im Allgemeinen bei Auszubildenden beliebt und haben zu einem besseren Verständnis der Konzepte zur Verbesserung der Sicherheit und Qualität und letztendlich zu optimierten Pflegeprozessen geführt¹⁰.

Universitäten haben damit begonnen, Schulungen zur Patientensicherheit in das Grundstudium der Medizin aufzunehmen^{11,12}. An der Johns Hopkins University in den USA wurde eine zehnstündige Schulung für Medizinstudierende im ersten Jahr eingeführt, die zu Verbesserungen hinsichtlich Wissens und Einstellungen sowie einer Zunahme des Engagements im Bereich der Patientensicherheit führte¹³. Daran schließt sich eine dreitägige Schulung für Medizinstudierende im zweiten Jahr an und zwar kurz vor ihrem Wechsel vom Hörsaal zur Klinik. Durch Vorlesungen und praktische Übungen erzielen die Studierenden Fortschritte in Bezug auf Wissen, Selbstwirksamkeit und Systemdenken¹⁴. Bemerkenswert ist, dass dieser Lehrplan durchgehend unter allen im zweiten Jahr unterrichteten Spezialthemen die bestmöglichen Bewertungen von den Studierenden erhält.

Darüber hinaus wiesen ältere Medizinstudierende, die in Großbritannien eine fünfstündige Schulung zum Thema Fehler in der Gesundheitsvorsorge besuchten, ein verbessertes Wissen auf¹¹.

Mit dem Ziel, in den deutschsprachigen Ländern das Thema Patientensicherheit in das Medizinstudium aufzunehmen, hat der Ausschuss für Patientensicherheit und Fehlermanagement der Gesellschaft für medizinische Ausbildung im Jahr 2016 einen Lernzielkatalog entwickelt, welcher Themen der Patientensicherheit und des Fehlermanagements in der medizinischen Grundausbildung behandelt. Dieser Katalog soll als Ausgangspunkt für eine vertiefte Auseinandersetzung der medizinischen Fakultäten mit diesen Themen dienen sowie als fachlich-

inhaltliche Orientierungshilfe für die Einbettung von Lehrgängen zur Patientensicherheit in bestehende Lehrpläne des Medizinstudiums^{15,16}.

In der Praxis haben Studien haben gezeigt, dass die Ergebnisse für die Patienten von Nutzen sind. Aiken und Kollegen fanden heraus, dass Krankenhäuser in den USA mit besserer Krankenpflegeausbildung eine niedrigere Patientensterblichkeit aufwiesen^{17,18}. Berry und Kollegen demonstrierten, dass eine verbesserte Sicherheitskultur und ein besseres Betriebsklima mit einer Abnahme der Patientenschäden und Krankenhaussterblichkeit verbunden waren¹⁹.

WAS SOLLTE GELEHRT WERDEN?

Der bahnbrechende Bericht *To Err is Human* aus dem Jahr 1999 des *Institute of Medicine*⁶ und nachfolgende Veröffentlichungen haben weltweite Empfehlungen zur Förderung einer sichereren Gesundheitsversorgung beeinflusst. Diese Empfehlungen lenken den Fokus eher auf Kompetenzen als auf Inhalte, um das Verhalten von Gesundheitspersonal zu ändern.

Kompetenzen umfassen die Patientensicherheit im weiteren Kontext der Praxis. In seinem Bericht *Patient Safety Achieving a New Standard for Care* hat das *Institute for Medicine* fünf Kernkompetenzen identifiziert, die alle medizinischen Fachkräfte nachweisen sollten²⁰. Dazu gehören die Bereitstellung patientenorientierter medizinischer Versorgung, die Fähigkeit zur Arbeit in interdisziplinären Teams, der Einsatz evidenzbasierter Praktiken, die Anwendung von Qualitätsverbesserungskonzepten und die Nutzung von Informatik.

Mehrere einflussreiche Gruppen und maßgebende Einrichtungen haben Anstrengungen unternommen, um Kompetenzen zu ermitteln, die für die Förderung eines sichereren Gesundheitswesens wichtig sind^{20,21-25}.

Das *American College of Graduate Medical Education* und das *American Board of Medical Specialties*²² definierten Kompetenzen in den Bereichen Patientenversorgung, medizinisches Wissen, praxisorientiertes Lernen und Weiterentwicklung, zwischenmenschliche und kommunikative Fähigkeiten, Professionalität und systembasierte Praxis (siehe Tabelle 1).

Tabelle 1. Vom *American Board of Medical Specialties* identifizierte Kernkompetenzen und Kriterien für *Maintenance of Certification*

Patientenversorgung	Die Fähigkeit, Patientenversorgung zu gewährleisten, die mitfühlend, angemessen und wirksam ist, mit dem Ziel Gesundheitsprobleme zu behandeln und die Gesundheit zu fördern
Medizinisches Wissen	Nachweis von Wissen über etablierte und sich entwickelnde biomedizinische, klinische, epidemiologische und verhaltenswissenschaftliche Forschung sowie die Anwendung dieses Wissens in der Patientenversorgung

Praxisorientiertes Lernen und stetige Weiterentwicklung	Nachweis der Fähigkeit, die Versorgungsqualität der eigenen Patientinnen und Patienten zu untersuchen und zu evaluieren, wissenschaftliche Nachweise zu bewerten und zu integrieren, sowie die Patientenversorgung auf der Basis kontinuierlicher Selbstbewertung und lebenslangen Lernens zu verbessern.
Zwischenmenschliche und kommunikative Fähigkeiten	Demonstration von zwischenmenschlichen und kommunikativen Fähigkeiten, die zum effektiven Informationsaustausch und zur Zusammenarbeit mit Patientinnen und Patienten, deren Familien, sowie mit Kolleginnen und Kollegen führt
Professionalität	Nachweis der Verpflichtung zur Wahrnehmung der beruflichen Verantwortung und der Einhaltung ethischer Grundsätze
Systembasierte Praxis	Demonstration einer klaren Vorstellung von dem größeren Kontext und dem System der Gesundheitsfürsorge und einer dementsprechenden Vorgehensweise sowie die Fähigkeit, zusätzliche Ressourcen des Systems effektiv zu nutzen, um eine optimale Versorgung zu gewährleisten

American Board of Medical Specialties: <https://www.abms.org/board-certification/a-trusted-credential/based-on-core-competencies/>

Das Programm zur Patientensicherheit der Weltgesundheitsorganisation (WHO) nennt elf Hauptthemen, die im Rahmen der medizinischen Ausbildung behandelt werden sollten. Diese Liste basierte ursprünglich auf dem *Australia Patient Safety Education Framework*^{26,27}.

Das erste Thema betrifft das Konzept und die Definition der **Patientensicherheit**. *Human Factors* beschreiben die Interaktion der Arbeitnehmer innerhalb des Arbeitssystems der Gesundheitsfürsorge und wie bestimmte interne Faktoren (Wissen, Fähigkeiten) und externe Faktoren (Stress, ineffektive Kommunikation, Produktionsdruck) mit medizinischen Fehlern und unerwünschten Ereignissen in Verbindung gebracht werden können. **Systemfehler** und Patientenschäden können auf Faktoren zurückgeführt werden, die auf mehreren Ebenen des Gesundheitssystems auftreten. Diese Systemebenen umfassen den Patienten, Aufgaben, Einzelpersonen, das Team, Tools, das Management und die Organisation. Kommunikation und **Teamarbeit** schließen Patientinnen und Patienten und ihre Betreuungspersonen sowie die interdisziplinäre Zusammenarbeit ein, um eine qualitativ hochwertige Versorgung zu gewährleisten. Die Fähigkeit, Systeme und die in ihnen verborgenen Fehler zu erfassen und Vorfälle an Kollegen zu kommunizieren, ist entscheidend für das **Lernen aus Fehlern**. Die Möglichkeit, **Qualitätsverbesserungs-Tools** zu verwenden, ermöglicht das Schließen von potentiellen Lücken nach diesen Ereignissen. **Die Zusammenarbeit mit Patientinnen und Patienten** und ihren Betreuungspersonen ist für die Optimierung der Sicherheit unerlässlich. Dazu gehört ein ethisch korrektes und angemessenes Verhalten bei der **Bewältigung klinischer Risiken** und Ehrlichkeit gegenüber Patientinnen und Patienten im Zusammenhang mit

medizinischen Fehlern. Die **Infektionskontrolle** identifiziert potenzielle Gefahren und verhindert Infektionen im Zusammenhang mit der Gesundheitsfürsorge, insbesondere durch die Anwendung universeller Vorsichtsmaßnahmen. **Invasive Verfahren** sind ein besonders risikoreicher Teil der Gesundheitsversorgung. Schäden können durch den sinnvollen Einsatz von Checklisten und Standardarbeitsanweisungen reduziert werden. Die **Arzneimittelsicherheit** befasst sich mit den allgegenwärtigen Risiken, die mit allen Phasen der Medikamenteneinnahme verbunden sind, insbesondere für verschiedene Altersgruppen, Hochrisiko-Medikamente und Übergänge in der Pflege.

Es gibt eine zunehmende Anzahl von Lehrplänen für Patientensicherheit sowie Überprüfungen ihrer Erfolge und Herausforderungen^{10,28-34}. Die Weltgesundheitsorganisation hat einen Leitfaden für Lehrpläne entwickelt, um Medizinstudierenden grundlegende Lektionen im Bereich der Patientensicherheit zu vermitteln, die es ihnen ermöglichen, sicher zu praktizieren²⁶. Es enthält ein Lehrerhandbuch und ein umfassendes, einsatzbereites, themenbasiertes Programm mit einem vollständigen Foliensatz.

Aus der Erkenntnis heraus, dass Menschen in allen Ländern mehrheitlich von anderen Fachkräften als Medizinerinnen und Medizinern betreut werden, folgte unmittelbar auf den Lehrplan für die Medizinstudierenden ein allgemeiner, multiprofessioneller Lehrplan für Patientensicherheit. Ziel war es, die Durchführung von Schulungen zur stationären Sicherheit zu unterstützen, unter anderem in den Bereichen Geburtshilfe, Pflege, Pharmazie, Zahnmedizin und Medizintechnik³⁵.

HERAUSFORDERUNGEN BEI DER UMSETZUNG

Es wird manchmal gesagt, dass es in der akademischen Medizin am schwierigsten sei, einen neuen Kurs in den Lehrplan aufzunehmen. Universitäten sind bekannt für ihre professionelle Bürokratie, wozu auch der Widerstand gegen Veränderung zählt. Es besteht oftmals die Tendenz, die bestehende Organisationsstruktur beizubehalten, auch wenn offensichtlich ist, dass sie den institutionellen Zielen nicht dienlich ist.

Es wurden Hindernisse bei Änderungen der Hochschulbildung im Allgemeinen festgestellt, die sich auf Einstellungen, bestehende Strukturen und Ressourcen beziehen^{36,37}. Ein schwieriges Unterfangen scheint auch die Einführung von Patientensicherheit in Schulen für Gesundheitsberufe darzustellen, wie es eine Studie von Leotsakos et al.³⁸ nahelegt.

Zu den Hindernissen bei der Umgestaltung der Hochschulbildung zählen folgende:

1. Mangel an Bewusstsein (u.a. mangelndes Interesse, Engagement, Einbindung), Unterstützung, Professionalität, Politikgestaltung und Anerkennung
2. Konservative Disziplinarstruktur der Hochschulbildung, ineffiziente Kommunikation, Widerstand gegen Veränderungen, überfüllter Lehrplan, Konzentration auf inhaltliches Lernen
3. Bedarf an mehr Ressourcen, einschließlich Finanzierung; Arbeitsdruck und Zeitmangel; fehlender Zugang zu Informationen, Mangel an einheitlichen Rechtsvorschriften und Platzmangel [36]

Die Einbeziehung der Patientensicherheit in die Ausbildung zu Gesundheitsberufen ist auch mit besonderen Herausforderungen verbunden. Dazu gehören 1) mangelndes Problembewusstsein, 2) mangelnde Übereinstimmung, einschließlich des *heimlichen Lehrplans*, 3) mangelndes Engagement und fehlende Beteiligung, 4) mangelnde Führung, 5) die disziplinentorientierte Struktur der medizinischen Wissenschaft und Gesundheitsfürsorge, 6) Widerstand gegen Veränderung, 7) überfüllter Lehrplan, 8) historischer Fokus auf inhaltsbasiertes Lernen, 9) Mangel an Know-how

und Unterstützung für Lehrkräfte, einschließlich Finanzierung, 10) hoher Arbeitsdruck, parallele Arbeitsanforderungen und Zeitmangel sowie 12) Beweislücken bei bewährten Verfahren. Mangelndes Bewusstsein und mangelnde Übereinstimmung sind bekannte Hindernisse bei der Einhaltung von Richtlinien durch Ärztinnen und Ärzte sowie im Hinblick auf Verhaltensänderungen³⁹. Kursleitende sträuben sich oftmals, Patientensicherheit als wichtigen Forschungszweig anzuerkennen⁴⁰. Viele müssen von der Relevanz dieses Faches für andere Fächer überzeugt werden, was bei den Grundlagenwissenschaften wie Anatomie, Physiologie und Biochemie nicht der Fall ist.

Ein *heimlicher Lehrplan*, der die „Praxis der realen Welt“ widerspiegelt, ist tief in der Kultur und im Verhalten von Gesundheitsorganisationen verankert. Dieser *heimliche Lehrplan* hält autoritäre und hierarchische Strukturen und unprofessionelles Verhalten aufrecht, sabotiert die Teamarbeit und stärkt die paternalistische Einstellung gegenüber Patientinnen und Patienten⁹. Studierende und Auszubildende beobachten, wie sich ihre erfahreneren Kolleginnen und Kollegen verhalten, konträr zu dem, was sie womöglich im Hörsaal gelernt haben. Diese Faktoren tragen unter den Fakultätsmitgliedern zu mangelndem Engagement und unzureichender Beteiligung bei. Dies kann durch den Mangel an visionärer und befähigender Führung, welche die Patientensicherheit mehr in den Fokus rücken würde, noch verstärkt werden.

Die disziplinierte Struktur der medizinischen Fakultäten ist selbst ein Hindernis⁴⁰. Fakultätsmitglieder in einzelnen Abteilungen verzichten möglicherweise nur ungern auf Raum im Lehrplan und den damit verbundenen Status. Auch an unserer eigenen Universität wurde der Versuch, Studierende der Medizin und der Pflege gemeinsam in Patientensicherheit zu unterrichten, durch miteinander kollidierende Zeitpläne der jeweiligen Fakultäten enttäuscht.

Auch Fachschulen kämpfen bereits mit dicht gedrängten Lehrplänen. Da die in der Klinik verbrachte Zeit begrenzt ist, haben die Studierenden weniger Möglichkeiten, mit häufig auftretenden Problemen der Patientensicherheit konfrontiert zu werden. Die Möglichkeiten für ein interdisziplinäres Training in Praxissituationen sind sogar noch eingeschränkter [41]. Außerdem sind die Fakultäten daran gewöhnt, inhaltliches statt kompetenzbasiertes Lernen anzubieten. Zudem herrscht oftmals ein Mangel an Lehrpersonal und diejenigen Lehrkräfte, die vorhanden sind, schrecken manchmal davor zurück, Themen zu unterrichten, die außerhalb ihrer Disziplin und Expertise liegen⁴².

Führungskräfte in Fachschulen und Universitätskliniken spielen daher eine wichtige Rolle für einen erfolgreiche Veränderung des Lehrplans. Dies erfordert die Schaffung eines Umfelds, in dem Veränderungen akzeptiert und vorgenommen werden können. Unzureichende Unterstützung in Bezug auf Zeit, Finanzierung und Beratung sind große Hindernisse bei der Genehmigung von Reformen und deren Umsetzung⁴³.

WAS GETAN WERDEN SOLLTE

Um den Lehrplan zu ändern, den Auszubildenden Kompetenzen und ein Bewusstsein für die Sicherheitskultur zu vermitteln und um letztendlich Verhaltensänderungen zu bewirken, müssen Stakeholder aus dem medizinischen Ausbildungsbereich und Gesundheitsorganisationen aktiv werden.

Für eine Organisation, die sich auf einen derartigen Lehrplanwechsel einlässt, ist Kommunikation und Engagement von Lehrenden und Mitarbeitenden von Anfang an unverzichtbar^{44,45}. Dabei ist es wichtig, über die Gründe für die vorgeschlagenen Änderungen und die damit verbundenen

Prozesse aufzuklären. Es ist von entscheidender Bedeutung, den Mitarbeitenden, die daran beteiligt sind, berufliche Entwicklungsmöglichkeiten zu bieten. Dies sollte einschlägige Schulungen und Aktivitäten umfassen, die es ihnen ermöglichen, sich am Veränderungsprozess zu beteiligen.

Das *Lucian Leape Institute* der *National Patient Safety Foundation* berief eine Expertengruppe ein, die Empfehlungen zur Verbesserung der Ausbildung in Patientensicherheit herausgab⁴⁶. Obwohl sie in den USA für die Reform medizinischer Fakultäten entwickelt wurden, sind die meisten dieser Empfehlungen auf den internationalen Kontext und auf andere Ausbildungsrichtungen im Gesundheitswesen übertragbar. Die Empfehlungen konzentrieren sich zunächst auf die Entwicklung von Lernkulturen, die Sicherheit, Professionalität, Zusammenarbeit und Transparenz betonen. Der Schwerpunkt liegt dabei auf der Förderung zwischenmenschlicher Fähigkeiten und interdisziplinärer Teamarbeit. Es sollten Mittel bereitgestellt werden, um die betreffende Fakultät bei der Entwicklung der für die Bereitstellung der Lehrpläne erforderlichen Fähigkeiten zu unterstützen. Die Änderungen sollten sich auf die Auswahl der Studierenden erstrecken, deren Eigenschaften diese neuen Kompetenzen widerspiegeln. Patientensicherheit sollte als Wissenschaft konzeptualisiert werden und die berufliche Erstausbildung sollte sich auf Kernkompetenzen in denjenigen Bereichen konzentrieren, die in diesem Editorial bereits beschrieben wurden. Dieses Lernen sollte über die Grund- und Spezialausbildung hinausgehen und zu lebenslangem Lernen führen. Die nationalen Akkreditierungsanforderungen sollten an die Erreichung dieser Kompetenzen angepasst werden. Die Auswirkungen dieses neuen Satzes von Bildungsprioritäten sollten bewertet sowie finanzielle und andere Anreize angeglichen werden, um die Änderungen zu unterstützen. Viele der Empfehlungen richten sich an akademische sowie an externe Führungskräfte in noch höheren Positionen, wie etwa in Bildungsministerien und Akkreditierungsstellen, da diese Personen eine wichtige Rolle bei der Umsetzung von Veränderungsprozessen spielen⁴⁷.

Es gibt eine Vielzahl von Tools und Strategien, die eingesetzt werden können, wobei eine ausführliche Erörterung allerdings nicht Gegenstand dieses Editorials sein kann. Dazu gehören sowohl High-Tech- als auch Low-Tech-Simulationen^{48,49} und die Verwendung standardisierter Patientinnen und Patienten. Standardisierte Schulungen zum Einsatz von Tools zur Verbesserung der Teamarbeit und Kommunikation, wie *TeamSTEPPS* und das *Comprehensive Unit Based Safety-Programm* (CUSP), können dabei helfen, Wissen zu vertiefen, Einstellungen zu ändern und Ergebnisse zu verbessern⁵⁰⁻⁵².

Das traditionelle Lernen am Modell ist nach wie vor ein entscheidender Bestandteil des Lehrens. Dies ist besonders wichtig, um Werte und Verhaltensweisen zu vermitteln, die eine Sicherheitskultur und optimales Lernen fördern und um die Vermeidung von und den adäquaten Umgang mit Fehlern zu unterstützen. Die Zusammenarbeit mit Patientinnen und Patienten – wann immer möglich – ist ein weiterer bedeutender Teil der Ausbildung⁵³.

Es gibt hervorragende Standardlehrbücher^{54,55} sowie eine wachsende Anzahl kostenloser Online-Ressourcen, die Informationen, Anleitungen und Schulungen zur Patientensicherheit anbieten⁵⁶⁻⁶⁰.

FAZIT

Es ist unabdingbar, das Gesundheitspersonal weltweit auf sichere Patientenversorgung vorzubereiten. Wir sind der Meinung, dass die Patientensicherheit als neue Grundlagenwissenschaft für die Ausbildung in Gesundheitsberufen betrachtet werden sollte. Die Übertragung des Forschungsfeldes Patientensicherheit in sichere medizinische Verfahrensweisen

ist jedoch auch ein sehr praxisnahes Unterfangen. Um die Patientensicherheit in die Lehrpläne von Fachschulen und Ausbildungsprogrammen zu integrieren, sind umfangreiche Reformen erforderlich. Diese Organisationen müssen ihren Fokus vom reinen Erwerb von Wissen auf die Entwicklung von Kompetenzen und Verhaltensänderungen lenken.

Der neue Lehrplan muss Kompetenzen vermitteln, die im Zusammenhang stehen mit patientenorientierter Betreuung, Arbeit in interdisziplinären Teams, Anwendung von evidenzbasierten Praktiken sowie von Qualitätsverbesserungskonzepten. Dazu zählt auch, sowohl die Sichtweisen der Studierenden als auch Einstellungen und Kenntnisse zu verändern. Studierende sollten in der Lage sein, individuelle Sicherheitsprobleme durch „Systemlinsen“ zu sehen und mögliche Lösungen identifizieren und testen zu können.

Wir sind uns bewusst, dass die Integration des Themas Patientensicherheit in die allgemeine und berufliche Bildung mit Herausforderungen verbunden ist. Ein großes Hindernis ist die vorherrschende Kultur der Scham, der Schuldzuweisung und der Leugnung medizinischer Fehler. Der *heimliche Lehrplan* steht im Wettbewerb mit den Versuchen, eine Sicherheitskultur zu schaffen und optimales Lernen zu ermöglichen.

Unterschiedliche Akteure in den Bereichen Ausbildung und Gesundheitsfürsorge müssen Maßnahmen ergreifen. Kommunikation von Top-Führungskräften und Transparenz in der gesamten Einrichtung sind während des Prozesses erforderlich. Koordinierung wird ebenfalls notwendig sein, um den Studierenden die Möglichkeit zu geben, ihre neuen Fähigkeiten in der Praxis zu üben.

Es stehen nun genügend Tools zur Verfügung, so dass jede Organisation gute Startbedingungen hat. Dennoch gibt es noch viel zu erlernen, etwa wirksame Strategien für die Schulung von Auszubildenden im multidisziplinären und praxisorientierten Umfeld sowie die Anpassung von Lehrmaterialien an lokale Gegebenheiten. Innovationen sind immer noch erforderlich. Frühzeitige Erforschung und Evaluierung lassen uns das Ziel, die Patientenversorgung sicherer zu machen, rascher erreichen.

Interessenkonflikt

Die Autoren erklären, dass sie keine Interessenkonflikte im Zusammenhang mit diesem Artikel haben.

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