Patient Safety in Medical Humanitarian Action: Medical error prevention and management

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PATIENT SAFETY IN MEDICAL HUMANITARIAN ACTION.

Medical error prevention and management

Thesis presented to obtain the degree of
Docteur en Santé Globale, Université de Genève
Docteur en Science de la Santé, Université de Lyon1
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Date of the thesis defence: 20 February 2020

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Acknowledgments

Thanks are due, first of all, to the members of my doctoral committee for their patience and support.

I am particularly grateful to those who, from the sidelines, have been an unwavering help and to those who had to bear with me as I invested my time and energy in this confounded undertaking.

The two oversight institutions, the University of Geneva's Institute of Global Health and Claude Bernard University, Lyon 1, both deserve special mention for having believed in my project and for having accepted me within their doctoral program.

I should also like to pay tribute to all humanitarian workers who, relentlessly, in spite of the difficulties and risks that their work involves, try to bring effective aid to their contemporaries. I hope that this modest labour on my part will be able to contribute to making them even more effective…

Keywords: Medical error, Patient safety, Humanitarian Medicine, Safety culture, safety risks

Mots-clés : Erreur médicale, Sécurité du patient, Médecine Humanitaire, Culture de la sécurité, Risque de Sécurité

1. List of Publications

Published articles

Article 1

Title: 'A Call for the Application of Patient Safety Culture in Medical Humanitarian Action: A Literature Review'

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This article was submitted to and published in the Journal of Patient Safety in March 2020.

Article 2

Title: 'Knowledge, Attitudes and Expectations of Medical Staff toward Medical Error Management Policies in Humanitarian Medicine: A Qualitative Study'

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This article was submitted to and accepted for publication in the Journal of Patient Safety with minor modifications January 2020.

Oral Presentation:

Title: 'Medical Humanitarian Action and Patient Safety: The End of an Exception?'

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This presentation (see Annex 1) was made at the Geneva Health Forum on 19 April 2016 in a parallel event organized by J.-M. Biquet and titled 'Quality of Care after Sudden Onset Disasters: Good Will Is Not Enough'.

Under Preparation

Symposium

Title: 'Patient safety: Management of medical errors in Medical Humanitarian Action'

Foreseen for Autumn 2020, the symposium aims at opening the debate and sharing the experiences in the medical humanitarian sector on patient safety, with a focus on medical error management. Expected partners for the symposium: CERAH, WHO, MSF, ICRC

Training

Title: 'Patient safety: Management of medical errors in Medical Humanitarian Action'

Thematic short Course organised (spring-summer 2020) by CERAH in partnership with MSF and ICRC aiming at training the medical manager of medical humanitarian action on management of medical errors in the field

2. Abstract in English

Patient safety has been recognized for some 20 years as one of the essential elements of healthcare quality[1] and has become an integral part of healthcare systems – at least in OCDE countries. It encompasses regulations, tools and strategies that affect all sectors of medicine. Today, research and implementation in the area of patient safety pertain above all to healthcare systems in the most developed countries whereas two thirds of estimated safety incidents occur in low- or mid-income countries.[2]

An exploratory phase aiming at developing the research strategy was made through discussions during informal meetings with international patient security specialists as well as with actors in the humanitarian sector. It confirmed that patient safety, per se, and the detection and management of medical errors have not yet been translated into the humanitarian assistance sector in a structured and adapted way. In order to understand the reasons for this gap in relation to criteria of healthcare quality as defined in the healthcare systems of countries where the headquarters of major international medical organisations are based, this research aimed to understand what the current status and perspectives of patient safety in medical humanitarian action are. An initial phase explored developments in the knowledge of safety and risk management that have dealt with the phenomenon of error and have developed theories and models regarding risk management at the origin of patient safety. Then, the current state of knowledge and the main developments in patient safety and especially medical error management were explored, before moving on to current limits and the stakes of implementation. This research on Google Search (Keywords: Patient safety and risk management) was followed by a rapid literature review on PubMed (Keywords: Patient safety, medical error, adverse event, review, systematic review, since 2013). 104 articles on the 245 references found, met the criteria and were analysed. In total a database of more than 1,200 articles has been established. In parallel, the characteristics of medical action as carried out by medical humanitarian organisations were analysed through a systematic literature review on PubMed and Embase databases. The searched keywords were: Patient safety, medical

error, humanitarian, since 2000. 39 articles on the 308 references retrieved, met the inclusion criteria. This part of the research was the subject of a first article accepted by the “journal of Patient Safety” (in print).

The lessons learned in patient safety practises in OCDE healthcare systems show the necessary conjunction of action at three levels: at the macro level, regulations, the determination of objectives and a clear legal framework; at the micro level, personnel engaged in healthcare and its management to be sensitised, trained and directly involved; and at the meso level, healthcare institutions to be catalysts of patients safety owing to their commitment and leadership. It is at this level that the tools, processes and a favourable environment are created, institutions being responsible for establishing error-detection systems and a participatory management framework for correction and learning.

The second phase of our research was centred on semi-directive discussions with medical and paramedical personnel active within six medical humanitarian organisations. The selected organisations respected the following criteria: International humanitarian organisations based in an OECD country; active throughout the world with national and international staff; having a medical department implementing the organisation’s medical policies; and whose medical action was, in terms of budget, the major area of activities (with the exception of ICRC, historically a medical organisation having diversified its portfolio of activities). A first interview was done with the medical director or the responsible of the quality of care of those organisations. Then, 39 interviews were done by Skype or face to face with medical and paramedical staff of those organisations responding to the following criteria: international staff with minimum 2 years of experience in the humanitarian sector. 36 interviews were analysed, the others being of too poor quality of recording to be transcribed effectively. The selected interviews integrally transcribed were coded and analysed by themes and sub-themes (Atlas ti ©). The objective was to understand the knowledge, attitudes and practises of these personnel with regards to patient safety and medical error management as well as their

expectations regarding the needs, as they perceived them, to integrate the preoccupation with patient safety and risk management into institutional priorities within their sector. The results of this research were reported in a second article presented and accepted with minor modifications by the “Journal of Patient Safety”.

It appeared clearly that, while there may not yet be a structured approach in the sector regarding patient safety and, specifically, medical error management, this clearly corresponds to an expectation on the part of the humanitarian personnel interviewed. The reasons cited to explain this lack fell into roughly two groups. First, the specificity of medical humanitarian action such as the mind-set and mode of operation oriented to urgency (tendency to move from one priority to another depending on the level of urgency) as well as national and international personnel encompassing highly varied medical cultures. To this one might add the absence of a regulatory system in the sector as well as external pressures pushing toward investments in safer healthcare provision, and, finally, a great diversity of activities and intervention contexts as well as in the level of control of the humanitarian organisations regarding the care dispensed. Second, there are factors common to those found in OCDE country healthcare systems such as the absence of the ingredients of a safety culture: leadership; a learning, rather than a blaming, culture; appropriate support of personnel regarding sensitisation, training and development of tools for reporting and analysing medical error as well as clear guidance for the management of consequences.

Regarding the expectation of the persons interviewed, while they all acknowledged their role in the implementation of safety for their patients, they clearly identified the responsibility of their organisations to invest in the means of translating into practice the desire for a better awareness of patient safety. To achieve this, they call for collaboration among organisations to share experiences and to develop tools of implementation.

This research, to our knowledge the first of its kind, demonstrates the eagerness of the medical and paramedical staff engaged in humanitarian action to commit to an internal cultural revolution towards a safer healthcare provision, even in precarious situations.

Catching up the delays in adopting adapted patient safety and medical error management policies would reinforce the accountability to the vulnerable populations assisted by these organisations and save more lives, the essence of humanitarian purpose.

3. Abstract in French

La sécurité des patients est reconnue depuis une vingtaine comme un des éléments essentiels de la qualité des soins[1]et est devenu une partie intégrante des systèmes de santé, tout au moins dans les pays de l'OCDE. Elle se déclinée en règlementations, outils et stratégies qui touchent tous les secteurs de la médecine. Aujourd'hui les recherches et applications de la sécurité des patients concernent surtout les systèmes de santé des pays les plus développés alors même que deux-tiers des incidents de sécurité estimés se produisent dans les pays à revenu faible ou moyen[2].

Une phase exploratoire visant à élaborer la stratégie de recherche a été menée au travers d'entretiens non-structurés avec d'experts internationaux sur la sécurité des patients et de responsables du secteur humanitaire. Cette phase a permis de confirmer que la sécurité du patient et la détection et gestion des erreurs médicales n'ont pas encore eu de traduction structurée, adaptée au secteur de l'assistance médicale humanitaire. Afin d'essayer de comprendre les raisons de ce décalage par rapport aux critères de qualité de l'offre de soins tels que définis dans les systèmes de santé de pays dont sont pourtant originaires la plupart des organisations médicales humanitaires, cette recherche vise à comprendre quels sont le statut actuel et les perspectives de la sécurité des patients dans l'action médicale humanitaire. Une première phase s'est penchée sur les développements dans les sciences de la sécurité et de la gestion des risques ayant étudié le phénomène de l'erreur et ayant développé des théories et modèles sur la gestion du risque à l'origine de la sécurité du patient. La recherche a ensuite abordé l'état de connaissance actuelle et les principaux développements en matière de sécurité des patients, et de la gestion des erreurs médicales en particulier, avant de s'attarder aux limites et enjeux actuels de sa mise en œuvre. Cette recherche sur Google Search (Mots-clés : Patient safety and risk

management) a été suivie d'une revue de littérature rapide sur PubMed (Mots-clés : Patient safety, Medical error, Adverse event, Review, Systematic review since 2013). 104 articles sur les 245 articles trouvés répondaient aux critères. Au total, une base de données de plus de 1.200 articles a ainsi été constituée. En parallèle a été mené une documentation et analyse des caractéristiques de l'action médicale telle que déployée par les organisations médicales humanitaires à travers une revue systématique des articles sur les bases de donnes PubMed et Embase. Les mots-clés utilisés étaient : Humanitarian, patient safety, since 2000. 39 articles sur les 308 références trouvées répondaient aux critères. Cette partie de la recherche a fait l'objet d'un premier article accepté par la revue « Journal of Patient Safety (en attente d'impression).

Les leçons apprises dans les pratiques en matière de sécurité des patients dans les systèmes de santé de l'OCDE, montre la nécessaire conjonction d'actions à trois niveaux : au niveau macro, des règlementations, déterminations d'objectifs et un cadre légal clair ; au niveau micro, du personnel impliqué dans les soins et leur gestion qui soit sensibilisé, formé et impliqué ; et au niveau méso des institutions de soins, catalyseurs de la sécurité des patients grâce à l'engagement et au leadership. C'est à ce niveau que des outils, des processus et un environnement favorable sont initiés, car ces institutions ont la responsabilité d'établir des systèmes de détection d'erreur et un cadre de gestion participatif pour la correction et l'apprentissage.

La deuxième phase de la recherche s'est centrée sur des entretiens semi-directifs avec du personnel médical et paramédical actifs au sein de 6 organisations médicales humanitaires pour connaître l'état actuel des développements en matière de sécurité du patient et de la gestion des erreurs médicales. Les organisations sélectionnées répondaient aux critères suivants : Organisations humanitaires internationales basées dans un pays de l'OCDE ; actives partout dans le monde avec du personnel national et international, ayant un département médical déterminant leurs propres politiques médicales ; Et dont l'action médicale était, en termes budgétaires, l'activité principale (à l'exception du CICR, organisation médicale à la base dont l'activité s'est diversifiée dans le temps). Un premier

entretien a été mené avec les responsables des départements médicaux ou le responsable de la qualité des soins de ces 6 organisations. Ensuite, 39 entretiens ont été menés par Skype ou en face à face avec du personnel médical ou paramédical qui correspondaient aux critères suivants : personnel international avec 2 ans d'expérience minimum dans le secteur humanitaire. 36 entretiens ont été retenus pour analyse, les autres étant de trop mauvaise qualité d'enregistrement pour être exploitables. Les entretiens retenus, entièrement retranscrits ont été codés et analysés par thèmes et sous-thèmes (Atlas ti©).

L'objectif était de comprendre les connaissances, attitudes et pratiques de ce personnel dans ces domaines et entendre les attentes de ce même personnel en ce qui concerne les besoins pour intégrer la préoccupation de la sécurité du patient et la gestion des risques dans les priorités institutionnelles de leur secteur. Les résultats de cette analyse ont fait l'objet d'un deuxième article présenté et accepté, moyennant modifications mineures, par la revue « Journal of Patient Safety ».

Il apparait clairement que s'il n'existe actuellement pas encore dans le secteur d'approche structurée de la question de la sécurité du patient et plus spécifiquement de la gestion des erreurs médicales, cela répond clairement à une attente de la part du personnel humanitaire interviewé. Les raisons invoquées pour expliquer ce manque sont de deux ordres. Il y a d'abord celles en lien avec les spécificités de l'action médicale humanitaire telles que la mentalité et le mode d'action tourné vers l'urgence (tendance à passer d'une priorité à l'autre selon le degré d'urgence), un personnel national et international de culture médicale très variée. A cela s'ajoutent l'absence d'un système de régulation dans ce secteur d'activité tout comme de pressions extérieures poussant à investir dans la sécurité du patient et enfin une grande diversité des activités et des contextes d'intervention ainsi que dans le niveau de contrôle des organisations humanitaires sur les soins prodigués. D'autre part, il y a des facteurs communs à ceux que l'on a pu retrouver dans les systèmes de santé des pays de l'OCDE comme l'absence des ingrédients principaux de la culture de la sécurité : le leadership ; la culture de l'apprentissage et non du blâme ; un soutien approprié du personnel en matière de sensibilisation, formation et

développement d'outils pour le rapportage et l'analyse des erreurs médicales ; ainsi qu'une guidance claire pour la gestion de leurs conséquences.

En matière d'attentes des personnes interviewées, si elles reconnaissent leur rôle dans la mise en œuvre de la sécurité de leurs patients, elles identifient clairement la responsabilité de leurs organisations pour un investissement clair dans les moyens de traduire dans les faits leur désir d'une meilleure prise en compte de la sécurité des patients. Pour ce faire, elles appellent de leurs vœux une collaboration entre organisations pour un partage d'expériences et le développement d'outils et d'approche.

Cette recherche, la première du genre selon nos informations, identifie la motivation du personnel médical et paramédical du secteur humanitaire à s'engager à mener une véritable révolution culturelle pour rendre l'offre de soins plus sûre, même dans des situations précaires. Rattraper le retard dans l'adoption de politiques en matière de sécurité du patient et de la gestion des erreurs médicales renforcerait la « redevabilité » de ces organisations envers les populations vulnérables qu'elles assistent et permettrait de sauver plus de vies, l'essence même de l'action humanitaire.

4. Table of Content

5. General Introduction

Patient safety is a concept that has only recently come fully into its own in the medical care sector. The recognition of error, as a subject of systemic concern, has been a slow process despite many individual calls[3] and legendary initiatives, such as the development of standards of care by Florence Nightingale.[4] The publication of the United States Institute of Medicine (IOM) report in 2000, To Err is Human: Building a Safer healthcare System (1999),[5]mentioning 44,000 to 98,000 Americans dying every year from medical errors, sparked a massive investment in error prevention and management. The awareness of numerous cases of incidents during medical care, with severe consequences for the patient, and their aftermath in terms of image, legal, social and psychological effect,[i] have forced healthcare systems and institutions – in the countries of the Organisation for Economic Co-operation and Development (OECD) at least – to establish comprehensive mitigation and prevention strategies. This came very late in comparison to other high-risk sectors (aviation, nuclear industry…) and can be explained by various factors: the lack of visibility of the consequences of medical errors (in the worst-case scenario, one patient may die at a time, hiding the extent of the problem); the very idea of doctors making mistakes or errors creates a cultural dissonance[6] (medical doctors today still enjoy high social status; this is embedded not only in medical professionals' minds but also in the belief of the patients and, more widely, the belief of the general population); the complexity of medical care (involving different disciplines, practised in different locations for the same patient, with ever more complex medical cases); the litigation risks for the staff involved in a medical error and their institutions if it is disclosed.

i See for instance the 2006 Eurobarometer survey on medical errors available on https://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_241_en.pdf ; accessed 12 September 2019

The development of these new policies and practices to ensure safer medical care provision and complementing the already existing actions (pharmacovigilance, standards of care…) is known under the broad concept of patient safety.

Patient safety can be defined as "the identification, analysis and management of patient-related risks and incidents, to make patient care safer and minimize harm to patients".[7] It builds on the involvement of key actors at three levels: systemic, individual and institutional.

At the level of the healthcare system and its governing bodies, what is required is an environment conducive to the implementation of a political will, under legal and regulatory conditions, for individuals as institutions within the system to speak on, manage and work on preventing medical errors in a structured, responsible and safe manner. By developing recommendations and evaluating health services in terms of quality, the pertinent authorities can develop standards as well as global and national plans of action in the area of patient safety plus tools and guidelines to assist medical institutions and professionals in implementing measures for patient safety. They also have the capacity to nurture the links among the elements of the system, notably to influence universities and schools to develop the necessary training of individual medical staff in the concern, methods and management of patient safety.[8] National authorities play a major role in influencing society's perception of its relation to healthcare expectations and limits[9] while promoting actions.[ii]

At their level, the individual medical staff and managers of healthcare services are key actors in patient safety, not only because they are potentially involved in, or witnesses of, medical error commission, but because they must be fully engaged in the detection, analysis and management of medical errors and of their consequences. This supposes that they have been made thoroughly aware of the error-prone nature of their professional activities as well as understanding that error is human, meaning that there is not

[ii] For instance a call from the French Ministry of Health available on http://social-sante.gouv.fr/grands-dossiers/signalement-sante-gouv-fr/ Accessed on 18/3/17

necessarily negligence behind a deviation from what is generally considered the standard action to follow in a specific situation. These are requisites for them accepting to disclose detected errors then analyse them in search of lessons to be learned in order to avoid recurrence.

At the medical institution level, the creation of a safe, supportive learning environment is crucial to involving the staff in proper management of medical errors and their consequences and improving medical practices. Creating a no-blame culture and providing adapted support to staff when establishing reporting systems of medical errors are necessary conditions that a committed leadership must provide in order for errors to become a source of learning and subsequent improvement.

Medical error is now better understood,[10] is recognized as an important cause of harm (third cause of death in the U.S.A.[11]), and strategies, policies and tools have been developed at medical-institution and health-system levels to minimize the risks of error and to manage the occurring cases.[12] The consequences of medical error are impressive. For instance, a study sponsored by the Society for Actuaries for the U.S.A. alone estimated the cost of medical error, for 2008, at $19.5 billion, of which 80% is additional medical costs: prescriptions, in- and outpatient costs, ancillary services.[13] The human and economic costs for society are coupled with the legal, financial and reputational consequences for the involved medical staff and medical institutions.

Twenty years of research, experience-sharing and investments have allowed the establishment of patient safety as a discipline in itself, and as an attribute of healthcare systems.[14] Patient safety concept and strategies have now percolated – in OECD countries at least – into all specialties of medicine and all care-giving settings: from ambulatory to home-based care, from general practice to secondary and tertiary level of care.[15] Reports highlight improvements in safety of healthcare provision since the beginning of the 2000s. (For instance, from 2010 to 2014, the overall rate of hospital-acquired conditions declined by 17% in the U.S.A. Improvements were observed in about 60% of safety measures monitored by AHRQ.[16] In Great Britain, a systematic analysis of underlying risk factors lead

to actions enabling a diminution of 20 to 30% of the falls of patient in hospitals[17]). However, considerable frustrations are emerging over what has (not) been achieved so far. The awareness that patients must be recognized as agents of their health has not yet translated into an acceptable role for them in error detection and management and its prevention. One of the most difficult tasks of patient safety specialists is to find appropriate measurement strategies to assess where priorities must be assigned in error prevention and to quantify the benefits of proposed measures. Healthcare systems experiencing ever greater budgetary constraints, along with pressures exerted on medical staff to increase productivity, do not favour investments in patient safety efforts. The movement towards patient safety of the last two decades, which complements continuous improvements of healthcare in the last centuries, will remain an endless battle owing to the evolution of medicine and the human nature of its practice. Technological evolution affects patient safety like a double-edged sword. On the one hand, it creates new opportunities and capacities to act on safety risks; on the other, it increases the complexity of medical practice, thereby increasing the risk of making errors. More research is needed to find appropriate measures to avoid and manage the risks. Presently, patient safety mainly targets hospital settings. There is still much effort needed in looking at the specificities of other areas of healthcare provision such as primary care.[18] Today, research and patient safety initiatives are to be found mainly in developed countries despite estimations that two thirds of medical errors occur in low- or middle-income countries.[2]

It took a long time for patient safety to become a recognized necessary attribute of quality care provision and to be translated into policies, methods and practices. While there are still considerable challenges and much research is still necessary to overcoming their assessed limits, the attention to safety corresponds to the ethical, moral, legal, economic and social obligations of the medical professions and the management of healthcare services.

There is one area of medical practice that seems totally unexplored: medical humanitarian action. A Humanitarian medicine can be defined as "a set of medical or public health practices whose sole intent is to selflessly accommodate and address the tension created between compelling health needs and the ongoing deprivation of resources in a given population or community."[19]

An initial review of the literature and interviews with humanitarian aid actors strongly suggest that there is presently no global strategic thinking nor organized practice in the area of patient safety and specifically in medical error prevention and management. For instance, it was only in the 2018 version of the Sphere standards, a reference document in the humanitarian sector identifying norms to be observed in humanitarian response[20] and having specific chapters on health-related activities, that patient safety was mentioned several times and a specific paragraph devoted to adverse event management and prevention.

While, a priori, we can understand the difficulties imposed by the precariousness of humanitarian contexts (scarcity of resources, insecurity, competition among priority needs…), there are at least three sets of reasons calling for a real investment in patient safety: 1. ethical responsibilities: medical ethics as much as humanitarian ethics[21] (calling for the non-malfeasance to patients and/or beneficiaries of aid); 2. legal duties (entering into a contractual relation, the medical staff is expected to deliver a service which is not detrimental to the patient); and 3. practical realities (patients' complaints regarding alleged sub-standard care, although poorly documented, are reported[22] and deserve proper management; media start to relay stories of alleged medical error in the sector;[iii] medical humanitarian action is implemented in more and more developed healthcare

iii See for instance two cases related to vaccination campaigns in South Sudan and in Syria. Available on https://www.bbc.com/news/world-africa-40135814 https://www.bbc.com/news/world-africa-40135814 and https://www.newsweek.com/15-syria-children-dead-after-measles-vaccination-271525 https://www.newsweek.com/15-syria-children-dead-after-measles-vaccination-271525. Accessed on 15 September 2019.

systems as in the Middle East or in transit or destination countries for migrants where the requirements in terms of quality by authorities and populations are high.

Although there are no reasons why patient safety could not, and should not, be addressed to improve the quality of care delivered in medical humanitarian action, it is reasonable to suppose that a simple transfer of strategies and experiences in patient safety from developed countries' healthcare systems may be difficult due to the specificities of humanitarian action.

Within the framework of this research, we sought to address the following questions.

Primary Question:

What are the present status and perspectives of patient safety, and medical error management in particular, in medical humanitarian action?

Specific Questions

- What are the characteristics, challenges and limits of patient safety strategies, policies and practices implemented in health systems of OECD countries?
- What are the specificities of medical humanitarian action affecting the possible adoption of OECD documented policies and practices of patient safety?
- What are the knowledge, attitude and expectations of medical and paramedical staff active in humanitarian organisations, regarding patient safety in general and medical error management in particular?

We began by exploring the evolution in safety and risk management science pertaining to medical error which gave rise to the theories and models of risk management at the origin of the patient safety discipline. We explored the genesis and the main developments of patient safety to describe the present limits and challenges of patient safety implementation (Annex 2). To limit the scope, this research focused on the experiences and practices of patient safety in hospitals. Confronted with a vast array of concepts and

debates on the appropriate terminology to use in the discipline of patient safety, we developed a glossary of the main terms related to patient safety used in the literature (Annex 3). We then documented and analysed the specificities of medical action deployed in humanitarian contexts (Annex 4) and how this may impact patient safety. This is the focus of the first published article.

The second part of the research went on to document the current knowledge, attitudes and practices in medical humanitarian organisations concerning patient safety and, in particular, error management and prevention and to explore the expectations of staff regarding further investments in this area. For this, we interviewed medical and paramedical staff active in international humanitarian organisations. The results were presented in the second article.

6. Articles

Methodological contributions

The research was done in two steps, each requiring a distinct methodology.

Phase 1: Patient Safety and Patient Safety in Medical Humanitarian Action: The State of the Art

Three strategies were developed in parallel for the literature review: 1. An exploratory literature review on patient safety; 2. Followed by more systematic literature review (rapid literature review) on reviews and systematic reviews articles on the same topic: and 3. a systematic literature review on medical humanitarian action and patient safety.

General Literature Overview on Patient Safety

The doctoral candidate (J.-M. Biquet) conducted a Google search of relevant sources related to patient safety research and practices presenting and analysing present strategies, policies, experiences and challenges on patient safety: evolution of risk management, experiences in other economic sectors, analysis of specific elements leading to medical errors, practices developed to manage them and avoid their recurrence. This search was guided by advice from specialists of patient safety and professionals in

humanitarian action consulted in the preliminary phase of the research. In this context, J.-M. Biquet followed an MOOC on “Leading Healthcare Quality and Safety” developed by George Washington University in the United States.

Rapid Literature Review on Selected Criteria on Patient Safety

Objective: to have a state-of-the-art appraisal of knowledge from present strategies, policies and practices in healthcare systems.

Method: a rapid literature review of all articles in PubMed related to patient safety, covering “reviews” or “systematic reviews” in the last five years and with “review” in the title; papers using the concepts of patient safety and medical errors or adverse events, written in the last five years, were collected and analysed.

For the selection process, two reviewers (J.-M. Biquet and P. Michel) independently screened the titles and abstracts yielded by the search against the inclusion criteria to identify relevant abstracts. Full reports were obtained for all the titles that appeared to meet the inclusion criteria even in cases where there were disagreements between the reviewers. The same two reviewers read the full-text articles obtained and selected those that met the inclusion criteria, categorizing the articles. Thereupon followed a qualitative narrative synthesis by J.-M. Biquet, who created lists of articles based on themes (authors, titles, main messages).

Systematic Literature Review on Medical Humanitarian Action and Patient Safety

Objective: to have a state-of-the-art appraisal of patient safety in medical humanitarian action.

Method: a systematic review of all articles on Embase and PubMed published since 1/1/2000, in French or English, mentioning the concepts of patient safety and humanitarian medicine. This part was managed by J.-M. Biquet. The selected articles were categorized by J.-M. Biquet according to their characteristics: call for patient safety improvements; ethical dimension of medical humanitarian action; training or management of staff; tools related to quality of care.

There was also a database search strategy to find studies on patient safety in medical humanitarian action:

Articles were searched for the following terms:

PubMed search key: ((((((("patient safety"[MeSH Terms] OR ("patient"[All Fields] AND "safety"[All Fields]) OR "patient safety"[All Fields]) AND (humanitarian[All Fields] AND ("medicine"[MeSH Terms] OR "medicine"[All Fields]))) OR (medical[All Fields] AND humanitarian[All Fields] AND ("Practice (Birm)"[Journal] OR "practice"[All Fields]))) AND (English[lang] OR French[lang])))) AND ("2000/01/01"[PDat] : "2018/10/30"[PDat])) Sort by: PublicationDate Filters: Publication date from 2000/01/01 to 2018/09/31

Embase search key: ('patient safety'/exp OR 'patient safety') AND ('humanitarian'/exp OR humanitarian)

The three strategies combined led to the creation of a database of more than 1,200 articles.

Phase 2: Knowledge, Attitudes and Practices as Well as Expectations of Medical Humanitarian Actors Regarding Patient Safety

We approached eight international medical humanitarian organisations (six responded positively) in order to know the present status of patient safety in terms of strategy and policy and to be able to interview some of their active international medical and paramedical staff. The selection criteria for the organisations were: having a medical department enacting the organisation's medical policies; based in Organisation for Economic Co-operation and Development (OECD) countries but active throughout the world; working with national and international staff; medical action being the major area of activity in terms of budget (with the exception of ICRC, historically a medical organisation, having diversified its portfolio of activities)

In order to learn qualitative research methods, J.-M. Biquet took a course at the University of Geneva. The lecturer, Prof. Claudine Burton-Jeangros, agreed to review the methodology used for the research and to comment on an early draft of the article.

J.-M. Biquet selected the organisations to be approached after discussion with, and approval by, the doctoral committee. He also designed and tested the interview guide. The final version of the interview guide was drafted with D. Schopper. The selected organisations respected the following criteria: International humanitarian organisations based in an OECD country; active throughout the world with national and international staff; having a medical department implementing the organisation's medical policies; and whose medical action was, in terms of budget, the major area of activities (with the exception of ICRC, historically a medical organisation having diversified its portfolio of activities).

In addition to interviews with six medical directors or those responsible for quality of care and three legal advisors (the others declining the interview for confidentiality reasons), 39 interviews were done with medical and paramedical staff of those organisations. The interviewees respected to the following criteria: international staff with minimum 2 years of experience in the humanitarian sector. 36 interviews were analysed, the others being of too poor quality of recording to be transcribed effectively. The selected interviews integrally transcribed were coded and analysed by themes and sub-themes (Atlas ti ©).

All interviews were done by J.-M. Biquet. He did the transcription of interviews using Express Scribe© and the analysis with the data analysis software Atlas TI© (coding) to extract the trends and the main elements. The preliminary analysis results were discussed with the doctoral committee.

The writing of the two articles was carried out by J.-M. Biquet. All drafts were reviewed and commented by the members of the doctoral committee before their final approval for submission.

Article 1

Published in the Journal of Patient Safety, March 2020.

A Call for the Application of Patient Safety Culture in Medical Humanitarian Action: A Literature Review

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Abstract

Objectives: The aim of the study was to assess lessons learned on patient safety in OECD countries and assess if they are applied or can be applied to humanitarian medicine.

Methods: 1. A 2013-2018 rapid literature review of reviews and systematic review of articles (PubMed database) on “patient safety” and “medical error” to look for lessons learned regarding patient safety in OECD countries; 2. a rapid literature review (PubMed and Embase databases) on “humanitarian medicine” and “patient safety”, from their creation to 2018, to find any articles related to patient safety in humanitarian medicine. In both reviews, articles specifically related to one device, disease or medical act were excluded. These reviews were complemented by a Google search.

Results: 1. Of the 245 references retrieved, 104 met the inclusion criteria. 2. Of 308 references, 39 respected the inclusion criteria. In OECD countries, patient safety comprises correlated measures taken at three levels. The micro level focuses on individual staff involved in healthcare provision or management; the meso level focuses on medical institutions; the macro level focuses on national healthcare systems. Only one reference mentioned the implementation of a medical error reporting and analysis system in medical humanitarian organisation.

Conclusions: Adopting strategies and a culture of safety will require adapting to and addressing the variety of intervention contexts and responding first to the fears and

expectations of humanitarian staff. Medical humanitarian organisations, in the absence of an overarching authority for the sector, have a major responsibility in the development of a general patient safety policy applicable in all their operations.

Keywords: patient safety, safety culture, humanitarian medicine, medical error, literature review

Introduction:

Medical humanitarian organisationsiv are used to taking risks and to deploying ingenuity to provide medical care to victims of crises. Besides trying to overcome the obstacles to access to care, these organisations have long been concerned with the improvement of the quality of their services such as professionalization of staff, development of tools and guidelines, creation of joint platforms to analyse and share lessons learned. Unlike what is taking place in healthcare systems in Organisation for Economic Co-operation and Development (OECD) countries, most of them being of high-income, there is one domain, "the dark side of quality"[1] or the prevention and management of medical errors, which seems presently not fully explored and addressed by humanitarian aid providers. Human action is prone to error. Over the last two decades, the recognition that this also holds true for medical staff has sparked initiatives to analyse incidents where errors were committed and use them in learning processes. However, only when researchers aggregated what was seen, until then, as a series of individual cases of serious errors did the safety issues in healthcare appear so strikingly. The IOM's 2000 report To Err is Human[2] was a wake-up call for the healthcare sector. Error or adverse event, "an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient",[3] is now recognized as a major cause of harm (the third cause of death in the USA).[4] It carries a heavy reputational and

[iv] Medical humanitarian organisations can be international organisations or non-governmental organisations providing medical services in humanitarian crisis. There are, for instance, more than 700 of them collaborating in coordination mechanisms for the health response to crises. See: https://www.who.int/health-cluster/partners/current-partners/en/ 3

financial cost for healthcare systems. In Europe, 15% of hospital expenditure is related to treating consequences of safety incidents,[5] and for society as a whole, the economic loss by medical error represents up to 23 million DALYs (Disability-Adjusted Life Year) per year in the world.[6] Ensuring a safer provision of healthcare falls under the umbrella of patient safety, to wit "the absence of preventable harm to a patient during the process of healthcare and reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment."[7] Considered an integral component of healthcare systems and institutions, it is an important subset of the quality of care.[8] We wanted to assess if humanitarian medicine, defined as "a set of medical or public health practices whose sole intent is to selflessly accommodate and address the tension created between compelling health needs and the ongoing deprivation of resources in a given population or community",[9] has integrated patient safety into delivery of patient care. After an assessment of the current knowledge, lessons learned and discussions on medical error prevention and management in OECD countries in hospital institutions, this article explores the integration of patient safety principles into the care delivered by aid organizations. Finally, suggestions are provided for a path forward in developing a stronger patient safety environment for the delivery of medical care by humanitarian organisations.

Methodology

Data Sources

We used the rapid literature review method[10] to find lessons learned regarding patient safety strategies and practices. The review was conducted in September 2018 and included studies published between 2013 and September 2018 in the PubMed bibliographic database for the lessons learned from patient safety. In parallel, we did a rapid literature review on PubMed and Embase databases to find research related to patient safety in medical humanitarian action. To complement these rapid literature

reviews, we searched Google for articles and textbooks related to lessons learned in patient safety as in quality of care in humanitarian action.

Search Strategy, Study/Paper Selection; and Data Analysis for the First Review of "Lessons Learned Regarding Patient Safety"

The inclusion criteria were peer-reviewed reviews and systematic review articles evaluating methods or tools aiming at improving the safety of care. Excluded were articles related to a specific pathology, medical act or medical material or concerning ambulatory or primary care services. The reference lists of selected articles were manually searched for additional citations. The search terms in PubMed were (Box 1): "patient safety" and "medical error" and a list of MESH terms in order to be as exhaustive as possible; filters were: review, systematic reviews, having "review" in the title. For the selection process, two reviewers (J.-M. Biquet and P. Michel), specialists in global health and patient safety, independently screened the titles and abstracts yielded by the search against the inclusion criteria in order to identify relevant abstracts. Articles with a title or abstract that did not meet one or more review criteria were rejected. Full reports were obtained for all the titles that appeared to meet the inclusion criteria even in cases where there were disagreements between the reviewers. The same two reviewers read the full-text articles obtained and selected those that met the inclusion criteria, categorizing the articles according to the following study characteristics (Fig1): articles related to: evaluation of tools; methods of patient safety; training or working conditions of staff; measurement or costs of medical errors; terminology used in patient safety; experiences of patient safety in non-OECD countries; safe management of drugs; disclosure of medical error; health information technology; safety culture. Thereupon followed a qualitative narrative synthesis. We created lists of articles per themes (authors, titles, main messages).

Search Strategy, Study/Paper Selection; and Data Analysis for the First Review of "Patient Safety in Medical Humanitarian Action"

The search key words (Box 2) were: "patient safety" and "humanitarian". The selection criteria were articles explicitly calling for or describing aspects of patient safety or quality

of care in medical humanitarian action. Excluded were articles not directly linked to humanitarian action or the quality of clinical practices or articles related to a specific disease or device (Fig.2). The selected articles were categorized according to their characteristics: call for patient safety improvements; ethical dimension of medical humanitarian action; training or management of staff; tools related to quality of care.

Results

The database search on patient safety and secondary healthcare (Fig. 1) identified 245 articles, of which 141, related to a specific disease, medication or medical act or to the use of highly sophisticated technology, were excluded. Also excluded were articles unrelated to patient safety in hospital care. The remaining 104 underwent a full text review. For medical humanitarian action, 308 articles were identified, of which 39 met the inclusion criteria and subsequently underwent a full text review (Fig. 2).

Lessons Learned Regarding Patient Safety Policies, Strategies and Practices

In OECD countries, at least and according to literature, patient safety efforts comprise correlated partially dependent measures at three levels. The micro level initiative focuses on individual staff involved in healthcare provision or management; the meso level, medical institutions; and the macro level, the national healthcare systems. At the macro level, laws and regulations influence (through incentives and disincentives) the reduction of medical errors and the improvement of safety by identifying patient safety obligations[11] and establishing legal and regulatory management of occurring cases. Accreditation bodies, such as The Joint Commission (TJC) in the U.S., determine accreditation requirements for healthcare professionals and institutions. Ministries of health, as professional organisations, are also empowered to reinforce links between different elements of the system, notably by motivating medical schools to develop training on patient safety methods and management,[12] and to leverage society's perception of healthcare risks and limitations.[13] At the meso level, healthcare organizations, the cornerstone of healthcare provision, are the link between micro and macro levels, the enablers of patient safety through commitment and leadership,[14] the crossroads of

frequently conflicting imperatives: quality of care vs efficiency. It is at their level that tools, processes and favourable environments are initiated, as they have the responsibility to establish error detection systems and a participatory management framework for remediation and learning. At the micro level, medical staff must be sensitized to the risk of error; must understand that involvement in an error does not equal negligence or incompetence; must learn to implement preventive and corrective actions. Their active participation in the management of errors is a necessity supposing favourable working conditions.[15,16]

Accomplishments in Error Detection and Safety Culture

The complexity of patients' conditions (multi-morbidities), the importance of team work in patient care management,[17] and extra-medical elements like stress, administrative burden or logistical aspects are some of the factors leading to errors.[18] The analysis of these factors requires a multi-disciplinary approach.[19] Root cause analytical grids can spot contributing factors[20] for which reactive measures can then be conceived such as sensitization strategies, staff training, protocol revision, work environment adaptation and improvement of communication. Depending on medical institutions' priorities, extensive root cause analysis may be limited to the most serious incidents. Classification methods assist in identifying points of vulnerability or failure in care processes.[21] A proper internal feedback mechanism on lessons learned from errors along with selected strategies for safety improvement are then key to preventing staff from perceiving such reporting and analysis as just another administrative burden.[22]

Error identification is structured through different data collection methods,[23] each with its advantages and limitations. Voluntary reporting requires a serious commitment from staff and may lead to under-reporting. Direct observation of clinical procedures contributes to detecting system errors but also requires resources. Trigger tools are less labour-intensive, but their validity has been questioned. Mortality-morbidity conferences require clear and complete patient files, clear case definitions and teamwork abilities.[24] Other sources of data such as patient complaints[25] complement these methods. Generally,

medical institutions use a combination of methods to reach the fullest vision of reality and to respond with preventive actions.

Beyond tools to collect and analyse data, collective investment in a safer provision of healthcare is underpinned by a common safety culture. This concept is defined as "an integrated pattern of individual and organizational behaviour, based upon shared beliefs and values that continuously seeks to minimize patient harm".[26] Within healthcare institutions, it translates into participatory mechanisms of reporting and analysis of errors (as opposed to the blame culture) and an accepted openness to system latencies.[27] In contrast to a traditional "blame-shame" culture, where those involved in a medical error may be sanctioned for what is considered culpable weakness, it is incumbent upon institutions to create a climate in which individual staff members understand that errors can be learned from and that they can expect management's support[28] and guidance. To keep this focus among competing imperatives implies genuinely strong and visionary leadership.[29]

Unexplored Territory and Limitations

Patient safety, as a discipline with its own modalities and culture, is in constant evolution. In addition to improvements like hygiene,[30] increased reliability of medical devices and updated standards of care, patient safety recognizes that humans are prone to error, and thus becomes a continuous source of learning to improve medical practice. Beyond the development of techniques and processes to detect and act on care-related risks,[31] specialists see leadership, human resource management and comprehensive therapeutic pathways as the challenges for breakthroughs in patient safety.[32]

While the literature highlights undeniable improvements in patient safety since the beginning of the 2000s, much remains to be done.[33] Technology can provide a means of preventing errors, but there is tension between the promise of technology's contribution to decreasing human error and the documented evidence of increased risk of incidents arising from its ever greater complexity.[34] The slow integration of safety into healthcare planning strategies is linked to the complexity of healthcare practice. Not only does this

practice encompass a variety of professions, but it also involves large teams interacting at different levels of intensity, along different hierarchical lines and possibly performing in different locations.[35] Moreover, medicine is expected to develop a response to increasingly complex medical problems like co-morbidities and evolution of diseases,[36] making the identification of a problem's causal factors more difficult and requiring a systems approach. There are still many bridges needed between medical and legal professionals to agree on a regulatory environment providing a fair balance between, on the one hand, responsibility and compensation mechanisms[37] and, on the other, measures favouring patient safety, particularly the anonymity of error reporting and the facilitation of disclosure to patients.[38] Even proper evaluation of patient safety actions tends to produce patchy results and requires further investment in the search for adapted measurement methods.[39] The role of the patients in patient safety is still a matter of research.[40] Their involvement in patient safety efforts seems pertinent and beneficial[41] beyond their right to play a significant role in the management of their own health. Currently, health budgets in OECD countries do not sufficiently address the need for research and investment in patient safety, notably in primary care.[42] In low and middle income countries, patient safety remains embryonic.[43,44] Admittedly, there are still discussions on optimal approaches to improve safety of care.[45]

Patient Safety in Medical Humanitarian Action: A Humanitarian Exception?

Regarding medical care in humanitarian contexts, be they conflicts, natural disasters or significant deficiencies in access to health services for population groups, the initial literature review as well as discussions with humanitarian practitioners show that there is as yet no structured strategic thinking on patient safety. Only one initiative of patient safety policy implementation was identified,[46] although several articles call for such development.[47,48,49]

A priori, it could be considered that, since humanitarian contexts are intrinsically precarious owing to a scarcity of resources, to insecurity and to competing needs, simply succeeding in providing healthcare services is a considerable achievement. Yet there are

at least four reasons to call for an increase in the safety of care provided by medical humanitarian organizations. First, ethical responsibilities, based on both medical ethics and humanitarian values,[50] require respect of the principle of non-maleficence in providing care to patients. Second, medical staff have the legal obligation to act with respect for the rights and integrity of their patients. Third, complaints of patients against humanitarian organizations for alleged substandard care are already a reality. (For instance, Médecins Sans Frontières' legal department received at least 15 complaints within two years following the earthquake in Haiti (Interview MSF in January 2013), and medical errors have indeed been reported.v). Fourth, inclusion of patient safety initiatives would complement the present efforts of medical humanitarians to improve the overall quality of the services they provide to the neediest populations. Striving for safer healthcare provision is not a luxury,[51] even in the context of humanitarian healthcare delivery.

The Characteristics of Humanitarian Medicine

Medical humanitarian action embodies the values of solidarity and humanity and is mostly carried out in countries whose health systems are failing their populations at a specific time or in areas hit by a conflict or a natural disaster. By providing vital services in circumstances generally associated with disasters, both natural and man-made, it evokes images of heroism and urgency. Neither literature nor practice provides clarity on when medical humanitarian action is supposed to begin or end. This leads to medical humanitarian projects having multiple forms such as obvious emergencies, targeted structural support, assistance to substantially deficient healthcare systems, long-term projects, fighting the spread of a specific disease or medical assistance to a neglected

[v] Example: In 2014 a vaccination campaign in Syria resulted in the death of 18 children. The vaccinators, who couldn't read English, mistakenly used an anaesthetic product instead of sterile water as a diluent for the vaccine. Newsweek. September 2014. Available on http://www.newsweek.com/15-syria-children-dead-after-measles-vaccination-271525. Accessed on 13 January 2018.

population within a stable context. Aid organizations apply their own criteria in selecting the needs they will respond to and the means to be deployed.

The humanitarian sector is by and large not structured or regulated; therefore each organization operates and defines its own mandate independently.[52] There is no overarching governing body overseeing action, and no set of practical rules beyond what is locally imposed by each country's laws and regulations, while regulations and social norms differ from one region of the world to another.

In addition to the precariousness of the working environment, the lack of availability of qualified staff as well as the frequent lack of referral possibilities for complex cases are some of the factors pushing humanitarian aid medical volunteers to constantly take risks by pushing the limits of what can be done with scarce resources.[53] The aid provided is often a compromise between what should and what can be done, leading to demanding working environments for medical personnel, characterized notably by stress, long working days and different medical cultures among staff.[54] Having to compromise is also a source of moral distress for staff who are not always provided with the necessary institutional support.[55]

On top of the intrinsic complexity of medical care, motivational factors to invest in patient safety are not as advanced in the humanitarian sector as in OECD countries. Patients' rights are rarely well defined or even broadly understood, much less subject to oversight. Monitoring and counter-power structures lack organisation (patient associations, judicial mechanisms). The very conditions of vulnerability, amplified by crisis, do not allow communities to hold accountable those who have volunteered to respond to their needs, and local health authorities may have limited capacities to oversee the care provided. Medical humanitarian organizations are used to monitoring and evaluating their activities mainly in quantitative terms such as number of people accessing their services, encouraged to do so by their donors, to whom they are primarily accountable. Measuring the qualitative aspects of the care is left mostly to the initiative of individual aid workers and the good will of organizations.

Discussion

Humanitarian action is based on high moral values. The commitment to "do good" goes together with the desire to "do it well".[56] The internal push for quality improvements is a consequence of the professionalization of the aid sector reinforced by the values of their committed medical volunteers (Do No Harm, quality initiatives…). This leads to a multiplication of efforts to constantly revise procedures without, until now, a clear focus on patient safety. The awareness of the perfectible quality is already present.[57] The adoption of adapted patient safety strategies could reinforce the convergence of values and practices and systematize the increase of safer care. The specific conditions under which humanitarian medical interventions take place can be perceived as being in contradiction to the basic requirements of patient safety. Yet, this does not preclude the possibility of creating a working environment that limits the stress of the staff while providing the safest care for patients, in other words avoiding the addition of another layer of stress to a situation that is already very stressful for both patients and caregivers. The absence of an overarching authority and the multiplicity of contexts at the macro level, associated with the great diversity of medical cultures of the ever-changing staff (international and local) at the micro level, put the responsibility to develop an adapted model of patient safety for medical humanitarian action first and foremost on the shoulders of the meso level, the organizations themselves. As in OECD countries, the sparking of an internal discussion on the human nature of (humanitarian) medical action and the inherent associated and multifactorial safety risks seems a necessary first step.[58] It should aim at creating adherence to an institutional investment in the specific dimension of quality of care and should empower individuals to engage. It should involve an assessment of internal fears but also expectations, as well as proposals from individual medical and managerial staff to integrate an adapted response to each of them.

At the institutional level, the initiation of a collective action on risk prevention and management at project sites requires two correlated steps: a clear declaration of commitment from organizational leaders, setting out principles and goals to achieve, and

the provision of structured direct support empowering front-line medical and para-medical staff with training, tools and procedures. At a later stage, when internal policies with their associated procedures are established, aid organizations will be in a better position to lay out to the external stakeholders (authorities, communities and donors) the inherent safety risks of adverse events in humanitarian contexts.

The methodology of rapid literature review has an inherent limitation: a limited number of accessed databases. The research team tried to complement the method by searches on Google Scholar and by meeting specialists of medical humanitarian action and of patient safety in OECD countries. The very limited number of articles focusing on patient safety in medical humanitarian action forced the research team to include articles that mentioned patient safety without elaborating what it exactly meant and how to implement it.

Conclusions

The use of a carbon copy of patient safety strategies and tools implemented in OECD countries does not seem appropriate given the range of operational realities in medical humanitarian aid.

The diversity of intervention circumstances and activities, such as the level of control over medical care provision and evolution of the project from acute emergency care to long term care, indicates that a proper assessment of each situation as well as local regulations, practices and beliefs would be useful in medical error management. These assessment criteria could be used to adapt current strategies and tools for practical implementation of overall patient safety at the operational level, depending on the acuteness of the emergency and availability of qualified medical staff. Reviewing medical care facilities, personnel and care delivery processes of current aid projects with an eye to patient safety, while applying lessons from what is presently implemented in OECD countries, should make it possible to provide a new framework for safer humanitarian medical aid delivery. Going beyond the challenge of offering access to healthcare in sometimes extreme conditions while working on safer delivery presents volunteers and their organizations

with a new challenge, based on a universal conviction that safety is part of what patients deserve regardless of the circumstances of delivery. This is a call for the application of patient safety culture to humanitarian medical aid.

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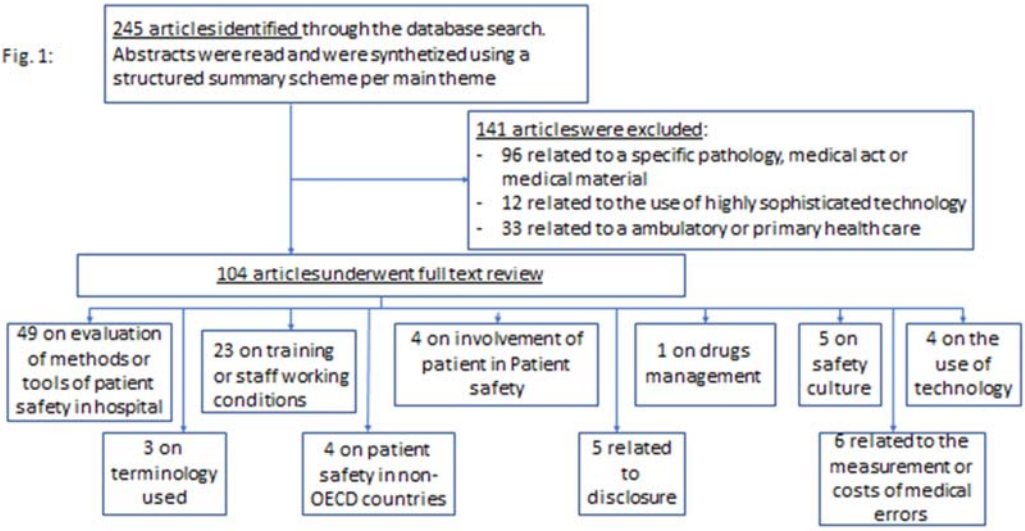
Box 1: Database search strategy to find studies on patient safety policies, strategies and practices

Titles and abstracts of articles published in English were searched for the following terms:

((("patient safety"[MeSH Terms] OR Patient Safety[Title/Abstract] OR (("patients"[MeSH Terms] OR "patients"[All Fields] OR "patient"[All Fields]) AND Safeties[Title/Abstract])) AND ("medical errors"[MeSH Terms] OR (medical error[Title/Abstract] OR medical errors[Title/Abstract]) OR (medical mistake[Title/Abstract] OR medical mistakes[Title/Abstract]) OR wrong procedure errors[Title/Abstract] OR (wrong site surgeries[Title/Abstract] OR wrong site surgery[Title/Abstract]) OR (surgical error[Title/Abstract] OR surgical errors[Title/Abstract]) OR (Critical[All Fields] AND (medical incident[Title/Abstract] OR medical incidents[Title/Abstract])) OR

medical critical incidents[Title/Abstract] OR (wrong patient surgeries[Title/Abstract] OR wrong patient surgery[Title/Abstract]) OR Never Event[Title/Abstract] OR Never Events[Title/Abstract] OR (diagnostic error[Title/Abstract] OR diagnostic errors[Title/Abstract]) OR Misdiagnosis[Title/Abstract] OR Misdiagnoses[Title/Abstract] OR (false negative reaction[Title/Abstract] OR false negative reactions[Title/Abstract]) OR (false positive reaction[Title/Abstract] OR false positive reactions[Title/Abstract]) OR (observer variation[Title/Abstract] OR observer variations[Title/Abstract]) OR Observer Bias[Title/Abstract] OR (interobserver variation[Title/Abstract] OR interobserver variations[Title/Abstract]) OR (inter observer variation[Title/Abstract] OR inter observer variations[Title/Abstract]) OR (inter observer variabilities[Title/Abstract] OR inter observer variability[Title/Abstract]) OR (intraobserver variation[Title/Abstract] OR intraobserver variations[Title/Abstract]) OR (medication error[Title/Abstract] OR medication errors[Title/Abstract]) OR Medication Error[Title/Abstract] OR drug use errors[Title/Abstract] OR (inappropriate prescribing[Title/Abstract] OR inappropriate prescribings[Title/Abstract]) OR (inappropriate prescription[Title/Abstract] OR inappropriate prescription,[Title/Abstract] OR inappropriate prescriptions[Title/Abstract]) OR over prescribing[Title/Abstract] OR (medication reconciliation[Title/Abstract] OR medication reconciliations[Title/Abstract] OR medication reconciliationv[Title/Abstract]) OR (Near[All Fields] AND Miss[All Fields] AND Healthcare[Title/Abstract]) OR (("delivery of healthcare"[MeSH Terms] OR ("delivery"[All Fields] AND "health"[All Fields] AND "care"[All Fields]) OR "delivery of healthcare"[All Fields] OR "healthcare"[All Fields]) AND Near Miss[Title/Abstract]) OR (("delivery of healthcare"[MeSH Terms] OR ("delivery"[All Fields] AND "health"[All Fields] AND "care"[All Fields]) OR "delivery of healthcare"[All Fields] OR "healthcare"[All Fields]) AND Near Misses[Title/Abstract]) OR (("delivery of healthcare"[MeSH Terms] OR ("delivery"[All Fields] AND "health"[All Fields] AND "care"[All Fields]) OR "delivery of healthcare"[All Fields] OR "healthcare"[All Fields]) AND Close Call[Title/Abstract]) OR (("delivery of healthcare"[MeSH Terms] OR ("delivery"[All Fields] AND "health"[All Fields] AND "care"[All Fields]) OR "delivery of healthcare"[All Fields] OR "healthcare"[All Fields]) AND Close Calls[Title/Abstract]) OR (radiotherapy setup error[Title/Abstract] OR radiotherapy setup errors[Title/Abstract]) OR (adverse event[Title/Abstract] OR adverse events[Title/Abstract] OR adverse events,[Title/Abstract]))) AND ((Review[ptyp] OR systematic[sb]) AND "2013/11/10"[PDat] : "2018/11/08"[PDat])) AND review[Title] AND ("2013/11/10"[PDat] : "2018/11/08"[PDat]

Fig. 1:



Flowchart showing the selection of publications on patient safety and medical error or adverse event, 2013-2018

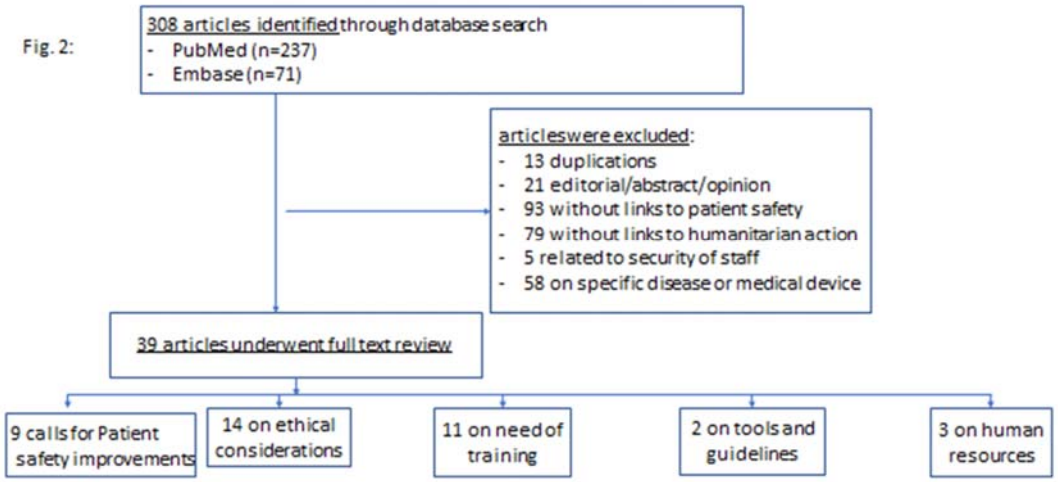
Box 2: Database search strategy to find studies on patient safety in medical humanitarian action

Articles were searched for the following terms:

PubMed search key: ((((((("patient safety"[MeSH Terms] OR ("patient"[All Fields] AND "safety"[All Fields]) OR "patient safety"[All Fields]) AND (humanitarian[All Fields] AND ("medicine"[MeSH Terms] OR "medicine"[All Fields]))) OR (medical[All Fields] AND humanitarian[All Fields] AND ("Practice (Birm)"[Journal] OR "practice"[All Fields]))) AND (English[lang] OR French[lang])))) AND ("2000/01/01"[PDat] : "2018/10/30"[PDat])) Sort by: PublicationDate Filters: Publication date from 2000/01/01 to 2018/09/31

Embase search key: ('patient safety'/exp OR 'patient safety') AND ('humanitarian'/exp OR humanitarian)

Fig. 2:



Flowchart showing the selection of publications on patient safety and humanitarian medicine, 2000-2018

Article 2

Submitted to and accepted for publication in the Journal of Patient Safety, January 2020.

Knowledge, Attitudes and Expectations of Medical Staff towards Medical Error Management Policies in Humanitarian Medicine: A Qualitative Study

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Abstract

Background Patient safety, a major component of quality of care, is now an attribute of health care systems in developed countries at least. While there is ever more research on this subject in developed countries, humanitarian medicine, mainly implemented in resource-poor countries, has yet to structure its own set of policies and strategies on patient safety and the management of medical errors.

Objectives We assessed the knowledge, attitudes and expectations of medical humanitarian staff regarding the development of policies and strategies related to patient safety and medical error management in medical humanitarian action.

Methods We conducted 36 semi-structured interviews with international medical and paramedical staff active in six medical humanitarian organisations after having interviewed the medical directors or the person in charge of quality of care and the legal advisors. Interviews were transcribed verbatim and subjected to a thematic analysis.

Results The interviews confirmed the current absence of clear investments in dealing with safety risks in the selected medical humanitarian organisations. The difficulties experienced by medical staff in reporting medical errors such as blame culture, lack of training, absence of leadership committed on patient safety are non-specific. Other arguments are related to the specific conditions of humanitarian settings: coexistence of different medical culture; absence of international or local regulations or external pressures; great diversity of activities and contexts.

Conclusions Interviewed staff expressed high expectations of receiving guidance from their organisations and support to adopt clear patient safety and medical error management policies adapted to their complex operational and clinical realities.

Keywords: Medical error, Patient safety, Humanitarian Medicine, Safety culture, safety risks

Introduction

Patient safety is defined as "*the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment*."[1]. The management of medical errors, "a *failure to carry out a planned action as intended or application of an incorrect plan*"[2], is an essential part of patient safety[3]. Management of medical errors is most often done with a retrospective approach based on the implementation of an error reporting system.[4] In the last 20 years patient safety has become a priority in healthcare systems of countries of the Organisation for Economic Co-operation and Development countries (OECD) and beyond. [vi]

One sector of medical activities, the health care provided by humanitarian aid organisations[vii], seems not to have been influenced yet by this groundswell. A recent literature review[5] found only one initiative of humanitarian policy on medical error reporting and management[6] and some articles calling for such development[7,8,9]. There is no internationally agreed definition of humanitarian action, but it commonly refers to the

[vi] OECD is regularly assessing the state of patient safety in healthcare systems of their country members and contributes to the exchange of experiences. See https://www.oecd.org/health/patient-safety.htm Accessed on December 10, 2019, More and more articles can be found in literature on initiatives developed in low- or middle-income countries.

[vii] Medical humanitarian organisations can be international organisations or non-governmental organisations providing medical services in humanitarian crisis. There is for instance more than 700 collaborating in coordination mechanisms for the health response to crises. See: https://www.who.int/health-cluster/partners/current-partners/en/ Accessed on December 12th, 2019.

assistance provided by professional aid organisations to save life and alleviate suffering in time of crisis[10]. Concerning specifically Humanitarian medicine, we selected the following definition: "*a set of medical or public health practices whose sole intent is to selflessly accommodate and address the tension created between compelling health needs and the ongoing deprivation of resources in a given population or community*"[11]. It is performed by committed medical and paramedical staff assisted by support staff of medical humanitarian organisations which are numerous and decide independently the scope of their action and where to intervene. Contexts and the range of humanitarian interventions vary, from war-torn contexts, zones affected by natural disasters, to offering care to impoverished populations in stable contexts. The scarcity of means, the very diverse types of aid projects as much as shortage in quantity and quality of staff available to run them seem to be constant features of (medical) humanitarian action.

Besides trying to overcome the obstacles to access to care[12], humanitarian organisations have long been concerned with the improvement of the quality of their services through a process of professionalization, edition of guidelines, adoption of the WHO surgical checklist[13], quality drugs procurement policies[viii]. One domain though seems not yet to be addressed in a structured way: the management of medical errors.

In order to understand this gap, this research focussed on assessing the knowledge, attitude and expectations of medical and paramedical staff active in humanitarian organisations, regarding patient safety in general and medical error management in particular.

Method

We employed qualitative methods to capture humanitarian medical or paramedical staff perceptions of risk management; barriers they think explain the presently limited developments of medical error management strategies; and their expectations for the future.

[viii] See for instance the guidelines for the procurement of medical supplies aid organisations funded by the European commission must abide to. Available on https://www.dgecho-partners-helpdesk.eu/actions_implementation/procurement_in_humanitarian_aid/medical_supplies. Accessed on November 16th, 2019

Sampling

Eight organisations, a convenient choice based on previous contacts, were purposefully chosen to reach a relevant representation of the diversity of the sector (Anglo-Saxon and Latin organisations; emergency oriented or long-term philosophy). The selection criteria were having a medical department enacting the organisation's medical policies; based in Organisation for Economic Co-operation and Development (OECD) countries but active throughout the world; working with national and international staff; medical action being the major area of activity in terms of budget (with the exception of ICRC, historically a medical organisation, having diversified its portfolio of activities). From the eight organisations contacted, six responded positively (the seventh never responded; the medical director of the eighth declined, judging it impossible to convince his leadership to invest in patient safety). These six organisations were: the Swiss and Belgian sections of Médecins Sans Frontières (MSF); Médecins du Monde-France (MDM); Save the Children-UK (SC); International Rescue Committee–USA (IRC); International Committee of the Red Cross (ICRC).

After the signature of a research agreement, we interviewed the director of the medical department and/or the person in charge of quality of care to learn about the status of patient safety efforts related to medical error management. The medical directors or the human resource departments provided contacts of some active medical and paramedical staff corresponding to the selection criteria: active international medical or paramedical staff with a minimum of two years' experience in humanitarian action. These criteria were chosen in order to maximize the chances of meeting interviewees knowing their organisations' policies and who have carried out several missions. The recruitment of volunteers was done by the main researcher through snowballing until saturation, with a minimum set of five per organisation.

Participants were contacted by an invitation e-mail letter and provided an information sheet on the project (confidentiality, anonymization, purpose, use of the data) and a consent form.

Data Collection and Analysis

An interview guide of semi-open questions (Annex 1) was developed by the research team and pilot-tested on three humanitarian medical staff to assess acceptability and feasibility. The final guide was designed in English and French by two researchers[ix].
All interviews were conducted by one Researcher. The interviews, face-to-face or via Skype and lasting from 45 to 120 minutes, were carried out from April 2017 to January 2018 without any offer of compensation. Interviewees were either still on mission, transiting between two field assignments, or based at the Headquarter of their organisation after several missions. The same researcher transcribed and coded verbatim each interview (Atlas Ti 8); carried out thematic analysis of the transcripts; and proceeded to the data extraction, analysis and review. Data were tabulated by themes and subthemes, then summarised and shared among the research team for discussion. Trends and illustrative quotations were compiled.

Results

1) Demographic Profiles of the Participants

Among the 48 participants contacted, 39 responded positively (81%). The analysis comprised thirty-six interviews, three were abandoned owing to the poor quality of the recording and concomitant impossibility of producing an intelligible transcription.
The 23 women and 13 men interviewed (Table 1) had an average field experience in medical humanitarian action of 7 years and 4 months (from 2 to 23 years). Nineteen were Europeans, eleven Africans, five came from the Americas and one from Oceania. Sixteen of them had worked for more than one humanitarian organisation, and several continued to do clinical work in their country of origin between missions. They considered themselves to have been middle or senior managers in their last field assignment.

2) Institutional Policies and Strategies Related to Patient Safety

[ix] The research protocol was presented in April 2017, for approval, to the Geneva "Commission cantonale d'éthique de la recherche" (CCER). The Commission exempted this protocol from ethics review.

Currently, none of the six organisations has a fully operational structured institutional policy on patient safety and on medical error management. Sensitization level and actions on patient safety differ depending on the organisation: one was implementing a pilot project of quality measurement through score cards and a clinical incident reporting system in three missions. Another had a serious adverse-event reporting system sparsely used and promoted. A third had started an internal reflection on the quality of care in its medical services and ways to improve it. A fourth was considering implementing a reporting system for any major incident (medical or other). The last two were not yet developing an institutional approach to patient safety. While they were convinced that medical errors were sometimes committed in their organisations' work, medical directors and those responsible for quality in the six organisations reported that they were informed of such occurrences either rarely or only long afterwards
There were no noticeable differences in the answers provided by the interviewees would they work presently at Headquarters or at the field level or according to their professional background, sex or origin.

3) Knowledge of the Concepts of Patient Safety and Medical Error

Most interviewees had already heard of the concept of patient safety, and more than half of the interviewed staff had already encountered patient safety policies in their professional life, outside of their humanitarian experiences (in medical institutions they worked for or during their studies). They confirmed a current absence of clear policies on patient safety and medical error management in their organisations while acknowledging efforts undertaken institutionally in quest of better quality of care. All had seen, participated in or at least heard about medical errors occurring in humanitarian projects. All considered that to err is human, hence anybody can err, even if there was some confusion in differentiating between medical error, intended deviation from a protocol and negligence.

The problem I think is that we use the term "error" when we mean somebody did something bad or wrong, and I think the term there we want to focus on is negligence. – Medical doctor, 5 years' experience in 2 organisations

When asked what the causes of medical errors were, the most spontaneously mentioned factors were: work overload, distraction, lack of training/supervision, miscommunication or a combination of these factors.

Medical errors seemed barely discussed within the organisations.

> *That is what I find sad in humanitarian action… It must be such a compelling situation [in order for us] to be able to question ourselves. Even the daily minor errors that we all make and will make again, those… they do not lead superiors to question themselves.* – Nurse X, 3 years' experience

4) Prevention and Management of Medical Errors

The interviewees' experience, regardless of the organisation, was that detected cases of medical error were rarely well managed (analysis, search of explanatory factors, recommendations from lessons learned). In the end, it depended on the team leader.

> *This is on case by case. There is in fact nothing generalized, standard or which has been approved. This is done according to who is the boss.* – Nurse, 15 years' experience in 3 organisations

Information of an error occurrence might be forwarded to the upper hierarchical level (coordination and/or headquarters) but usually triggered no feedback/support. This created frustrations, because, according to them, either the case was immediately hidden, or no proper analysis was done, and a "culprit" eventually sanctioned.

> *Most of the time it is discussed internally in the team that is working there, to understand what happened and how to deal with it and, if you have a really experienced team leader, even to find solutions for it, how to learn from it. It is the optimal case… Most of the time… you sit in the evening and talk about it… it shouldn't happen, what a stupid guy or a stupid nurse.* – Paramedic, 8 years' experience in 3 organisations

According to interviewees, patients and their relatives were rarely informed.

> *I think, in my experience, in this case, the information given to the family is just: "Ben, we are sorry, despite all our treatments, the patient didn't survive." We don't enter into details because it would expose the medical staff and would expose the organisation.* – Midwife, 15 years' experience

Good practices related to error detection or prevention were mentioned as happening regularly across organisations, although depending on the team initiatives: mortality and morbidity reviews, meeting of the entire medical team after an incident, or maternal death audits.

5) Factors Explaining the Absence of Comprehensive Medical Error Management Policies

When asked why medical humanitarian action had up to now escaped the almost 20-year-old structured investments in medical error management, the main explanations spontaneously given were: the emergency mode (among so many priorities, patient safety gets subsumed, while the emergency mentality incites to focus exclusively on what is most pressing); fear of negative perception by colleagues or hierarchy (blame culture); lack of resources (to develop processes); lack of pressure to do it (staff and local populations unaware of patients' rights).

Cultural differences were said to play an important role: variety of staff without a common medical culture; communication difficulties between professional categories; different perceptions of responsibilities. The risks of consequences in case of disclosure of errors, even only internally, were acknowledged but discussed only if probed.

Humanitarian action's emergency mode, by virtue of either the nature of the intervention or the organisation's internal culture, was frequently mentioned and considered an excuse not to include medical error management as a priority, yet, according to interviewees, it is out of line with the evolution of projects developed by humanitarian organisations, which runs from simple substitution in emergency to support of institutional health care in a stable context. The instability of the contexts regularly affecting the provision of medical services was seen as an inherent part of any humanitarian action and in essence a starting point for action, not a reason to prevent change. Interviewed staff fully recognized the challenge of implementing proper strategies and procedures related to medical errors management in their organisations. The vast variety of contexts, circumstances and work conditions plays a significant role. The varying level of control the organisations have over care provided in their projects

was perceived as a clear difficulty in determining responsibilities and in enforcing potential policies related to medical error management: the organisation may have direct control over the care provided by its own staff; the project can be managed through a mix of health ministry and organisation staff; the project can consist of a distant support to the local health ministry by the provision of necessary inputs (drugs, medical material…).

The organisational structure was seen as a hindrance to the development of medical error management policy: support to field teams at the medical department level is organised in silos and does not favour investments in transversal issues.

> *"Organisations should be pushed to do more, and I think if organisations don't do it, it is not because of a lack of interest but because, for example, of the way [the organisation] is constructed … you have people focused on paediatric care or specific diseases. And then safety of patient is a very transversal issue"* – Midwife, 3 years' experience

6) Expectations with regard to a policy on medical error management

Interviewees clearly saw the responsibility of making care safe at the level of both the individuals and the institution employing them. The latter should provide the means, working conditions and guidance enabling a practical enforcement of safety. The state was mentioned as possibly co-responsible by defining policies and framework.

There was unanimity on the need, if not the urgency, to develop clear medical error management policies adapted to medical humanitarian action.

> *Yes, I think it is very important. We should be held accountable for this because it is not because you are humanitarian that you are exempted from all of these things that we do back in our home country.* – Nurse Y, 3 years' experience

The main quoted expectations regarding such a policy referred to procedures, tools and guidance to clarify how to do it (prevention and management of errors), and explanations and objectives to explain why to do it (awareness of safety risks and their consequences). The need for sensitization and training arose with the need of a framework clarifying responsibilities.

The medical errors observed by interviewees did not lead to any institutional or legal consequences. When evoked by the interviewer, the idea of negotiating immunity for

the staff in case of medical error, in acknowledgement of all the difficulties in implementing proper medical services in humanitarian settings, was rejected by all interviewees.

Two thirds of the interviewees considered it more appropriate for each humanitarian organisation to develop its own medical error management policy and strategy, adapted to its specific operations. The other third favoured a broad initiative from the World Health Organisation. In any case, interviewees thought that there must be enough flexibility to enable project sites to adapt the general framework to local specificities. Many interviewees favoured collaboration among humanitarian organisations through sharing of experiences.

> *Me, I think on this that we should have experience sharing. It would be super-important, between organisations, that we learn from each other... I think that if we, at our level, try to work alone, it will take a lot of time.* – Midwife, 23 years' experience

The general proposals of interviewees to improve medical error management in medical humanitarian action reinforced the above mentioned expectations such as more collaborative experience-sharing among actors, sensitization of donors to secure necessary funding for this, more training and sensitization of staff and management and better interaction with patients as well as with local health ministries.

> *"I think we have been going around the edges a lot, with all our efforts, around quality improvement, quality care... And, you know, I am not aware of how to start it. But that there just needs to be a more thoughtful focus on the full patient safety pieces out tackling it out of support or supervision and systems.* – Nurse, 18 years' experience

Discussion

This study is the first to explore some of the reasons why patient safety and medical error management in particular are not yet a priority for medical humanitarian organisations, despite patient safety being now recognized as a discipline in itself[14] and medical error management promoted by the World Health Organisation[15].

The difficulties experienced by humanitarian medical staff in reporting and managing medical errors correspond to what is experienced in OECD countries: blame culture[16],

lack of training,[17] absence of leadership committed to patient safety[18,19]. Several studies done in OECD countries point to the reluctance among medical staff to admit and disclose errors, preventing them from detecting, analysing and conceiving means of avoiding error reoccurrences[20,21]. To overcome this barrier, studies have highlighted elements to focus on: strong organisational and leadership support for safety; sensitisation about, and training on, error-reporting systems; a shared vision and blame-free culture.[22]

However, other difficulties mentioned by the interviewees, related to the specific conditions of humanitarian settings, add further complexity. These include the emergency mode and mentality pushing the organisation to shift from one priority to the next leaving the issues considered less urgent for later, the coexistence of; different medical cultures among the staff as well as the assisted populations; the absence of regulations or external pressures to invest in medical error management; the great diversity of activities and contexts of intervention with varying levels of control on the care provided.

All these difficulties, taken in isolation or together, were nevertheless not considered by interviewed staff as sufficient in themselves to justify an absence of structured investments in patient safety in general and medical error management in particular by the humanitarian sector. While acknowledging their part of responsibility in error prevention and management, they clearly emphasized the responsibility of their organisation in providing them support and guidance as reported in other researches.[23] The field experience of the interviewees made them realistic regarding the time and effort needed to change the internal mentalities concerning medical errors. Also, to become an area of collective action, it must become, as in OECD countries since 2000, a subject of discussion.[24]

Concerning the external factors as the absence of local regulations and of local recognition of patients' rights or the routine lack of automatic patient involvement in the care processes, there was a clear perception that it is incumbent on the organisations to

actively engage in an overall change relating to their duties and accountability in the domain of medical errors prevention and management.

To engage in change, the humanitarian sector has a range of assets enabling quick progress. A significant part of the interviewed international staff has already a good knowledge of patient safety. The high staff turnover amongst organisations may also favour cross fertilization on this subject. And, far from starting from scratch, the sector can benefit from the lessons learned in implementing patient safety and medical error management policies in OECD countries.

Strengths and limitations

The strengths of this study include its multicentre design, incorporating the perspectives of diverse organisations, levels of responsibility and types of professionals. The validity and transferability of our work is supported by the consistency of our results across the interviews.

The results represent the opinions of those interviewed and cannot be generalized, although the recurring experiences described, and opinions expressed tend to show a common desire for investment in patient safety and medical error management strategies. Questions raised, notably on interviewees' experiences with medical errors, are sensitive and may induce answers influenced by a social desirability bias. The review of interview transcripts and analysis was done by one researcher only even if the results were discussed with the research team.

Conclusions

Medical humanitarian organisations, while doing highly commendable work, still suffer from a lack of consistent incorporation of medical error management into their efforts to improve the quality of care. Reasons evoked by the interviewees can be divided in two categories: those which are commonly found in healthcare institutions in OECD countries, namely blame culture, absence of leadership committed to patient safety, lack of training and the ones related to the specificities of medical humanitarian action. If the latter add complexity, interviewed staff consider they are not sufficient to prevent a real

investment by medical aid organisations in adapted patient safety and medical error management strategies.

This research demonstrates the aspiration of humanitarian health care workers to invest in what can be considered an internal cultural revolution with regards to patient safety. Interviewees mostly perceived this to be the responsibility of their organisations and linked it to the duty of organisations claiming their commitment to be accountable to the beneficiaries of their actions.

The expressed call by interviewees for more experience-sharing among organisations suggests considerable scope for institutions like the World Health Organisation to convene global reflections in this area.

More research is needed to know how to apply lessons learned from OECD countries in humanitarian settings and to further understand how existing barriers can be overcome, given that the field is ripe for change. Our findings suggest that the medical and paramedical staff committed to humanitarian values are keen to participate in institutional developments in the domain of patient safety and medical error management that will help to save more lives and alleviate suffering, the ultimate purposes of humanitarian action.

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Table 1: Professional background of interviewees

Interviewed staff	**Nurse**	**Medical practitioner**	**Midwife**	**Surgeon / Anesthetist**	**Paramedic**	**Total**
MSF-CH	3		2	2		7
MSF-B	2	3	1			6
MDM	4	1	1			6
SC	3	2				5
IRC	2	3			1	6
ICRC	4			1	1	6
Total:	**18**	**9**	**4**	**3**	**2**	**36**

Annex 1: Interview Guide

Interview guide for in-depth interviews

FRONT-LINE STAFF

Date interview (dd/mmm/yy)	**Mode interview :** ☐ **F2F** ☐ **Skype**	**Place of the interview :**	☐ **Information sheet received:** ☐ **Consent form signed and sent**	**Date of transcription (dd/mmm /yy)**	**Date of coding (dd/mmm /yy)**	**Identification code of the interview:**

	Main Question	**Probing Questions** *(probing questions to help interviewers in case of limited or no answer)*
Theme 1: Experience of Patient Safety (PS) & Medical Error (ME)		
1.1	*What is your experience of patient safety in MHA or not?*	a. Have you already heard about this concept? b. Are you familiar with policies implementing PS? c. Is PS an individual, institutional or national responsibility?
1.2	*What is, according to you, a ME?*	a. Do you make a difference between ME and adverse event (AE)? b. What are the causes or contributing factors of ME? c. Do you consider that any medical staff does/can do a ME?
1.3	*Have you witnessed ME during your humanitarian experience?* *(Description)*	a. How was it handled? b. Was the management of the case responding to what you considered as appropriate? c. How would you have expected the case to be managed?

Provision of definition and explanations on the concepts of patient safety and medical error

Theme 2: Management of ME in their organisation		
2.1	*Does your organisation have a policy or strategy on PS?*	

2.2	*If yes, please provide information on this PS policy*	a. How have you been informed? b. Do you consider it useful to manage and prevent medical errors? c. What are the missing and the strong points of the policy? d. Which prevention and management procedures exist? e. Is ME a subject of discussion in your organisation? f.
2.2	*If no, do you think it would be interesting to have a PS policy to manage and prevent ME in your organisation?*	Would it be interesting to have such policy? Why

In general terms, what are the needs in terms of the determination and adoption of a PS strategy in MHA?

Theme 3: Factors pushing for the adoption of a PS strategy in MHA		
3.1	*Is PS pertinent for medical practice in humanitarian settings?*	a. If yes, what should be developed b. If no, why?
3.2	*According to you, which factors or considerations should make PS an important concern for aid organisations providing medical care?*	*c.* Ethics (medical and humanitarian) d. Legal e. Accountability to patients f. Practical (stated policy)

In global terms, what are the difficulties or challenges in the determination and adoption of a PS strategy in MHA?

Theme 4: Factors making the adoption of a PS strategy in MHA difficult/not feasible		
4.1	*Which elements can explain the absence of a PS policy in your organisation and in general in medical humanitarian organisations?*	List local, institutional, international factors Are the following factors important? a. Absence of resources at their disposal b. Absence of legal framework on the responsibility of the medical staff in MHA c. A blame culture d. Absence of willingness from the organisation and/or staff and/or management e. No procedures of error reporting and analysis f. Precariousness of the medical activities g. Consequences in case of disclosure of ME to patient h. Absence of compensation framework i. Never thought about it j. Security risk k. Fear of defensive medicine l. Too much differences between staff (MoH, organisation, partners…)

		Any other?

In global terms, what are the needed conditions for the determination and implementation of a PS strategy in MHA?

Theme 5: Necessary ingredients to allow a definition & implementation of a PS strategy in MHA		
5.1	*According to you, which (pre-) conditions should be met to develop a PS strategy of adapted to MHA?*	*Suggestions:* a. Legal framework (immunity, partial immunity…) b. Training of staff c. Sensitisation of the management d. Sensitisation of staff e. Proper procedures, tools and means f. Absence of blame culture g. A clear institutional policy framing responsibilities and security of the staff h. …
5.2	*Who is responsible for creating these favourable conditions?*	a. Each organisation b. Each medical project c. Host state d. WHO e. …

5.3	*What would you propose to enhance patient safety in Medical Humanitarian action?*	
Conclusion		
6	*Before to conclude, have you anything you would like to add?*	

Closure of the interview: thanks, and reminder of the confidentiality of the interview.

7. Conclusions and Perspectives

It took a long time, in OECD countries, for patient safety to become a recognized and necessary component of quality care provision and to be translated into policies, methods and practices. If patient safety is in constant evolution and faces many challenges, it responds to the deontological, moral, legal, economic and social obligations of the medical professions and the management of healthcare services. We saw that the example of successful strategies of error prevention in other high-risk industries, exemplified by the aviation industry, [23] was not sufficient in itself to have the medical profession and institutions immediately embrace the recognition of errors and search for structured strategies to prevent them[24]. A series of ingredients are considered as essential for a comprehensive investment in patient safety: A strong organisational and leadership support for safety; sensitisation about, and training on, error-reporting systems; a shared vision and blame-free culture.[25]

Through interviews with medical and para-medical staff active in the humanitarian sector, we found that medical humanitarian action is confronted with the same initial difficulties as health care institutions in OECD countries: the effect of errors committed is rarely visible and therefore not yet a subject of discussion and research; and among medical staff employed by aid actors, as the resident medical staff, in some contexts at least, are highly considered by the communities they work in and their doings are not questioned..

We saw, through the literature review, that patient safety, gradually built up to become a major domain of investments in many countries, notably the high-income countries, is based on the conjunction of actions at three interdependent levels: the macro level, authorities who set the laws and regulations framing the rights and duties of the profession and institutions exercising clinical practices ; the meso level, the medical institutions, enablers of patient safety through training, implementation of tools, commitment and leadership; and the micro level, individuals directly or indirectly

participating in the patient care, whose active involvement is the cornerstone of the prevention and adequate management of medical errors and their consequences.

As in other high-risk industries, an adequate working climate is considered a key ingredient in gaining the active participation of all involved actors in the improvement of safety in healthcare provision. The safety culture[26] creates the environment within which the staff involved in clinical care dare to overcome their potential reluctance to speak about incidents, to participate voluntarily in its analysis and learn its lessons.

Beyond the implementation of adequate tools and strategies to detect, report and analyse incidents so as to produce clear recommendations to avoid their recurrence, at medical institutions but also medical departments, units or teams, this safety culture supposes: the clear commitment of the leadership to its enforcement; an active fight against the traditional blame culture; a proper support of the medical profession to not only learn how to methodically analyse incidents but to cope with the difficult experience of having participated in the commission of a perhaps harmful error and being in a position to disclose it appropriately to the patients and/or their relatives.

Interviews with medical and paramedical staff active in the humanitarian field have demonstrated two important lessons confirmed by the medical directors and/or those responsible for quality of care in the organisations involved in the study: 1. there is as yet no strategic thinking about patient safety translating into policies and investments, although there is a clear preoccupation with improving the quality of the care provided or supported by the organisations; 2. there is a willingness on the part of the staff to be trained and supported to implement patient safety as a priority of their organisation.

Otherwise, the explanations provided by the medical and paramedical staff interviewed on the current absence of structured strategies of prevention and management of medical errors can be divided into two categories: 1. the specificities of medical humanitarian action and 2. the absence of the main ingredients of a safety culture (leadership, no-blame culture, appropriate support of the staff in sensitization, training and guiding tools to report, analyse and disclose medical errors). For the latter point, the inspiration of how

the healthcare systems and institutions in OECD countries were able to develop and nurture this safety culture seems relevant. Collaborations, or at least consultations, with specialists in patient safety could allow medical aid organisations to build up their appropriate strategies for the development of an internal safety culture.

Related to the specificities of medical humanitarian action, interviewees point additional difficulties to circumvent in order to conceptualize structured and overall strategies of patient safety adapted to their operational realities: the emergency mode of aid organisations (the need to focus on the most pressing among the various other priorities); the highly varied types of projects and work conditions; the countries of intervention having limited resources and being also frequently characterized by social and political instability; the great variety of staff with different medical cultures and a considerable turnover; the limited duration of humanitarian projects (from some months to several years); the absence of regulatory bodies able to develop, impose and monitor patient safety policies in a sector with a multitude of independent aid organisations; and the different levels of control over the care provided to the patients (from projects totally managed by the staff of the humanitarian organisation up to an external support from the ministry of health structure and staff).

The role of medical aid organisations in developing patient safety strategies and medical error management tends to be reinforced by the absence of an overarching regulatory body for the sector coupled with regulatory deficits notably in the establishment of healthcare standards[27] in countries of intervention where medical errors are estimated to be very high.[28,2] Additionally, there is a great variety of medical cultures among the staff of medical aid organisations. Embarking in the definition of adapted patient safety policies requires a clear commitment and investment decided at the higher level of the organisation so that that priority becomes an institutional one. Entrusted with ensuring that the quality of care provided through their projects is accountable to their donors as much as to the beneficiaries of their action, medical humanitarian organisations have the

power and the leverage to conceive, at least for their own actions, policies and strategies ensuring the safety of medical practices they implement and support.

While stating their ambitions in terms of patient safety, a specific subset of the quality of care they intend to ensure, they have the responsibility to set up appropriate support to the front-line medical and paramedical staff. This will come to pass by developing internal mechanisms and tools first, to sensitize the staff regarding the phenomenon of medical errors; second, to train the staff and particularly the medical managers to detect and manage consequences of occurring cases, to report cases in an appropriate manner through appropriate channels; and third to draw lessons from occurring cases to be reinjected into the entire organisation and its project recommendations for implementation. The organisations' leadership has a crucial role in this process, as much in the allocation of resources and means to develop and implement the decided policies as in determining the appropriate support mechanisms for the staff involved in the error making.

The great variety of medical contexts tends to require a high degree of autonomy to allow the project's medical managers to determine how the guiding principles in the organisation's policy can be translated into locally adapted objectives. This supposes that the initial assessment has equipped the field teams with a proper knowledge of local regulations, habits and capacities to, at least, respect local legal requirements and set-up locally realistic plans to improve the patient safety while preserving the security of the staff and the organisation. This tends to reinforce the necessity to invest in sensitisation and training of staff to develop the necessary competence.

In order to have humanitarian staff starting to offer medical services, these organisations must first mobilize financial and human resources, negotiate access in contexts of intervention, ensure the acceptance of their presence and activities by all stakeholders, and more – all challenges demanding substantial energy and capacities before the first medical intervention. Moving into the development and implementation of adapted patient strategies will require dedicated staff as well as extra resources to effect what

could be seen as a real cultural revolution. The active support of donors will therefore be necessary to secure the resource allocations for: the development of internal guidelines; adapted sensitization and training material; training of staff for the analysis of medical error and proposal of recommendations; training of staff on how to disclose the error to the family and/or relatives if appropriate; securing an appropriate arbitrage mechanism to discuss problematic cases; etc.

Initiating discussion of medical error even internally could pose a serious risk for the reputation of the organisation and its staff. It will mean opening a Pandora's box of complex questions. Who is responsible in the event of an error severely affecting a patient – the staff involved or the organisation they work for? When, how and to whom should the detected error be disclosed while respecting ethical precepts and ensuring the security of the staff member(s)? What compensation for the harmed patients is to envisage and what equitable criteria are to be applied across contexts to determine a fair level of compensation? What should or should not be reported to national medical and judicial authorities?

More research and reflection are needed to provide acceptable answers to these various crucial questions.

The expressed desire, by the staff interviewed in the course of this research, of collaboration among aid organisations to develop adapted patient safety and medical error management strategies can be a valuable avenue to pursue in the search for adequate solutions. Such collaboration and experience sharing can easily lead to the development of standardized terminology, sensitization and training tools inspired by the existing training schemes and curricula used in healthcare systems of OECD countries but based on traditional environments and realities encountered in medical humanitarian projects. Adequate options in response to the above questions could be developed under the auspices of the World Health Organisation, which is already providing guidance and standards on patient safety for healthcare systems.

If presently a non-problem (as long as cases of error are not known, disclosed and publicised) absent from cost evaluation, pursuing the definition of a patient safety strategy for humanitarian organisations will represent an important investment in time and energy. It supposes the development of qualitative objectives as well as the usual quantitative ones (number of hospitalisations, of consultations, of vaccinations…) which are naturally scrutinized, be it by the donors wanting to know the result of their investments or by the organisations themselves whose objectives are mainly and legitimately determined by public health considerations.

Medical humanitarian action embodies values of solidarity and humanity by being deployed in places where health systems fail, and by providing vital services in circumstances generally associated with catastrophe: war, natural disaster or huge epidemics like Ebola or cholera. Indeed, it is still associated with heroism.[x] This reputation is nevertheless tarnished by various concomitant phenomena: the constant attempts at politicising aid, by which states try to hijack the benefit of the aid deployed to cover the absence of other options at their disposal; an increased resistance from the population affected by crisis, notably owing to false promises or expectations;[29] media scandals as "Oxfamgate",[xi] which create the impression of a gap between public discourse on values and principles and perceived reality. Daring to accept the existence of medical error and to openly discuss may create, if not adequately handled, the risk of increasing distrust.

To tackle a hidden but real phenomenon is a responsibility of organisations that put accountability and quality at the forefront of their identity.[xii] Confronted with a constant

[x] Ex.: World Food Program: "What Makes a Humanitarian Hero" available on: https://medium.com/human-development-project/what-makes-a-humanitarian-hero-440202edded8 Accessed on October 16, 2019

[xi] See for instance https://www.thetimes.co.uk/article/the-times-view-on-the-oxfam-scandal-abuse-of-power-kf8w6x2gw accessed 28 August 2019

[xii] Accountability to beneficiaries is one of the most shared values among aid organisations and is mentioned as a priority in the various sectoral initiatives to develop standards of good practice. For instance, The Code of Conduct for the International Red Cross and Red Crescent Movement and Non-Governmental Organizations (NGOs) in Disaster Relief adopted in 1994 (See https://www.icrc.org/en/doc/assets/files/publications/icrc-002-1067.pdf); The Common Humanitarian

need of adaptation,[30] medical humanitarian aid organisations have everything to gain by integrating patient safety into their efforts and trying to devise by themselves what is adapted to their realities while ethically and practically sound. It may help to avoid as much as possible the judicialization of occurring cases that occurred in OECD countries,[31] without having secured mechanisms of prevention and mitigation.

Opening the discussion with national health systems will also open the door to collaboration, to the prevention of unnecessary tensions. This is another area needing further investments. Legal advisors of medical humanitarian organisations may have great added value in understanding various local regulations and practices and in drafting of agreements with local health ministries regarding medical error management, prevention and dispute settlement.[32,33]

There is no doubt that the incorporation of patient safety through structured strategies will be a long and demanding process. Making a qualitative step from “acting for access to care for vulnerable populations” to “acting for access to quality care for patients belonging to vulnerable populations” will involve numerous challenges as soon as specific proposals and their practical application gain momentum. It must necessarily begin by daring to open the discussion within the sector, one of the ambitions of this research. There is no reason why the “specialness” of the aid system, to paraphrase one of the interviewees, doing a fantastic job, should evade all the rules and the safety procedures expected in quality care provision.

Standards adopted in 2015 (See CHS alliance https://www.chsalliance.org/); The Sphere standards (last edition in 2018: https://spherestandards.org/wp-content/uploads/Sphere-Handbook-2018-EN.pdf).

Annex 1: Oral Presentation during the Geneva Health Forum, April 2016

Medical Humanitarian Action and Patient Safety: The End of an Exception?

Humanitarian actors embody the values of solidarity and humanity by going to those countries whose health systems fail their populations, and by providing vital services. Humanitarian medical staff accept the risks and the difficult working environment that these missions present because they believe it is necessary to respond to suffering wherever it occurs.

Historically the humanitarian sector has grown organically, in response to the demands of emergencies and human suffering. As a result, there is no single, uniform set of norms and standards. However, as the sector has become increasingly institutionalized, there has been a constant push towards professionalization, improved standards, and quality assurance.

There is no doubt – as I have personally witnessed in MSF – that humanitarian medical staff do an admirable job, bearing witness to much more than mere good intentions. But strange though it may seem, "patient safety"[xiii] has not yet penetrated the aid sector vocabulary and policies, neither as a discipline nor as a central pillar in the prevention of harm to the patient in medical care delivery. A Google search for the terms "humanitarian action" and "patient safety" results in only two articles that mention both concepts.

[xiii] "We define patient safety as a discipline in the healthcare professions that applies safety science methods toward the goal of achieving a trustworthy system of healthcare delivery. We also define patient safety as an attribute of healthcare systems that minimizes the incidence and impact of adverse events and maximizes recovery from such events." Emanuel L, Berwick D, Conway j, *et al.* What Exactly Is Patient Safety. In: Henriksen K, Battles JB, Keyes MA, et al. Eds. Advances in patient safety: new directions and alternative approaches. Rockville, MD: Agency for Healthcare Research and Quality 2008;1:1–18.

My aim here is to explore how it came to be that humanitarian medical practice has been an exception to the principle of patient safety, a principle that has otherwise been integrated into almost all areas of medicine. I shall also look at the forces that are pushing humanitarian medical providers to ending this exception.

Why Such an Exception?

While there is little consensus about the definition of "humanitarian medicine" or "medical humanitarian action", this sort of medical action is generally associated with catastrophic situations: war, natural disaster, immense epidemics like Ebola or cholera. Medical humanitarian action evokes an image of heroism and urgent response in dangerous situations.

Dr Philippe Calain, an aid actor himself, offered this definition for the concept of humanitarian medicine: "a set of medical or public health practices whose sole intent is to selflessly accommodate and address the tension created between compelling health needs and the ongoing deprivation of resources in a given population or community".[xiv] This definition is interesting in that it does not associate the action with acute emergency. It corresponds to this reality: medical humanitarian action is multiform and consists of a range of medical situations from emergencies to support to a healthcare system; from long-term projects to tackle the spread of a disease to providing basic medical assistance to a vulnerable population in a totally stable context.

Taking MSF as the archetypal medical humanitarian actor, we can see that almost half of its projects play out in stable contexts,[xv] far from active conflicts or sudden disasters. MSF projects are selected for their relevance to the organization's priorities as much as for the medical needs uncovered during situation assessments. The final decision to undertake a

[xiv] Calain P. In search of the "new informal legitimacy" of Medecins Sans Frontieres. Public Health Ethics 2012;5:56–66.

[xv] See http://cdn.msf.org/sites/msf.org/files/msf_international_activity_report_2014_en.pdf Accessed on April 12th 2016.

project as well as its objectives and timeframe, are determined by the organisation, even if the process involves negotiation with the local medical authorities and other stakeholders. It is the humanitarian organization itself that decides which resources will be allocated to a project. This decision has implications for other projects, as any allocation of energy or of other means to one project reduces the resources available for another projects. The project performance standards – including standards of care – are frequently left for the organization itself to decide and monitor on its own.

In the vast majority of countries where humanitarian medical aid is deployed, little attention is paid to the concept and principle of patient safety, in terms of frameworks, clear procedures, or policies. It is hardly surprising that the medical humanitarian sector, which has emerged from such operational environments, has been slow to embrace patient safety as a common discipline.

We can delineate three main challenges for the creation of a rigorous patient safety culture in medical humanitarian action.

The Contexts of Intervention

In many contexts, there are more pressing concerns – such as the immediate security of both the patients and the humanitarian staff – that take precedence over considerations of patient safety. Humanitarian medical personnel often work in precarious situations with limited resources and under less than ideal working conditions. It is common to work without any real reference system, with the humanitarian staff solely responsible for the resources mobilized and sent by their organization. Medical cultures differ depending on the context, with widely varying written norms (when they exist at all), numerous ways of defining and perceiving quality of care, and differing levels of expectations (norms/standards). Societies frequently conceive of the medical world's relationship with patients in a paternalistic way: with doctors holding knowledge and power and patients expected to docilely accept whatever treatment is dispensed. In such a context, there is little pressure on the medical providers to focus closely on quality of care. The availability

of suitable qualified local medical staff also varies widely depending on the situation: this too affects the quality of care provided.

Organizational Characteristics

Humanitarian organizations employ heterogeneous, cosmopolitan medical staff, whether recruited locally or internationally. The effect of this is that many different medical cultures are represented within any single organisation. Projects are often planned and implemented extemporaneously, a drawback compounded by short-term engagement of staff members, resulting in considerable turnover both within individual projects and in the organization overall. The relationship with local health systems varies from one situation to another. Some projects use an independent structure created by the humanitarian organization; some are done in full collaboration with, or under the control of, the local health ministry; others are developed using health ministry resources but under full responsibility and supervision of the humanitarian organization.

In these differing contexts, the official frame of responsibilities is often unclear or undetermined. If a general agreement with the local authorities does exist, it often neglects to spell out who holds responsibility for what, and, more importantly, what the consequences might be in the event of a serious breach of care.

The General Context of Humanitarian Medical Action

The humanitarian sector, by and large, is neither structured nor regulated. Each organization operates independently, with no overarching governing body or common sets of rules. There is little published research or documentation on medical humanitarian activities and patient safety. A search on PubMed and Embase, for example, turns up not a single result linking the terms ‘patient safety’ and ‘humanitarian medical aid’.

While there have been impediments to the development of a rigorous patient safety culture in the medical humanitarian aid sector, we can nonetheless identify some promising developments in that direction. Broadly speaking, there are two main reasons for such an evolution.

Humanitarian Organizations Are Aiming to Become More Accountable to Their "Beneficiaries"

The ethical and quality-assurance framework of many medical humanitarian organizations is rooted in the standards required by the Western world. Both within organizations and across the sector, there is a clear push for professionalization of the aid sector in general as well as for the development of high-quality aid, emphasising the well-being of the patient.

"Do no harm"' is a central value to humanitarian action in general, and it reflects perfectly the culture of patient safety in medical ethics. These concepts are inextricably tied to notions of accountability to beneficiaries of humanitarian action, a major subject of discussion across the sector.

A General Trend Toward a Culture of Patient Safety All over the World.

There is an increasing number of examples of medical institutions in low- or middle-income countries implementing measures and tools to improve patient safety. Even if these are isolated instances, they nonetheless reflect a trend towards improved standards in medical care. There is a general demand from societies for more accountability from the humanitarian sector as humanitarian action is viewed with a critical eye from increasingly discerning beneficiaries. Even remotely situated and poor patients have begun to express their concerns and questions about the care they receive from humanitarian medical providers. In those places where expectations of medical standards are high, such as the Middle East, or in contexts where dissatisfied patients are likely to seek judicial intervention, like Haiti (with its proximity to the U.S. culture of litigation), the

resulting pressure draws attention to the risks of patients' dissatisfaction and is a strong external factor impelling to better quality of care.

"Do No Harm" as an Operational Value

The scientific literature demonstrates that patient safety is preceded by the development of a more general culture of safety.[xvi] In settings that cater to individuals who demand a high level of quality, it is crucial that the institutional medical environment be sensitized to patient safety concerns, and that staff work as a team to address these concerns. Increasingly, patient safety is enshrined in health policies in high-income countries, but there is still fear, resistance, and difficulty in shifting from a culture of blame and hiding problems to a culture of learning from one's mistakes. In order for the humanitarian sector to undergo such a paradigm shift, humanitarian health institutions must cultivate a climate favourable to patient safety. Only then will they be able to make this difficult qualitative step.

Medical humanitarian personnel are at the forefront of the response to the pressing needs of victims of crises and emergencies. The development of a patient safety culture, including policies, tools and means, will allow the sector to innovate and increase the quality of its care, and deliver it in a responsible manner. As the Lancet, in a recent editorial, put it: "Patient safety needs to be integrated into the foundation of quality care – safety is not a special programme."[xvii]

The first step, therefore, is for the humanitarian medical sector to end its exception from the patient-safety groundswell.

[xvi] "An integrated pattern of individual and organizational behavior, based upon shared beliefs and values, that continuously seeks to minimize patient harm which may result from the processes of care delivery" Aspden, Philip, Institute of Medicine (U.S.), and Committee on Data Standards for Patient Safety. Patient Safety Achieving a New Standard for Care. Washington, D.C.: National Academies Press, 2004. http://search.ebscohost.com/login.aspx?direct=true&scope=site&db=nlebk&db=nlabk&AN=112058.

[xvii] Patient safety is not a luxury. The Lancet 2016;387:19.

Annex 2: Patient Safety: State of the Art

Developments in Safety Science

Any human activity contains some risk, defined as "the probability that an incident will occur".34 While risk management practice is ancient (noted as far back as the Renaissance period35), the analysis of risks and accidents as a subject of science had to wait until the 1970s to see a flowering of research.36 Similarly, the fallibility of humans has long been recognized (ERRARE HVMANVM EST, attributed variously to the Roman philosophers Seneca and Saint Augustine). Error is a normal cognitive process.[37] But, regarding the notion of risk, it is only in the second part of the twentieth century that theories and models of error processes were developed, allowing organized and structured actions of prevention and mitigation.

1.1 James Reason's "Swiss Cheese Model"

The human factor, defined as "the study of the interrelationships between humans, the tools they use, and the environment in which they live and work",[38] is one major factor behind accidents (among others such as material defect, environmental variations etc.).

The aviation sector pioneered in research to understand accidents[xviii] and invested hugely to understand the human factor. Until serious investigations and research were undertaken, accidents were imputed to the pilot.

Scientific analysis and observation enabled researchers to understand that plane accidents, 70% to 80% of which are attributable at least partly to human error,[39] are mostly the end result of a series of causes, with the unsafe acts by the crew only the last.[40] Consequently, prevention measures could be imagined at various levels, which have had a significant effect on the number of accidents and fatalities since the 1970s. Air travel is now one of the safest forms of transportation.[xix]

[xviii] A specialized agency of the United Nations, the International Civil Aviation Organisation (ICAO) was even created in 1944 to promote the safe and orderly development of international civil aviation throughout the world. See http://www.icao.int/Pages/default.aspx Accessed on September 17, 2018.

[xix] According to a report of Allianz Insurance company, although the air traffic has constantly grown, in 1959 the chance to have a fatal accident was 1 every 25'000 departure (USA & Canada) and in 2015 is 1 on 77

James Reason, a psychologist, is one of those researchers whose work on human error remains an important reference in the area of safety.[41] With his observations and reflections on possible causes explaining the genesis of errors committed by front-line workers, he initiated a real paradigm shift in the understanding of human error. Human errors are not necessarily the result of a lack of ability on the part of front-line workers; they may also be the culmination of a series of prior errors (at the management level, in the maintenance processes etc.)

Starting by clarifying the separation between intentional and non-intentional actions,[42] he made the distinction between what he designated as active errors and latent errors. Active errors are those whose effects are in direct relation to the occurrence of the adverse event and are committed by the front-line actor. Latent errors are those whose contributing factors are lying dormant within the system. Such errors are committed by people who are likely unaware that they are participating in a process that will result in an accident.

In a production process, various human errors, even very small, can contribute (contributing factors), each at its own level, to the occurrence of the accident. However, each error alone is not necessarily sufficient, by itself, to cause the accident.

Reason offers also a differentiation between various types of human error: slips (errors made under the influence of fatigue, stress or distraction), lapses (memory error) and mistakes ("deficiency or failure in the judgemental and/or inferential processes involved in the selection of an objective or in the specification of the means to achieve it, irrespective whether the actions directed by this decision-scheme run according to plan").[43] Slips and lapses are skill-based errors, while mistakes can be rules-based errors (bad application of the rules) or knowledge-based errors (the person has no idea what to do without clear rules, nor how to react to a specific situation).[44]

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29 million departures (USA & EU), 100 time less than bicycle accident risk.
http://www.skybrary.aero/bookshelf/books/3297.pdf. Accessed on July 12, 2016

The understanding of this differentiation allows the determination and implementation of specific actions to avoid future errors of the same kind: intelligent decision support systems (checklists), training, clearer written procedures for maintenance, environmental interface design, self-knowledge about error types and mechanisms.[45] One of the consequences of Reason's approach to error has been, in some high-risk industries, to deviate from the usual search for a guilty person to blame. It offers new options on where to act in the quest to prevent errors:[46] beyond interventions to enhance the abilities of front-line workers, actions upstream in the complex interaction of humans, machines and systems.[47]

James Reason illustrated his reflections on human error in the famous "Swiss-Cheese Model" (Figure1), a milestone in safety science.

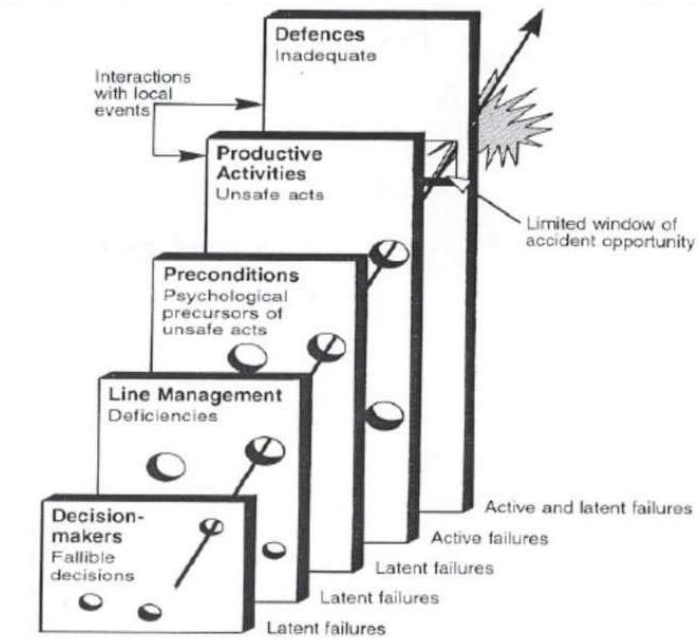

Figure 1. James Reason: The Swiss Cheese model48

Unawareness and/or unacceptance of errors as being rooted in system processes leads to the "vulnerable system syndrome" making an organisation more error-prone.[49] Organisations suffering from this syndrome share three main characteristics: the impulsion to search for a guilty party to blame in the event of a problem; the non-recognition that latent errors are points of vulnerability generated by the system; and a culture of organisation and management focused on productivity without caring for safety.[50]

In Reason's model, accidents are explained by a linear succession of actions or a chain of various elements. There is an accident when factor A + factor B + factor C etc. are activated or because factor A causes factor B which causes factor C…, leading to the accident. This linearity is one of the main sources of criticism of the model,[51] seen as an over-simplification of reality. Despite this criticism, the Swiss Cheese Model remains an essential landmark in safety science and its applications.[52]

1.2 Rasmussen's Migration of Acceptable Boundaries

The main limit of the linear model proposed by Reason is that it does not sufficiently consider the complexity of human-decision mechanisms. The decision-making process is always a compromise among competing needs, be they from within the organisation (performance, work relations…) or from the outside (legislation, media attention…).[53] According to Jens Rasmussen, an engineer working for the nuclear industry, those needs have the potential to act as various sorts of opposing pressures[54] on the worker (workload, efficiency…).

In Rasmussen's model, the starting point is not the accident but the organisation and the way it is structured and organized,[55] which create the potential to generate or prevent errors.

Each part of the organisation has its own logic, different from that of other parts, yet produces outcomes influencing the performance of the other parts. The organisation management will have to create the necessary arbitrage among logics in order to limit the

potential negative influences that each part of the organisation can have on the others.[56] This means that decision-makers must analyse the dynamic of each part of a system and the interaction(s) among the parts to arrive at the decision having the least likelihood of erroneous outcome.[57] In constant evolution, the interaction(s) among the parts of the system can lead to migration of the risks. This then implies constant monitoring of processes to adapt functional safety measures to the evolving nature and place of risks.[58]

Safety is never a given. It is the result of being constantly alert to any evolution and adapting accordingly. In this vision, the intention of the model is not to achieve a zero fault/error organisation but to make it reach an acceptable (low) level of risk. This level of acceptance varies depending on circumstances, if there were just one accident that attracted attention, the tendency would be to act forcefully to keep the risk to a minimum. After a while, attention, and therefore the investment of energy in safety, would tend to diminish, while the risk tolerance increased.[59]

This approach innovates by introducing the notion of competing influences explaining the variations in human decisions that could lead to taking risk up to the commission of error. In a dynamic society, safety is built up at various levels affecting each other in a hierarchical way: government will impose rules and regulations; companies will have their decisions influenced by market evolution; managers will attribute more or less importance and means to safety; staff will have access or not to training and guidance…[56] It also shifts from the notion of failure or error to the idea of variability of behaviour and human decisions to adapt to the situation.[59]

1.3 High Reliability Organisations

Psycho-sociologists, observing complex organisations, developed the concept of high reliability organisations (HROs). Such organisations or industries, despite the elevated level of complexity of their tasks and their exposure to risks, perform very well, with a very limited number of accidents (nuclear power plants, airplanes etc.).

High reliability organisations have common characteristics regarding their relation to risk.[60] First, they focus on detecting vulnerabilities (working a priori on risks) in

organisational structures or processes: detection of “near misses”, those events or situations that could have resulted in an adverse event but did not, either by chance or by timely intervention[61] through notably probabilistic risk assessment.[62] Thus, they do not limit their attention to accidents that happened (working a posteriori on occurred errors), as these are quite rare.[63] Second, they develop multiple redundant protective barriers at recognized vulnerable points of procedures to avoid accidents (technological or human redundant checks). Third, they have created a real culture within the organisation in which everyone shares the same constant concern for safety and respects and trusts each other’s competences beyond the hierarchical structure (collective mindfulness).[64]

Theorists of the HRO model have come up with this important notion of an organisational culture that creates the cement among the parts of the organisation in pursuit of a single goal: a safe organisation.[65] This cementing culture is never a given and must be constantly nurtured.[66]

Such industries take for granted that reality never completely matches what is described and promoted in guidelines. Standardization of processes and procedures is important, but, to respond to all real situations, they must demonstrate the flexibility (even allowing for violations of rules)[67] necessary to cope with the unexpected by accepting adjustments to what is advocated in guidelines (resilience).[68] From the point of view of human error, this model of high reliability organisation has shifted theory to a comprehensive and systemic approach:[48] there is a constant search for the optimization of the interaction between humans and technologies in the best possible design.[69]

Unlike Reason’s and Rasmussen’s, the high reliability organisation model focuses on risks and looks at successful processes, instead of failures, to extract a set of ingredients favouring safety and explaining the successes of the organisation.[51]

1.4 Organisational Approaches to Risk

Drawing on various theories, Amalberti and Vincent[12] categorize organisations according to their relation to risk, in three groups.

1. Ultra-resilient organisations: risks are known and managed. Owing to a careful analysis of previous accidents and their contributing factors, the organisation works at managing the risks and limiting its exposure to them. The resilience of the organisation is based on the teamwork of people sharing the same values and concerns about safety and capable of flexibility and adaptive judgement regarding the most appropriate behaviour (i.e. oil companies, chemical industry).

2. Ultra-adaptive organisations (HRO): risk is a recognized, important and integral part of the activity. The staff must be able to adapt to any circumstance and, even if accidents are frequent owing to high-risk exposure, the staff have the autonomy to make the decision perceived as the most adapted to each situation. There is a limited number of standards and procedures, but also constant sensitization and training to upgrade individual skills, based on the best decision-making processes when confronted with risks. (i.e. fishing industry, combat troops).

3. Ultra-Safe organisations: reliance mainly on the avoidance of risks. They develop their working procedures by standardizing and automatizing them as much as possible. This allows the staff to be interchangeable[67] (i.e. nuclear industry, civil aviation).

In figure 2, sectors of activities are categorized according to their level of exposure and the adapted style of risk management.[xx] Those on the left side rely on their capacity to adapt to risk in order to remain performing. Activities or industries on the right side avoid as much as possible the risks.

[xx] ASA= American Anaesthesiology Association patient status (level 1 = normal healthy patient; level 5 = moribund patient who may not survive without the operation

Ultra adaptive Model Embracing risk		**High reliability** Managing risk	**Ultra safe** Avoiding risk
Context: Taking Risks is the essence of the profession		**Context:** Risk is not sought out but is inherent in the profession	**Context:** Risk is excluded as far as possible
Deep sea fishing, military in war time, drilling industry, treatment of trauma, rare cancer		Marine, shipping, oil industry, fire-fighters, elective surgery	Civil aviation, nuclear industry, public transport, food industry, medical laboratory, blood transfusion
Safety Model: Power to experts to rely on personal resilience, expertise and technology to survive and prosper in adverse conditions.		**Safety Model:** Power to the group to organise itself, provide mutual protection, apply procedures, adapt, and make sense of the environment.	**Safety Model:** Power to regulators and supervision of the system to avoid exposing front-line actors to unnecessary risks.

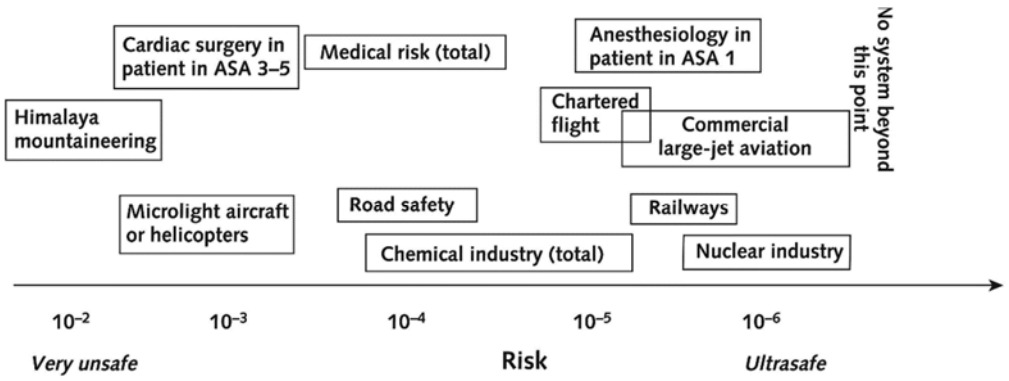

Figure 2: Extract from Amalberti & al. "Average rate per exposure of catastrophes and associated deaths in various industries and human activities "[70]

Safety science has evolved over time in function of various disciplines (psychology, engineering, psycho-sociology, law) and changes in focus: from individual human focus to a systems approach (from Reason to Rasmussen theories), from failures to risks (from Reason & Rasmussen approaches to high reliability organisation theories). This evolution allows a progressively greater overall understanding of risks, their nature and their causes. Their translation into safety and risk-management models requires adaptation to context as much as to the sort of activity. Looking at the complexity and diversity of medical activities, we can imagine that one model of risk management will not fit all sorts of activities, while all of them provide an interesting angle that suits, partially at least, the practice of medicine.[71]

Transposition of Safety Theories to Healthcare: Towards Patient Safety

2.1 Late Investment on Healthcare Safety

The recognition of error, as a subject of systemic concern in healthcare, took a long time despite many individual calls[3] and legendary initiatives, such as the development of standards of care by Florence Nightingale.[4] It was first met with scepticism[72] and is still today greeted with some reticence by the medical professions, as demonstrated by some surveys.[73]

The term "patient safety" was used for the first time in 1985 in the United States by anaesthesiologists who created the Anaesthesia Patient Safety Foundation (APSF).[74] But it was the publication of the U.S. Institute of Medicine (IOM) report To Err is Human: Building a Safer healthcare System in 1999[5] that sparked the interest in "medical errors" and consequently a huge investment in their prevention and management.

How can this interest in safety in healthcare activities, latter day compared to other sectors, be explained? And why not a simple replication of what had been implemented so successfully in the aviation industry?

Four main explanations can be given: 1. the limited impact, in terms of number of affected people, of each individual error in healthcare; 2. the intrinsic characteristics of the medical ethos; 3. the complexity of healthcare provision; and 4. the legal environment creating fears of litigation if errors are disclosed.

A. The Impact of the Error

First, there is a major difference in the scope of errors or accidents occurring in healthcare delivery compared to other high-risk industries. When a plane crashes, there are many victims, while in healthcare, only one patient at a time is harmed.[75] This lack of "critical mass" visibility has a natural suppressive effect on collective awareness of the extent of the problem.

In parallel, in some countries, there are quite limited external pressures for the disclosure of the errors and for a search for explanations and remedial action. (The USA is an exception.)

It is only when researchers aggregated what was up to then seen as a series of individual cases of error that the limitations of safety in healthcare appeared striking and triggered a general wake-up call: the IOM report of 1999 spoke of between 44,000 to 98,000 Americans dying

every year in the United States from medical errors, while up to 1 million patients endured adverse events every year.[5] In the U.K., a report in 2000, mentioned the figures of 400 deaths and of 10,000 patients enduring serious adverse event per year.[76] In Australia, according to research in 1985, there were 10,000 deaths each year and up to 50,000 permanent disabilities[77] due to medical errors.[xxi]

Parallel to and beyond the assessment of the problem's extent and its impact on the patient, evaluation studies exploring the indirect consequences for society are now important incentives for investments in safety. A study sponsored by the Society for Actuaries estimated the cost of medical error for the United States, for 2008, at $19.5 billion, of which 80% is additional medical costs: prescriptions, in- and outpatient costs, ancillary services.[12] In the U.K., clinical negligence claims alone cost an estimated at £400 million in 1998-1999.[78]

The increase of mortality rates and loss of productivity (missed workdays) adds $2.5 billion. In terms of quality adjusted life years (QALYs), the economic loss of deceased patients due to medical error represents up to $1 trillion per year in the US.[79] Extrapolating to the entire planet with 421 million hospitalisations per year, there would be up to 42,7 million adverse events causing 23 million DALYs (Disability-adjusted life years) loss per year (two thirds occurring in low- or middle-income countries).[2]

B. Medical Ethos

A second explanation for the late investment in safety by the medical professions is related to the medical ethos that places the medical doctor in a dominant[80] position of perceived excellence, reinforced by the asymmetry of access to information, even to the total detriment of the patient.[81] The simple idea of doctors making errors creates a cultural dissonance.[6] This is embedded not only in medical professionals' minds but also in the beliefs of the patients and, more widely, in the beliefs general population.

[xxi] According to studies done in comparable healthcare systems, between 700 and 1,700 patients die every year in Switzerland, due to medical error. See http://www.patientensicherheit.ch/fr/th-mes/S-curit--des-patients.html Accessed on September 9th, 2016

Further, the medical professions still sometimes consider medicine as craftsmanship needing total autonomy to attain excellence.[82] Even today, medical culture favours a person-centred approach to human error linked to two illusions: the punishment illusion, according to which the person who makes an error, if punished, will not make it again; and the perfection illusion, claiming that error-free performance is attainable – if one only tries hard enough.[83]

C. A Complex Human Activity

A third explanation for the slow progress in integrating safety into healthcare design strategy is linked to the complexity of healthcare practice. It not only encompasses different professions, it is often the result of large teams having interactions of different intensity, along different hierarchical lines and even performed in different locations.[84] Moreover, medicine is expected to develop a response to more and more complex medical problems (co-morbidities, evolution of diseases etc.),[12]rendering the detection and isolation of the causal factors of a problem more difficult.

The rapid evolution of technologies[85] to assist provision of care imposes a constant reshuffling of the procedures and human-machine interactions and uses ever more varied and varying technological means in its response. Individual staff involved in the medical management of a patient are submitted to constant pressure of using the latest technologies aiming at improving the care provided, which limit the possibilities to develop automatisms gained by experience.

Therefore, a simple transfer of practices or formulae from one organisation or commercial/industrial sector to another may not be suitable even though the pattern or the processes leading to an accident are essentially the same.[86,75]

D. A Non-Incentive Environment

Healthcare systems and services are costly and under constant pressure to increase the productivity of the diverse services (staff reduction per service, payment per act…).

The risk of litigation associated with the disclosure or the discovery of an error is a strong disincentive at individual and institution levels. Unlike the airline and nuclear industries which are under a regimen of strict liability, where the company, not the individual worker, is

responsible for the potential damages in a lot of countries, the medical staff can be considered as guilty of any mistake done in the medical treatment. Even if there is a differentiation between private practice and practice done in public institution (for the latter the medical institution will be the one accountable). In some countries, there are also special funds for medical hazard (Sweden, France, New Zealand), the fear of long and painful legal procedures remains important and maintains expensive malpractice insurance policies.

Despite this general environment, a multitude of research initiatives on error in healthcare appeared after the shock created by the publication of the IOM report, To Err is Human. Scientific medical publications quickly adapted to this new area of research.[xxii] Medical error is now better understood,[10] is recognized as an important cause of harm (third cause of death in the United States[11]), and strategies, policies and tools are developed at medical-institution and healthcare-system levels to minimize the risks of error and to manage the occurring cases.[12]

An alignment of pressures, both external (from society) and internal (within healthcare systems), has allowed the development of patient safety policies at institutional and national levels:[87] adoption of a legal framework; development of national policies with accreditation bodies using patient safety as one of their main criteria; public opinion and media pressures; educational strategies; and voluntary patient safety policies developed inside medical institutions.

[xxii] In PubMed, the research key "patient safety" for publications in the 60s gives 38 items, 2,452 for the 80s, 10,310 for the 90s, 35,677 for the 00s and 54,071 for the 10s (up to end June 2016)

2.2 Patient Safety as an Attribute of Healthcare Systems

Although it is in hospital care that safety risks are mostly documented, structured and evaluated, patient safety is now an integral part of overall healthcare system concerns and responsibilities.

The concept of patient safety itself has evolved with time, depending on the chosen focus and the evolution of its integration into healthcare design. From a state of "absence of injury",[5] it has progressively expanded to a process: "The avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of healthcare"[88], a frequently used definition of patient safety. It is now considered an attribute of healthcare systems or institutions.[13]

This is intrinsically linked to the concept of quality of care of which it is an important subset (other aspects are hospitality, catering etc., services peripheral to the care itself[89]).

The United Kingdom's NHS, for instance, has integrated patient safety into the definition of quality of care: "The quality of the [health] services is measured by looking at patient safety, the effectiveness of treatments that patients receive, and patient feedback about the care provided."[90]

In the United States, the Institute of Medicine identifies six dimensions of healthcare quality: healthcare must be safe, effective, patient-centred, timely, efficient and equitable.[91]

The responsibility of the state[92] and the level of demand in terms of quality and therefore patient safety are built into policies and strategies affecting healthcare provision at system, institution and individual levels and are so many conditions to delivering healthcare (HAS certification in France).[93]

2.3 Ingredients of Patient Safety

As already touched upon in the previous chapters, patient safety represents a global change of thinking for some aspects of care delivery. In this chapter, we shall discuss the various elements allowing a full and optimal development of patient safety for the benefit of the

overall quality of healthcare, the satisfaction of the care deliverer and the patients benefiting from care services, while contributing to an overall response of efficient healthcare delivery.

Patient safety is developed and implemented at three levels. It is applied, at the micro-level, by individuals/teams who are sensitized, trained and aware of their responsibilities. It is facilitated and supported through strategies developed by institutions, the meso level. And it is framed, at macro-level, by states' laws and policies integrating the expectations, priorities and representations of society.[94]

Although totally interconnected and interdependent, these three distinct levels of responsibilities, development and ingredients will be discussed separately.

2.3.1 At the Systemic Level

A. General and Legal Environment

Laws and regulations have an influence (incentives and disincentives) on the reduction of medical errors and the improvement of safety by framing patient safety obligations[95] of medical staff and institutions and by determining legal and regulatory management of occurring cases.[96]

They first clarify generally the responsibilities of healthcare systems and institutions toward society, notably taking into account demands in terms of risk management[97] and the nature of contractual links existing between the patient and the consulted medical professional and institution (obligation of means not of results,[98] implying the respect of certain conditions)[99.] They also allow identification of who must pay for patient safety and the consequences of an error, a thorny problem.[100]

To concretely assist staff to meet ethical requirements of patients' right to information regarding what happened to them, legislation can promote the disclosure[101] of errors: In some contexts,[102] (U.S.A.,[xxiii] U.K., Australia, Scandinavian countries) "apology or sorry laws" provide

[xxiii] For instance, in the U.S.A., 36 states have such laws. See www.sorryworks.net/apology-laws-cms-143 Accessed on July 2, 2016

some sort of protection to the medical staff so that apologies expressed cannot be used as proofs of malpractice in a court case.[103]

There are still many bridges needed between medical and legal professionals to agree on the legal and regulatory environment providing a fairer and optimal balance between, on the one hand, the search for responsibility and compensation mechanisms and, on the other, the search for measures to favour patient safety and prevention of error.[104]

By allowing the anonymity of error reporting, as in Australia, regulations may assist in increasing the number of reported cases.[105]

In the same vein of creating a favourable environment for working on reported errors, the determination of responsibility for compensation for alleged harm may have at least carry moral weight in influencing medical staff and medical institutions to set up a proper error reporting system.[106] (New Zealand has adopted a no-fault compensation system to manage complaints of patients of suspected malpractice. While it has affected the number of court cases, there is no tangible evidence that it assists in improving overall patient safety.)[107]

Other alternative and complementary systems of conflict resolution to litigation procedures, like mediation,[108] can reduce safety-related costs for health systems in terms of liability costs such as excessive precautions (defensive medicine)[109] and, therefore, may indirectly incentivize reporting of errors.

B. Determination of Rules and Overall Objectives

The state body in charge of the regulation of healthcare systems determines the requirements imposed on health professionals and institutions to be accredited and certified. By developing recommendations and evaluation of health services in terms of quality, the authorities can develop general and national plans of action in the area of patient safety as well as tools and guidelines to assist medical institutions and professionals to actively implement measures for patient safety.

As safety is a moving target[12] owing to the constant evolution of technology and environment and to the difficulty of maintaining efforts underway, including the sensitization of the entire staff (project fatigue), safety programs and projects must constantly be updated and reframed. In healthcare institutions that have not developed maturity concerning the preparation and implementation of safety culture,[64] an overall and centralised vision assists in selecting the priorities in project development around patient safety.

It is mainly at the overall level that the cost of medical errors is perceptible. Working from claims data for 2008 in the U.S.A., the American Society of Actuaries estimated the cost of medical errors to be $19.5 billion ($17 billion for direct cost of care, drugs and hospitalization; $1.4 billion following deaths due to medical errors, and $1.1 billion from losses in productivity of affected patients).[13]

C. Interconnection among Elements of the System

By having an overall understanding of trends, strengths and weaknesses of the healthcare system and its components, the national authorities in charge have the capacity to nurture the links between the elements of the system, notably to influence universities and schools to develop the necessary training of individual medical staff to the concern, methods and management of patient safety[8] and to influence the perception of society on its relation to healthcare expectations and limits[9] while promoting actions,[110]

The sensitization and training regarding professional staff on safety matters as on human and systemic contributing factors to errors are conditions allowing them to actively contribute to safety efforts.[8] Despite an increase in training methods (individual or team training) and curricula (computer-based[111] or in situ[112] simulation…) and in documented evidence of the effect of training,[113] there still seems to be much progress to be made: full integration of patient safety matters into medical students' training curricula[114] through provision of enough time and space for it.[115]

2.3.2 At individual Level

It is at the individual level that health staff contribute to medical errors in as much as they are key to detecting, analysing and reacting to those committed. Their active participation is a requisite for the success of any patient safety efforts.

A. Understanding of Human Nature and Humans' Error-Prone Activity

The active involvement of management staff supposes their belief in the human nature of their thus error-prone work. Through training and/or campaigns of sensitisation, medical staff and other professionals involved in the care system must be made to understand the nature of the problem, its magnitude as well as be convinced of their necessary collaboration in minimizing the risks and manage its consequences.

B. Convinced Regarding the Non-Blame Culture

Beyond the fear of sanctions coming from the hierarchy, staff involved in a medical error express their fear of sanctions from their peers.[116] Proper policies, but also demonstration that the medical institution is committed to managing reported errors in a non-judgmental manner, are requisites for staff support of a collective investment in patient safety.

C. Sensitized Regarding the Possibility of Learning from Error

To have the staff willing to report errors and/or to detect points of vulnerability in healthcare procedures, they must be convinced that such reporting will not only assist in managing cases in the best interests of the patients, the institution and its staff, but also that it will effectively assist learning important lessons that could be useful in other services or circumstances.[117]

D. Encouraged/Trained to Team Discussion and Work on Errors

Studies have demonstrated that communication (or absence thereof) among involved staff is among the main factors in coming to terms with errors.[118]

As mentioned earlier, the management of patients involves ever more medical specialisation. For hospitalized patients, teamwork is the basis of care management.

Attention to medical error detection and management implies coordination and communication between specialists and team members.[119]

2.3.3 At the Institution Level

Researchers still insist on the need to support the staff (with training as much as with psychological support)120 and to develop patient-centred care[121] through an effective organisational culture avoiding "tribalism and lack of engagement".[122]

As central fixtures in healthcare provision, medical institutions are the link between individual and healthcare system levels, the enablers of patient safety as much as the actors at the crossroads of conflicting imperatives: the quality of care provided and the search for efficiency.

It is at this level that the most mentioned, but the most blurred, characteristic of patient safety is developed: safety culture. This concept is abundantly touched upon in the literature and can be defined as "the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management".[123] Safety culture implies a comprehensive investment in the goal of safety: it is less an individual characteristic than a collective one of the health institution at management as well as at unit levels.[124] Safety culture is implemented within healthcare institutions in mechanisms of reporting and analysis of errors and near miss events, a diminution of the blame culture, a real openness to system latencies etc.[125]

A. No Blame but Just Culture

The direct link between the harmed patient and the medical professionals who oversee his/her medical management creates a sense of guilt and shame that leads to suffering also for the involved staff. They may adopt a defensive approach leading to hiding the facts.[126]

As illustrated by high reliability organisation theorists,[65] working on safety in a complex organisation means the creation of a safe environment for the staff.[127] The latter not only must be able to report cases without fear of blame but must be actively encouraged to do so.

Such a safe environment is an essential ingredient of what researchers consider a requisite for the organisation to act in favour of safe healthcare. From a traditional "blame-shame" culture by which actors of a medical error may be sanctioned for what is considered their weakness

or a “name-blame-train” culture considering that the actors in healthcare must be retaught what proper attitudes are or action to take, institutions have the responsibility to create a climate within which individual staff and managers absorb system thinking enabling learning from errors. A badly perceived effort in patient safety has two combining effects on error reporting and analysis: a persistent fear to speak to colleagues, a fortiori to patients, of problems occurring in the medical management of the patients,[128] and suspicion that the search for systemic causes to problems means disempowerment.[129] It eventually sparks controversies regarding who is responsible[130] while in fact it should allow a necessary clarification of the accountability of both organisations (systems) and individuals. Improved coordination has to be imagined[131] involving all actors: “when many are in charge, no one is”.[132]

Safety culture must remain a “just culture”, a concept responding to the necessity to also consider acts of recklessness for which punishment must be conceived.[133]

That an entire sector starts to speak of its error, while used to profiling its excellence, is a real paradigm shift.[134]

B. Error Detection System (Detection, Analysis, Feedback)

Applying lessons learned from safety science, medical institutions developed systems of detection and analysis of medical errors; policies and tools of prevention; and assistance mechanisms for the management of the error consequences.

The documentation of errors is developed through different data collection methodologies,[135] all having advantages and limits, such as voluntary reporting (needing a real commitment from the staff in reporting cases), direct observation of clinical procedures (resource demanding), mortality-morbidity conferences (requiring clear and comprehensive patient files and a clear case definition),[136] trigger tools[137] (less labour-intensive but with hindsight bias risk).[138] Eventually, other sources of data are used to complement these methods: informal and formal patient complaints and medico-legal claims of patients or relatives[139] as well as questionnaires

sent to clinical practitioners.[140] Often medical institutions use a combination of these methods to get the most complete view of reality.[141]

Inspired by Reason's research on human error, root causes analytical grids are developed looking at contributing factors.[142] Extended to apply also to system errors,[143], more comprehensive grids clarify the various contributory factors, such as clusters of root causes (e.g., London Protocol[144] promoted by HAS in France;[145] Yorkshire contributory factors framework[118], used mainly for training purposes).

The root cause analysis requires time and some experience.[146] Depending on the priorities and policies of the medical institution, its use is limited to the most serious error cases, often named "sentinel events" (cases having a dramatic consequence for the patient and which trigger an immediate investigation[147]).

The more medical errors and" near-misses" reported, the more there is a need to apply a method to determine where to invest energy in a complete root cause analysis and in the development of corrective or preventative measures:[148] classification methods assist in the determination of points of vulnerability or failure in the care process to decide where corrective/preventive actions are needed.[149] A scoring system[150] can be applied to the reported errors or the risks assessed independently of error occurrences.[151] Interdisciplinary meetings involving the different decision-making layers of the institution can select its priorities to develop action plans.[152]

Various methods are then promoted to develop action plans maximizing the chance of implementing successful and sustainable improvements in care processes and material used.[153]

The choice of wording to name the sort of incident to be reported is important and subject to debate.[154] Behind the search for the most relevant or precise terms, the choice of concepts is frequently guided by the purpose sought by its user.[155] It is not anecdotal, for at least 3 reasons.

First, for the scope of what is reported: literature on safety and many authors on patient safety use mainly the term “error” referring to the sole human nature of the cause of the problem that has had or could have had negative consequences on the health of the patient.[89]An error is “a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome”.[156] As specified in the IOM report To err is Human, only a fraction of adverse events is caused by human error.[5] The choice of terms and their definition can mean the underreporting of cases as sources of learning.[157]The extension of reflection on accident causation to beyond the human factor, to embrace system failures in the scope of what must be addressed, introduces a more inclusive term: incident. Eventually to limit the scope of data collection, the concept of “adverse event” is chosen: "an undesired patient outcome that may or may not be the result of an error”.[158]

A second reason to be careful in the choice of wording is negative connotations associated with terms: “error” carries the notion of guilt[159] and may contribute to limiting the neutrality of the event’s analysis and increasing the reluctance to report cases. Finally, the choice of terms and associated definitions, if too narrow, can facilitate or hinder the comparison of collected safety data shared among medical institutions.[160] It also has an important effect on the classification of reported incidents used to determine priorities in the development of corrective actions.[161]

Concerted efforts led by the WHO[162] brought some standardization of terms, but it nevertheless does not prevent varied interpretations.

C. Support of the Involved Staff

The buy-in of medical staff will be seriously influenced by the way their colleagues, the institution they work for and, more generally, the “system” treat those involved in error reporting[163] (mostly those involved in error commission). Participating in such an event can be profoundly distressing and also has consequences for future professional capacities. The recognition of the “second victim” phenomenon[164] (if not third victim when considering the institution itself)[165] and the need to provide a proper support is not yet widely recognized[166] or even taught to medical professionals.[167]

On the same level, the medical staff having to disclose to patients or their relatives the occurrence of a medical error and its consequences need proper training and a clear procedure designed by the institution to limit the harm to both patients and staff.[168]

D. Individual and Organisational Learning

The implementation of a reporting system for errors and near misses may become useful and used if its purpose is clearly stated and shared within the organisation.[169] If not, it risks being perceived as just another administrative burden.[170] With the imperative involvement of staff trained and dedicated to the analysis of reported cases,[171] a proper internal retro-information system on lessons learned and strategies chosen to avoid recurrences[172] must be set up: the documentation of errors must be a reporting AND learning system.[173]

It is an organisational responsibility to implement such a feedback loop.[174] It allows the realisation in due time that recommendations lead to implementation[175]of system improvements, becoming by itself a "winning staff hearts and minds" strategy feeding a virtuous circle of commitment to safety[176] that must be constantly nurtured. The link with universities and research centres provides opportunities to implement patient safety concerns in all the curricula of the training of present and future staff.[177]

The lessons to be taken from error occurrences and analysis imply participation not only of all the front-line staff, such as medical and paramedical specialists that may have different perspectives on the same processes[178], but also of the non-medical staff whose involvement[179] offers eventually a more comprehensive vision of what safety improvements can be implemented and how.[180]

E. Leadership

Facing possibly conflicting imperatives of productivity and patient safety implies that managers of medical institutions demonstrate a genuine commitment by providing clear plans and means to achieve safety, while offering a safe environment to discuss and act on the risk of errors.[181] Interviews with health system leaders can identify the elements necessary for teaching healthcare systems. Beyond the elements presented here, they must insist on the necessity of strong and visionary leadership as an overall structure enabling all the others.[182]

Reports highlight serious improvements in safety of healthcare since the beginning of the 2000s. (From 2010 to 2014, the overall rate of hospital-acquired conditions declined by 17% in the U.S.A. Improvements were observed in about 60% of safety measures monitored by AHRQ.[183]) But many frustrations are emerging regarding what has (not) been achieved so far.[184] While some authors mention the necessity of allowing time for change, citing aviation industry, which needed 30 years to achieve a real reduction in accidents,[185] numerous studies and analyses present reasons for the slow progress.[186]

2.4 Patient Safety: Some Still Problematic Issues

A. The Role of the Patients

The role patients can play in safety improvements in healthcare is still a matter of debate and research in medical circles,[187] despite their undeniable right to be informed of risks and to be full actors in all matter regarding their own health.[188]

Patients' perception of the quality of healthcare they receive, as well as of the human – and therefore error-prone – nature of medical acts, has an influence on the extent to which society trusts[189] the healthcare system and the medical profession.[190]

There exist many possible organised roles for patients, depending on country or medical institution: the constitution of patients' organisations may be favoured by the national government, as in France,[191] where they assist in the development of a fair representation of rights and duties of patients as much as in a real understanding of challenges related to healthcare provision.[192] Programs like the WHO's "Patients for Patients Safety" (PFPS), established in 2005,[193] aim at empowering patients and making them full actors of their health.

Patients' point of view regarding their own experiences is also a good indicator of the quality and safety of healthcare as it is not limited by professional and organisational boundaries.[194] Patients reported that experience surveys can deliver an interesting picture of the safety of the medical institution[195] and be a source of information on errors that might not have been detected by the medical professionals,[196], especially on preventable medical errors.[197]

Therefore, beyond moral considerations, it seems interesting to get patients involved in safety for its multiple potential effects: patient's satisfaction and well-being;[198] their understanding of the risks and limits of medical practice;[199] reputational aspects[200] in addition to value added from safety improvements. Such multi-layered potential has to be willingly and strategically organized.[201]

The quality of communication among patients and medical staff and institutions when a serious incident occurs seems also to have an effect on the willingness of patient to complain through costly judicial processes.[202] If both professionals and patients seem to favour the disclosure of adverse events,[203] this needs a proper environment and minimal training for the involved staff.[204]

B. Measurement Strategies

One of the biggest challenges, when working at safety improvements, is developing the ability to measure safety and safety improvements with the proper tools.[205] Various measurement methods have been developed over the last decades, all having their limits and advantages.[206] Proper evaluations of actions in patient safety tend to show patchy results[207] requiring investment in adapted measurement methods even if they are based on some level of interpretation.[208] Assessment of safety measurement methods of other industries is again a source of inspiration[209] but cannot be transferred blindly. The complexity of healthcare and care services led a prominent charity in the U.K. to conclude a report by showing directions but no definite answers on how to measure the five main dimensions of safety in healthcare (measures of harm, of reliability of the health structure, of the capacity to monitor safety, of the ability to anticipate problems and be prepared, and of the capacity to integrate and learn from safety information).[210] It remains an open challenge requiring innovation,[211], notably to analyse the cost-benefit of investing in patient safety.[212]

C. Potential Threats to Patient Safety Investments

The financial pressure on health systems and institutions and the related effect on productivity of healthcare staff do not play in favour of attention to the safety aspect of healthcare, despite the indirect costs for society. The efficiency of methods and strategies

adopted to tackle the problem of recurrent errors is also subject to measurement and leads to different appreciations depending on the chosen criteria.[213]

D. Innovation and Safety

Technology, in the form of assistance to diagnosis, monitoring of patients or data processing, as well as related tools, is a promising source of assistance for the front-line medical staff. But much research must still be done to validate the added value and/or real efficacy of implemented new technological tools.[214]

There is something of a paradox in the literature between the expected positive effect of technology on the decrease of human error and the documented evidence of increased complexity and thus the risk of incidents that it induces.[215]

E. Lack of Research

If the optimization of technology use must be considered,[216] present health budgets cannot meet the challenge[217] and will not address the need of research in patient safety.[218]

Moreover, even if quality of care is considered worldwide crucially important,[219] the investment and attention to patient safety differs from country to country.[220] It is still embryonic in the low- and middle-income countries. While it is known that it must be adapted to suit various health system specificities,[221], globalization and the absence of borders for health-related problems require a global and worldwide investment in patient safety.

Most research on patient safety is done in the most developed countries, although there are more and more documented initiatives in poor countries.[222] As culture has an influence on the perception of patient safety as much as relations among team members, more research is necessary to design adapted safety strategies.[223] Training curricula and tools must also be adapted to the different contexts.[224] Some worldwide projects sponsored by the international community are ongoing[225] (e.g. WHO initiatives like the “Clean your hands”[226] campaign or “Surgical Safety Checklist”[227] promotion). In the area of assistance to developing countries, some donors, such as USAID, are engaged in patient safety promotion[228] and calls for action are emerging.[229]

F. Missing Territories

Research and strategies of patient safety are mainly targeting hospital settings. There is still much effort needed in looking at the specificities of other areas of healthcare provision, such as in primary care.[18]

Already mentioned is the minimal documentation on patient safety in emergent and developing countries. There is another area of medical practice which seems totally unexplored: medical humanitarian action. Frequently deployed in poor countries by organisations coming from OECD countries, medical humanitarian action has specific characteristics that must be explored to explain this exception and envisage an adapted safety strategy.

Patient safety is now, in OECD countries at least, part of the normal concerns of patients, medical and paramedical practitioners as it is of healthcare institutions and systems. If there is still considerable resistance and discussions on its costs and on the ways to improve current practices, it is more how to achieve safety which is questioned than the very fact that better safety is needed.

The movement toward patient safety of the last two decades, which complements continuous improvements of healthcare in the last centuries, will remain an endless battle owing to the evolution of medicine and the human nature of its practice. The last push related to the input of risk management science was started by the recognition of numerous errors made. It is facilitated by the stability of the work conditions of medical staff: the organisation of care, the constitution of medical teams and the regulations organizing the management of patients is “secured”. With those conditions in place, the individual medical and management staff are invited to accept the fallibility of their actions and to revisit them; to detect what may have gone wrong at individual and team levels; and to learn through the establishment of new recommendations for improvement. Patient safety is built on two interlinked investments: the tools and design to work on error management and prevention, and the culture of safety

allowing all components of care management (medical and management staff) to bypass the question of responsibility and work on corrective measures.

Annex 3: Humanitarian Medical Action and Patient Safety

Definition of Medical Humanitarian Action and Links with Patient Safety

A tentative definition of humanitarian medicine or humanitarian medical action could be "the medical activities, allying clinical and public health medicine, practised in situations of humanitarian crisis.[230] It is done selflessly[19] with the sole intent to apply the right of access to healthcare for patients who would otherwise not access it."[231]

While the label "humanitarian action" is frequently associated with any initiatives aiming at providing help to needy people, in the frame of this research, we focus on medical humanitarian action developed by permanent and structured humanitarian actors (NGOs, international organisations) implementing medical care themselves in keeping with the above definition.

Compared to medicine developed in national healthcare systems, humanitarian medical action has two major differences: It is carried out frequently in highly precarious situations, and it is often implemented in parallel to the existing healthcare system offering services for only a part of the population (the one having geographical, financial and authorized access). It is implemented by actors whose sole interest is to alleviate suffering and to restore the dignity of victims of human or natural disasters or of people who cannot access the existing healthcare services.

Humanitarian action is foremost a struggle to overcome all obstacles to the delivery of aid responding to unattended needs. The aid provided often, therefore, remains a compromise between what should and what could be done.[232]

But patient safety, as conceived and developed in OECD countries' healthcare systems, has not yet "crystallised" as an area of documented initiatives for medical humanitarian actors. There is, for instance, very limited documentation of experiences, practices or questions related to patient safety in humanitarian contexts. A literature review done on PubMed and

Embase gives links to only one article addressing directly reporting of medical errors and their management.[22] Other articles mainly mention the need of more investment in safety and quality.

Some explanations of this limited focus on patient safety are related to the specificities of this form of medical practice.

Characteristics of Medical Humanitarian Action

We can distinguish a series of characteristics specific to this sort of medical response to patients' needs: the philosophy of humanitarian action, the contexts of medical humanitarian interventions and the characteristics of the medical humanitarian actors themselves.

A. The Philosophy of Medical Humanitarian Action

Medical humanitarian action embodies the values of solidarity and humanity by being developed in those countries whose health systems fail their populations, and by providing vital services in circumstances generally associated with catastrophic situations: war, natural disaster or massive epidemics like Ebola or cholera. It evokes an image of heroism[233] and urgent response in precarious situations. It refers first to the intention behind the action and remains open to what it is in terms of activities and how they are developed.

But goodwill is not enough to implement good intentions. Past experiences have shown the limits of the action itself and of those of the quality of what is offered to beneficiaries of medical assistance, as in Haiti after the 2010 earthquake, when only 10% of the humanitarian surgical teams deployed were considered competent and prepared to face the needs.[234] Evaluations of responses to major crises of the 1990s and 2000s regularly pointed the finger at the weaknesses of humanitarian action.[235] This has generated an important investment in research of improved quality of action,[236] notably professionalization of staff,[237] development of tools, guidelines,[238] specific training[xxiv] and creation of joint platforms to analyse and share

[xxiv] Ex. Master in Humanitarian Aid to CERAH Genève http: //www.cerahgeneve.ch/formations.html (accessed 06.06.2014); Master in Humanitarian Assistance of the Tuft University (USA): http: // fic .tufts.edu / education /

experiences and lessons learned. [xxv]

Improvement of humanitarian action, in terms of effectiveness, accountability and quality is a core theme of reflection for aid organisations. For instance, the medical humanitarian organisation Médecins Sans Frontières considers that "its primary responsibility is to improve the quality, relevance and extent of [its] own assistance… Obtaining quality clinical results while maintaining respect for the patient must be the major criteria used to evaluate the progress of our medical practice…"[239]

When facing substantial unaddressed medical needs and knowing that the care offered by their organisation is the sole option for the patients, humanitarian actors may decide what is acceptable in terms of quality of care in a debatable way.[240] This leads, if not well managed, to a risk of some sort of "charity mentality" through which "good intentions directed towards disadvantaged populations can lead to the misconception that in resource-poor environments, any healthcare is good healthcare, regardless of the quality of services".[241]

B. The Nature of Medical Humanitarian Action

Unaddressed health needs can be found everywhere and be of all sorts. Looking only at the direct provision of medical care by humanitarian organisation staff, medical action is multiform, and consists of a range of medical situations ranging from emergencies to the support to a health system; from long-term projects to tackle the spread of one specific disease to providing medical assistance for a neglected population within a totally stable context.

In a crisis endured by a population, the medical needs responded to are selected by the aid organisation in accordance with their own criteria. The addressed needs can be acute for an important group of population, or not. There is no clarity, either in the literature or in practice on when the action should start and when it should end. The means deployed to tackle the

maha / (accessed 06.06.2014), the NOHA Network of the European Union http://www.nohanet.org/en/ (accessed on 06/06/2014) or Master organized by Deakin

[xxv] Ex. Creation of ALNAP in 1997 (Active Learning Network for Accountability and Performance in Humanitarian Action) http://www.alnap.org/about/french Accessed on May 23, 2016.

selected objectives are left to the discretion of the aid organisation and are the result of a conscious choice determined by organisation's criteria and the limits imposed by the context. Medical aid, by essence, is a political act: the refusal of the fate of absence of access to healthcare. It is therefore frequently implemented in more or less frontal opposition to, or in rivalry with, local actors and authorities.

C. Contexts of Intervention

Medical humanitarian projects are developed in contexts where the local capacities of healthcare service provision, as other public services, are, at least momentarily, disrupted by events (natural disaster, conflict, societal tensions…) or where society or its rulers exclude some of its members from access to healthcare. These projects are implemented in addition, or as a substitute, to care services provided locally, either in parallel to the healthcare system services or integrated into them with a significant level of autonomy of decision-making regarding the sort of services and how they will be offered.

Frequently, but not always, as demonstrated by humanitarian action for migrants in Europe, the contexts of action are characterised by insecurity and social and political instability.

If medical aid actors must be registered and recognized by local authorities and must abide to the local laws and regulations, notably in terms of quality of care, the clarity of those regulations, as well as that of the mechanisms to implement them, may be limited and differ from one context to another. The events at the origin of the humanitarian action may have disrupted the capacity to ensure standards of care considered locally acceptable.

The vulnerability of the patients coupled eventually with the absence of knowledge of patients' rights owing to the absence of a culture of counter-power, limits the existence of external incentive for the optimisation of the quality of care.

D. Means of Action

The precariousness of the working environment arising from logistical constraints, the limited available and qualified staff, added to the absence of reference possibilities for complex cases, are as many factors explaining the need to constantly push the limits of what can be done to respond to acute needs with limited and therefore less than ideal means.[242]

The volatility of contexts of intervention eventually imposes frequent adaptation of the project focus (shift of priority for organisations aiming at responding to the "most urgent" needs of the "most vulnerable"), design (according to access to resources and means) and duration (having an effect on what can be achieved and which services to offer).

The cultural differences also effect the possibility of approaching every situation in the same way[243] for the delivery of care and the determination of the desired quality of relationship between the medical aid actor and the community.[244]

These specific characteristics of medical humanitarian action impose a constant need to adapt the action and develop innovative solutions to respond in a responsible manner to the needs it wants to address. This is a challenge for which at least some actors recognize that a lot is still to be done: "There is no doubt that we have ignored or failed in various medical issues over time, including a lack of attention to the information given to patients, to consideration of their concerns and choices, to the management of pain, and to the prescription of the most appropriate medicines. We must question our acceptance of this status quo and try to address what we are neglecting today."[245]

While the search for "zero fault" can become a major obstacle to the risk-taking inherent in crisis settings, the quality of action and the preparation to act according to acceptable standards of care are more and more questioned.

E. Nature of Actors

The humanitarian sector, by and large, is not structured and regulated. Each organisation operates and defines its own mandate independently, with no overarching governing body evaluating what is done and no common set of rules. In the quasi-absence of governance and any institutionalized professional body within the humanitarian sector,[246] efforts in search of improvements are made on a voluntary basis. The applied norms are very often only non-binding principles, standards and recommendations. Certification mechanisms[xxvi] that could

[xxvi] Like the services of a newly created entity HQAI (for Humanitarian Quality Assurance Initiative) created in 2015. See https://hqai.org/ Accessed on November 19, 2019

ensure a minimum of compliance with rules based on "soft law" are not yet sufficiently recognized as legitimate and credible. The process itself remains highly controversial.[247]

The conditions of work, as well as the limits to locally available and mobilized resources, create a unique set of features difficult to cope with for the medical personnel:[248] stress, long working hours and days, limited available technology, small number of staff of various medical culture origins etc. While these difficulties are often experienced with a positive outlook,[249] they are also a source of moral distress[250] for staff not provided with the necessary capabilities and support.[251] There is a high turnover of personnel in such organisations,[252,] affecting in turn the capacity to sustain the quality of services.

From this quick panorama, some lessons and consequences in terms of patient safety can be drawn.

First, humanitarian actors are frequently left with the responsibility of determining what is good, notably in terms of quality of care, without other references than the ones they choose.[253] This implies also a great responsibility on the part of the organisations regarding the means deployed to reach an acceptable level of quality of care.

Second, the care provided in such contexts is often constrained by other elements than what medical ethics guidance traditionally responds to: conflicts with the local authorities and/or communities on the action, its intentions and the way it is implemented or additional constraints like insecurity, scarcity of resources, total disorganisation of state functions…[254]

Third, the diversity of the local health capacities and expectations in terms of standards of care reinforces the difficulty for aid organisation to have standardized approaches and policies[255]for all contexts of action. There cannot be a “one size fits all” solution, and a blind copying of strategies and practices implemented in OECD healthcare system may not be appropriate.

The present lack of ownership of patient safety by the medical aid sector seems therefore to be related to at least three factors: the specificities of medical humanitarian action, the absence of motivational factors coming from the external environment (media or patient

pressure, applied regulatory frame of medical practice…) and the lack of proper research on which lessons learned from policies and practices of patient safety adopted in developed countries' healthcare systems could be adopted or adapted to its specific work environment.

Annex 4: Glossary

Terme(term)	original definition	Translation in French
Accident (Accident) Utilisé surtout en Australie. A tendance à être abandonné	Action ou situation où le risque se réalise et est, ou pourrait être, à l'origine de conséquences sur l'état de santé ou le bien-être de l'usager, du personnel, d'un professionnel concerné ou des tiers (CHUM) An event that involves damage to a defined system that disrupts the ongoing or future output of the system[5] An unintentional and/or unexpected event or occurrence that may result in injury or death.[256] An unplanned, unexpected, and undesired event, usually with an adverse consequence.[257]	• Un événement qui implique des dommages à un système défini qui perturbe la production en cours ou future du système • Un événement non intentionnel et / ou inattendu, ou une occurrence qui peut entraîner des blessures ou la mort • Un événement imprévu, inattendu et indésirable, généralement avec une conséquence négative.

Accident médical (Medical Mishap)	An actual or potential serious lapse in the standard of care provided to a patient or patients or harm caused to a patient or patients through the performance of a health service and/or healthcare professionals working within it. (WHO)	• Une faute grave réelle ou potentielle dans le standard des soins prodigués à un patient ou des patients ou des dommages causés à un patient ou des patients à la suite de la prestation d'un service de santé et / ou de professionnels de santé travaillant en son sein
Action humanitaire/ Assistance humanitaire (Humanitarian action/Humanitarian assistance	Assistance, protection and advocacy actions undertaken on an impartial basis in response to human needs resulting from complex political emergencies and natural hazards.[258] Saving lives, alleviating suffering and maintaining human dignity during and in the aftermath of crises.[259] The objectives of humanitarian action are to save lives, alleviate suffering and maintain human dignity during and in the aftermath of man-made crises and natural disasters, as well as to prevent and strengthen preparedness for the occurrence of such situations. Humanitarian action should be guided by the	• Assistance, protection et plaidoyer mis en œuvre de manière impartiale en réponse aux besoins humains résultant de situations d'urgence politiques complexes et de catastrophes naturelles. • Sauver des vies, soulager la souffrance et le maintien de la dignité humaine pendant et à la suite de crises. • Les objectifs de l'action humanitaire sont de sauver des vies, soulager les souffrances et de préserver la dignité humaine pendant et après des crises créées par l'homme et les catastrophes naturelles, ainsi que de prévenir et de renforcer la préparation à la survenue de ces situations.

	humanitarian principles of humanity, meaning the centrality of saving human lives and alleviating suffering wherever it is found; impartiality, meaning the implementation of actions solely on the basis of need, without discrimination between or within affected populations; neutrality, meaning that humanitarian action must not favour any side in an armed conflict or other dispute where such action is carried out; and independence, meaning the autonomy of humanitarian objectives from the political, economic, military or other objectives that any actor may hold with regard to areas where humanitarian action is being implemented. Humanitarian action includes the protection of civilians and those no longer taking part in hostilities, and the provision of food, water and sanitation, shelter, health services and other items of assistance, undertaken for the benefit of affected people and to facilitate the return to normal lives and livelihoods.[260]	L'action humanitaire doit être guidée par les principes humanitaires d'humanité, ce qui signifie la centralité de sauver des vies humaines et de soulager la souffrance partout où elle se trouve; l'impartialité, ce qui signifie la mise en œuvre des actions uniquement sur la base des besoins, sans discrimination entre ou au sein des populations touchées; la neutralité, ce qui signifie que l'action humanitaire ne doit favoriser aucune partie à un conflit armé ou autre conflit où une telle action est effectuée; et l'indépendance, ce qui signifie l'autonomie des objectifs humanitaires des objectifs politiques, économiques, militaires ou autres qu'un acteur pourrait avoir dans les zones où l'action humanitaire est mise en œuvre. L'action humanitaire englobe la protection des civils et qui ne prennent plus part aux hostilités, et la fourniture de nourriture, d'eau et d'assainissement, des abris, des services de santé et d'autres biens d'assistance, entrepris pour le bénéfice de personnes affectées et de faciliter

	Humanitarian assistance is aid to an affected population that seeks, as its primary purpose, to save lives and alleviate suffering of a crisis-affected population. Humanitarian assistance must be provided in accordance with the basic humanitarian principles of humanity, impartiality and neutrality.[261]	leur retour à la vie normale et aux moyens de subsistance. • L'aide humanitaire est une aide à une population touchée qui vise, comme objectif principal, à sauver des vies et alléger les souffrances d'une population touchée par la crise. L'aide humanitaire doit être fournie conformément aux principes humanitaires fondamentaux d'humanité, d'impartialité et de neutralité.
Culture juste (Just culture)	A just culture reconciles professional accountability and the need to create a safe environment to report medication errors; seeks to balance the need to learn from mistakes and the need to take disciplinary action.[133]	• Une culture juste réconcilie la responsabilité professionnelle et la nécessité de créer un environnement sûr pour signaler les erreurs de médication ; cherche à équilibrer la nécessité d'apprendre de ses erreurs et la nécessité de prendre des mesures disciplinaires

	The phrase “just culture” was popularized in the patient safety lexicon by a report (Marx D.) that outlined principles for achieving a culture in which frontline personnel feel comfortable disclosing errors—including their own—while maintaining professional accountability. In summary, a just culture recognizes that competent professionals make mistakes and acknowledges that even competent professionals will develop unhealthy norms (shortcuts, “routine rule violations”), but has zero tolerance for reckless behaviour. (AHRQ)	• L'expression « culture juste » a été popularisée dans le lexique de la sécurité des patients par un rapport (Marx D.) qui établit les principes d'atteindre une culture dans laquelle le personnel de première ligne se sente confortable de divulguer les erreurs, y compris les-leurs-tout en conservant la responsabilité professionnelle. En résumé, une culture juste reconnaît que les professionnels compétents font des erreurs et reconnaît que même les professionnels compétents peuvent développer des actions malsaines (raccourcis, "des violations des règles de routine"), mais a une tolérance zéro pour comportement imprudent.
	A culture in which frontline personnel are comfortable disclosing errors, including their own, while maintaining professional accountability, recognizing individual practitioners should not be held accountable for system failings over which they have no control, yet does not tolerate conscious disregard of clear risks to patients or gross misconduct.[262]	• Une culture dans laquelle le personnel de première ligne se sentent à l’aise de divulguer les erreurs, y compris les-leurs, tout en conservant la responsabilité professionnelle, reconnaissant que des praticiens individuels ne doivent pas être tenus pour responsables des défaillances du système sur lesquels ils n’ont pas de contrôle,

		mais ne tolère pas le mépris conscient des risques évidents pour les patients ou les fautes graves.
Culture de la Sécurité (Safety Culture)	La culture de sécurité des soins est une production collective. Elle désigne les valeurs et les croyances communes à un groupe en matière de sécurité, et qui constituent un cadre commun aux comportements (HAS) An integrated pattern of individual and organizational behaviour, based upon shared beliefs and values, that continuously seeks to minimize patient harm which may result from the processes of care delivery. (Aspden, CoE) [A culture that exhibits the following] five high-level attributes that [healthcare professionals] strive to operationalize through the implementation of strong safety management systems. (1) A culture where all workers (including front-line staff, physicians, and	• Un modèle intégré du comportement individuel et organisationnel, basé sur des croyances et des valeurs partagées, qui cherche constamment à minimiser les dommages au patient qui peuvent résulter de processus de prestation de soins. • [Une culture qui présente ce qui suit] cinq attributs de haut niveau que [les professionnels de soins de santé] visent à opérationnaliser à travers la mise en œuvre de systèmes de gestion de la sécurité fortes. (1) Une culture où tous les

	administrators) accept responsibility or the safety of themselves, their co-workers, patients, and visitors. (2) [A culture that] prioritizes safety above financial and operational goals. (3) [A culture that] encourages and rewards the identification, communication, and resolution of safety issues. (4) [A culture that] provides for organizational learning from accidents. (5) [A culture that] provides appropriate resources, structure, and accountability to maintain effective safety systems. (Forum of End Stage Renal Disease Networks)	travailleurs (y compris le personnel de première ligne, les médecins et les administrateurs) acceptent la responsabilité ou la sécurité d'eux-mêmes, de leurs collègues, des patients et des visiteurs. (2) [Une culture qui] priorise la sécurité au-dessus des objectifs financiers et opérationnels. (3) [Une culture qui] encourage et récompense l'identification, la communication et la résolution des problèmes de sécurité. (4) [Une culture qui] prévoit l'apprentissage organisationnel d'accidents. (5) [Une culture qui] fournit des ressources appropriées, la structure, et la responsabilité de maintenir des systèmes de sécurité efficaces.
	The safety culture of an organization is the product of individual and group values, attitudes, perceptions competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization's health and safety management. [263]	• La culture de la sécurité d'une organisation de la sécurité est le produit des valeurs individuelles et collectives, des attitudes, des perceptions, des compétences et des modes de comportement qui déterminent l'engagement, et le style et la compétence de gestion de la santé et de la sécurité d'une organisation.

	Organizations with effective safety cultures share a constant commitment to safety as a top-level priority, which permeates the entire organization. Noted components include (1) acknowledgment of the high-risk, error-prone nature of an organization's activities, (2) a blame-free environment where individuals are able to report errors or close calls without punishment, (3) an expectation of collaboration across ranks to seek solutions to vulnerabilities, and (4) a willingness on the part of the organization to direct resources to address safety concerns.[264]	• Les organisations avec des cultures de sécurité efficaces partagent un engagement constant de la sécurité comme une priorité de haut niveau, qui imprègne l'ensemble de l'organisation. Cela implique notamment les composants suivants (1) la reconnaissance du risque élevé générés par les activités sujettes à erreurs d'une organisation, (2) un environnement sans blâme où les individus sont en mesure de signaler des erreurs ou des échappées belles sans être punis, (3) une attente de collaboration à travers les niveaux pour chercher des solutions aux vulnérabilités, et (4) une volonté de la part de l'organisation pour orienter des ressources pour répondre aux préoccupations de sécurité.
	Culture of Safety: The result of an organizational commitment to safety permeating all levels from frontline personnel to executive management.	• Culture de la Sécurité : Le résultat d'un engagement de l'organisation à la sécurité imprègne tous les niveaux, du personnel de

	Features of a culture of safety include acknowledgment of the high-risk, error prone nature of an organization's activities, a just environment where individuals are able to report errors and near misses without fear of reprimand or punishment, an expectation of collaboration across ranks to seek solutions to vulnerabilities and a willingness on the part of the organization to direct resources for addressing safety concerns. (CPS) Safety culture refers to the beliefs, values and attitudes of patient safety shared by all members of the organisation. These shared values are reflected in the day to day operations of the organization.[265]	première ligne à la haute direction. Les caractéristiques d'une culture de la sécurité comprennent la reconnaissance du risque élevé, les activités par nature sujettes à erreurs d'une organisation, un environnement juste là où les individus sont capables de rapporter des erreurs et des accidents évités de justesse, sans crainte de réprimande ou punition, une attente de la collaboration à travers les niveaux pour chercher des solutions aux vulnérabilités et une volonté de la part de l'organisation de diriger les ressources pour répondre aux préoccupations de sécurité. • La culture de sûreté se réfère à des croyances, des valeurs et des attitudes de la sécurité du patient partagées par tous les membres de l'organisation. Ces valeurs communes sont reflétées dans les opérations quotidiennes de l'organisation.
Défaillance active (Active Failure)	Actions or processes during the provision of direct patient care that fail to achieve their expected aims, for example, errors of omission or commission. While	• Actions ou processus au cours de la prestation de soins directs aux patients qui ne parviennent pas à atteindre leurs objectifs attendus, par

	some active failures may contribute to patient injury, not all do. (Wade, 2002; Davies,2003) (COE) Active failures are sometimes referred to as errors at the sharp end, figuratively referring to a scalpel. In other words, errors at the sharp end are noticed first because they are committed by the person closest to the patient. (AHRQ) An error that is precipitated by the commission of errors and violations. These are difficult to anticipate and have an immediate adverse impact on safety by breaching, bypassing, disabling existing defences. (Khoja)	exemple, les erreurs d'omission ou de commission. Alors que certaines défaillances actives peuvent contribuer à blesser le patient, toutes ne le font pas. • Les défaillances actives sont parfois appelées erreurs à « l'extrême pointe », au sens figuré se référant à un scalpel. En d'autres termes, les erreurs à l'extrême pointe sont remarquées d'abord parce qu'elles sont commises par la personne la plus proche du patient. • Une erreur qui est précipité par la commission d'erreurs et violations. Celles-ci sont difficiles à anticiper et ont un impact négatif immédiat sur la sécurité en violant, en contournant ou en désactivant les défenses existantes.
Dommage ou Maladie Iatrogène (Iatrogenic injury) / ou Nosocomiale (nosocomial injury)	Any undesirable condition in a patient occurring as the result of treatment by a physician (or other health	• Toute condition indésirable survenant chez un patient à la suite d'un traitement par un médecin

	professional) …Pertaining to an illness or injury resulting from a procedure, therapy, or other element of care. (COE)	(ou autre professionnel de la santé) ... relatives à une maladie ou une blessure résultant d'une procédure, de la thérapie, ou d'un autre élément des soins.
	An infection acquired while receiving care or services in the healthcare organization. (Aspden)	• Une infection acquise en recevant des soins ou des services dans l'organisation de soins de santé.
	Injury originating from or caused by a physician (iatros, Greek for "physician"), including unintended or unnecessary harm or suffering arising from any aspect of healthcare management, including problems arising from acts of commission or omission. (Aspden)	• Blessures provenant de ou causées par un médecin (iatros, grec pour « médecin »), y compris des dommages involontaires ou inutiles ou des souffrances résultant de tout aspect de la gestion des soins de santé, y compris les problèmes découlant d'actes de commission ou d'omission.
	Resulting from the professional activities of physicians, or, more broadly, from the activities of health professionals. Originally applied to disorders induced in the patient by autosuggestion based on	• résultant des activités professionnelles des médecins, ou, plus largement, des professionnels de la santé. Initialement appliqué à des troubles

	a physician's examination, manner, or discussion, the term is currently applied to any undesirable condition in a patient occurring as a result of treatment by a physician (or other health professional), especially to infections acquired by the patient during the course of treatment.[266] Pertaining to an illness or injury resulting from a procedure, therapy, or other element of care. (Khoja)	induits chez le patient par l'autosuggestion basée sur l'examen, la manière, ou la discussion d'un médecin, le terme est actuellement appliqué à toute situation indésirable chez un patient survenue à la suite d'un traitement par un médecin (ou un autre professionnel de la santé), en particulier aux infections acquises par le patient au cours du traitement. • Relatif à une maladie ou un dommage résultant d'une procédure, thérapie, ou autre élément des soins.
Erreur (error)	A generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome.[149] The failure of a planned action to be completed as intended or use of a wrong, inappropriate, or incorrect plan to achieve an aim[157]	• Un terme générique pour englober toutes ces occasions dans lesquelles une séquence planifiée d'activités mentales ou physiques ne parvient pas à atteindre son résultat escompté. • L'échec d'une action planifiée à s'achever comme prévu ou l'utilisation d'un plan mauvais, inapproprié ou incorrect pour atteindre un objectif.

	Deviation in a process of care that may or may not cause harm to patients[267]	• Déviation dans un processus de soins qui peut, ou non, causer un préjudice aux patients
	An act of commission or omission that caused, or contributed to the cause of, the unintended injury[268]	• Un acte de commission ou d'omission qui a causé ou contribué à la survenue d'une blessure non intentionnelle.
	L'erreur découle d'une omission ou d'un acte non intentionnel, mais ne relève pas de l'infraction d'une « règle »[269]	
	L'exécution non conforme d'un acte prévu ou l'application d'un plan incorrect, peut se produire lorsque, pendant la planification ou l'exécution, on fait quelque chose alors qu'il ne fallait pas le faire (erreur par commission) ou lorsqu'on ne fait pas quelque chose alors qu'il fallait le faire (erreur par omission)[270]	

	Une erreur a été définie comme étant « une action planifiée qui n'a pas été exécutée comme prévu (à savoir, erreur d'exécution) ou l'utilisation d'un mauvais plan pour atteindre un objectif (à savoir, erreur de planification) ».[147] The failure of a planned action to be completed as intended (i.e., error of execution), and the use of a wrong plan to achieve an aim (i.e., error of planning) (Institute of Medicine, 2000). It also includes failure of an unplanned action that should have been completed (omission).[271] Une erreur est définie comme l'exécution non conforme d'un acte prévu ou de l'application d'un plan non correct" *erreur par commission : quand pendant la planification ou l'exécution d'une action on fait quelque chose qu'il ne fallait pas faire	• L'échec d'une action à se finaliser comme prévu (par exemple, erreur d'exécution), et l'utilisation d'un mauvais plan pour atteindre un but (c.-à-d. erreur de planification) (Institute of Medicine, 2000). Il comprend également l'échec d'une action imprévue qui aurait dû être finalisée (omission).

	* erreur par omission : lorsque l'on ne fait pas quelque chose que l'on aurait dû faire[156]	
Erreur (Mistake)	In some contexts, errors are dichotomized as slips or mistakes, based on the cognitive psychology of task-oriented behaviour. Mistakes reflect failures during attentional behaviours—behaviour that requires conscious thought, analysis, and planning, as in active problem solving. Rather than lapses in concentration (as with slips), mistakes typically involve insufficient knowledge, failure to correctly interpret available information, or application of the wrong cognitive heuristic or rule. (AHRQ) Deficiency or failure in the judgmental and/or inferential processes involved in the selection of an objective or in the specification of the means to	• Dans certains contextes, les erreurs sont divisées en erreurs d'attention ou méprises, selon la psychologie cognitive du comportement attentionnel. Les méprises reflètent des échecs lors de comportements attentionnels-comportement qui exige la pensée, l'analyse et la planification conscientes, comme dans la résolution active de problèmes. Plutôt que de manque de concentration (comme avec les erreurs d'attention), les méprises impliquent généralement des connaissances insuffisantes, une insuffisance d'interprétation correcte des informations disponibles, ou l'application d'une mauvaise règle ou heuristique cognitive. • La carence ou l'échec dans les processus de jugement et / ou déductif impliqués lors de la sélection d'un objectif ou dans la spécification des

	achieve it, irrespective whether or not the actions directed by this decision- scheme run according to plan (Reason, 1990, p.9) ; errors of conscious though including rule based errors that occur during problem solving when a wrong rule is chosen, and knowledge-based errors that arise because of lack of knowledge or misinpretation of the problem (Leape, 1994).[272]	moyens pour y parvenir, indépendamment de savoir si ou non les actions réalisées par ce schéma décisionnel se développent conformément au plan (Reason, 1990 , p.9); erreurs de pensée consciente, y compris des erreurs de règles qui se produisent pendant la résolution de problème quand une règle erronée est choisie, et erreurs basées sur la connaissance qui se posent en raison du manque de connaissances ou de mésinterprétation du problème (Leape,1994).
	A commission or an omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were any negative consequences. This definition excludes the natural history of disease that does not respond to treatment and the foreseeable complications of a correctly performed procedure, as well as cases in which there	• Une commission ou une omission avec potentiellement des conséquences négatives pour le patient qui aurait été jugée mauvaise par des pairs qualifiés et bien informés au moment où elle a eu lieu, indépendamment de savoir s'il y avait des conséquences négatives. Cette définition exclut le développement naturel de la maladie qui ne répond pas au traitement et les complications prévisibles d'une procédure correctement appliquée, ainsi que les cas dans lesquels il y a un

	is a reasonable disagreement over whether a mistake occurred.[273]	désaccord raisonnable quant à savoir si une méprise est survenue.
	An error that occurs when choosing inappropriate goals through conscious deliberation. The actions may conform exactly to the plan, but the plan is inadequate to achieve its indented outcome. (Khoja)	• Une erreur qui se produit lors du choix d'objectifs inappropriés par décision consciente. Les actions peuvent être exactement conformes au plan, mais le plan est inadapté pour atteindre son résultat escompté.
Erreur active (Active Error)	An error that occurs at the level of the frontline operator and whose effects are felt almost immediately (Kohn)	• Une erreur qui se produit au niveau de l'opérateur de première ligne et dont les effets se font sentir presque immédiatement.
	An error associated with the performance of the 'front-line' operator of a complex system and whose effects are felt almost immediately. (Reason, 1990, p.173) (CoE)	• Une erreur associée à la performance de l'opérateur de la 'ligne de front' d'un système complexe et dont les effets se font sentir presque immédiatement. (Reason, 1990, p.173)

Erreur d’attention// Erreur de mémoire (Slip/lapses)	Slips refer to failures of schematic behaviours, or lapses in concentration (e.g., overlooking a step in a routine task due to a lapse in memory, an experienced surgeon nicking an adjacent organ during an operation due to a momentary lapse in concentration) Slips occur in the face of competing sensory or emotional distractions, fatigue, and stress. Reducing the risk of slips requires attention to the designs of protocols, devices, and work environments—using checklists so key steps will not be omitted, reducing fatigue among personnel (or shifting high-risk work away from personnel who have been working extended hours), removing unnecessary variation in the design of key devices, eliminating distractions (e.g., phones) from areas where work requires intense concentration, and other redesign strategies. Slips can be contrasted with mistakes, which are failures that occur in attentional behaviour such as active problem solving. (AHRQ)	• Les erreurs d’attention se réfèrent à des défaillances de comportements schématiques, ou à un manque de concentration (par exemple, omettre une étape dans une tâche de routine en raison d'une défaillance de la mémoire, un chirurgien expérimenté entaille un organe adjacent lors d'une opération en raison d'une défaillance momentanée de la concentration) Les erreurs d’attention se produisent quand confronté à des distractions sensorielles ou émotionnelles concurrentes, à la fatigue et le stress. Réduire les risques d’ erreur d’attention nécessite l'attention sur la conception des protocoles, des équipements et de l’environnement de travail en utilisant des listes de contrôle-donc les étapes clés ne seront pas omises, en réduisant la fatigue chez le personnel (ou en évitant le travail à risque élevé au personnel qui a travaillé de longues heures), en supprimant la variation inutile dans la conception des équipements clés, en éliminant les distractions (par exemple, les téléphones) des zones où le travail exige une concentration intense, et d'autres stratégies de restructuration.

		Les erreurs d'attention peuvent être comparées à des méprises, qui sont les échecs qui se produisent dans le comportement attentionnel tels que la résolution active de problèmes.
	Errors which result from some failure in the execution and/or storage stage of an action sequence, (…) largely involving failures of memory, that do not necessarily manifest themselves in actual behaviour and may be only apparent to the person who experience them. (Reason, 1990, p.9); internal events [that] generally involve failures of memory. (Reason, 1997, p.71) (COE)	• Erreurs qui résultent de quelque défaillance dans l'exécution et / ou l'étape de stockage d'une séquence d'action, (...) impliquant largement les défaillances de la mémoire, qui ne se manifestent pas nécessairement dans le comportement réel et peut être qu'apparente à la personne qui les éprouvent. (Reason, 1990, p.9) ; événements internes [que] impliquent généralement des défaillances de mémoire. (Reason, 1997, p.71)
	A slip or lapse occurs when the action conducted is not what was intended. It is an error of execution. The difference between a slip and a lapse is that a slip is observable, and a lapse is not.[274]	• Une erreur d'attention ou de concentration se produit lorsque l'action menée n'est pas ce qui était prévu. C'est une erreur d'exécution. La différence entre une erreur d'attention et une erreur de concentration est que la première est observable, l'autre ne l'est pas.

	Errors that occur when individuals are functioning in the automatic mode. (Khoja)	• Erreurs qui se produisent lorsque les individus fonctionnent en mode automatique.
Erreur de Communication (error of communication)	Missing or wrong information exchange or misinterpretation or misunderstanding.[275]	•Un échange d'informations fausses ou manquantes ou une mauvaise interprétation ou un malentendu
Erreur de compétence/maîtrise (Error of proficiency)	Error due to lack of knowledge or skill. (Forum of End Stage Renal Disease Networks)	•Erreur due au manqué de compétences ou connaissances.
Erreur de jugement (error of judgment)	Une erreur commise par suite d'une défaillance cognitive dans l'évaluation de l'information, l'élaboration des plans et la détermination des conséquences probables d'une intervention prévue (CHUM) Error related to flawed reasoning[276]	• Erreur liée à un raisonnement vicié.
Erreur de non-respect des règles (Error of violation)	Conscious failure to adhere to procedures or regulation. (Forum of End Stage Renal Disease Networks)	• Echec conscient d'adhérer aux procédures ou règlements.

	A deliberate – but not necessarily reprehensible – deviation from those practices deemed necessary (by designers, managers and regulatory agencies) to maintain the safe operation of a potentially hazardous system. [7] Action de transgresser de mauvaise foi une loi, une règle de soin, une obligation, un engagement, un devoir au cours de la prestation de soins et de services dans le domaine de la santé et/ou des services sociaux. (CHUM) Appreciated by the individual as being required by regulation, or necessary or advisable to achieve an appropriate objective while maintaining safety and the ongoing operation of a device or system. (Runciman, 2003)	• Un écart délibéré - mais pas nécessairement condamnable - par rapport à ces pratiques jugées nécessaires (par les concepteurs, les gestionnaires et les organismes de réglementation) afin de maintenir la sécurité de fonctionnement d'un système potentiellement dangereux. • Apprécié par l'individu comme étant requis par la réglementation, ou nécessaire ou souhaitable pour atteindre un objectif approprié tout en maintenant la sécurité et l'exploitation continue d'un dispositif ou d'un système.
Erreur de planning (Error of planning)	The original intended action is not correct. (Kohn)	•L’action originellement voulue n’est pas correcte.

Erreur de procedure (Error of procedure)	Procedures were followed with the wrong execution.[277]	•Les procédures sont suivies d'une mauvaise mise en œuvre.
Erreur d'exécution (error of execution)	A correct action that does not proceed as intended. (Kohn)	• Une action correcte qui ne se déroule pas comme prévu
Erreur latente (Latent error// System error)	(Ou défaillance latente) : Un défaut dans la conception, l'organisation, la formation ou l'entretien d'un système qui engendre des erreurs et dont les effets sont généralement retardés. (EU) (or latent conditions), refer to less apparent failures of organization or design that contributed to the occurrence of errors or allowed them to cause harm to patients. (AHRQ) Latent failure/Latent error: errors in the design, organization, training, or maintenance that lead to operator errors. They may lie dormant in the system for lengthy periods of time. (Kohn)	• (ou conditions latentes), se rapporte aux échecs moins apparents de l'organisation ou de la conception, qui ont contribué à l'émergence d'erreurs ou leur a permis de causer un préjudice aux patients. •Echec latent / erreur latente : erreurs dans la conception, l'organisation, la formation, ou l'entretien qui mène à des erreurs de l'opérateur. Ils peuvent rester dormants dans le système pendant de longues périodes de temps.

	The delayed consequences of technical design or organizational issues and decisions. Also referred to as latent errors. An error that is not the result of an individual's actions, but the predictable outcome of a series of actions and factors that comprise a diagnostic or treatment process. (Khoja)	• Les effets à long terme de la conception technique ou des questions d'organisation et des décisions. Aussi appelé erreurs latentes. Une erreur qui n'est pas le résultat de l'action d'un individu, mais le résultat prévisible d'une série d'actions et de facteurs que comprennent un processus de diagnostic ou de traitement.
Erreur liée au médicament/Erreur Médicamenteuse (Medication error // Drug Adverse Event // Medication-related Adverse Events//Administration Error))	Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer.[277] A deviation from the prescriber's handwritten or typed medication order or from the order that the prescriber has entered into the computer system. Medication errors are typically viewed as related to administration of a medication, but they can also include errors in ordering or delivering medication.[278]	• Tout événement évitable qui peut avoir causé ou entraîné une utilisation de médicaments inappropriée ou nuire au patient alors que le traitement est sous le contrôle du professionnel de santé, du patient ou du consommateur. • Un écart par rapport à l'ordonnance médicamenteuse manuscrite ou dactylographiée du médecin ou de l'ordonnance que le médecin a entré dans le système informatique. Les erreurs de médication sont généralement considérées comme liées à l'administration d'un médicament, mais elles peuvent également inclure des erreurs

		dans la commande ou l'administration d'un médicament.
	Any preventable event that may cause inappropriate medication use or jeopardize patient safety. (Aspden)	• Tout événement évitable qui peut causer l'utilisation inappropriée de médicaments ou de compromettre la sécurité des patients
	Une erreur qui survient dans une ou plusieurs étapes du processus d'utilisation d'un médicament : prescription, transcription, préparation, administration ou monitorage. (CHUM)	
	Une erreur commise dans le processus comprenant la prescription jusqu'à l'administration d'un médicament (CHUM)	
	An error in the processes of ordering, transcribing, dispensing, administering, or monitoring medications, irrespective of the outcome (i.e., injury to the patient).[279]	• Une erreur dans les processus de commande, de transcription, de distribution, d'administration ou de surveillance des médicaments, quel qu'en soit le résultat (blessure pour le patient)

	A failure of some kind in the process of medication administration.[280]	•L'échec de quelque nature que ce soit dans le processus d'administration de médication.
	A discrepancy between what a physician orders and what is reported to occur. Types of medication errors include omission, unauthorized drug, extra dose, wrong dose, wrong dosage form, wrong rate, deteriorated drug, wrong administration technique, and wrong time. An omission medication error is the failure to give an ordered dose; a refused dose is not counted as an error if the nurse responsible for administering the dose tried but failed to persuade the patient to take it. Doses withheld according to written policies, such as for x-ray procedures, are not counted as omission errors. An unauthorized drug medication error is the administration of a dose of medication not authorized to be given to that patient. Instances of "brand or therapeutic substitution" are counted as unauthorized medication errors only when prohibited by organization policy. A wrong dose medication error occurs when a patient receives an amount of medicine that is greater or less than the	•Un décalage entre ce que le médecin prescrit et ce qui est rapporté comme s'étant produit. Les types d'erreurs de médication comprennent l'omission, le médicament non autorisé, la dose supplémentaire, la mauvaise dose, la mauvaise forme de dosage, la mauvaise mesure, le médicament détérioré, la mauvaise technique d'administration, et le mauvais timing. Une erreur d'omission de médication est l'incapacité à donner la dose prescrite ; une dose refusée n'est pas comptée comme une erreur si l'infirmière responsable de l'administration de la dose a essayé mais n'a pas réussi à persuader le patient de la prendre. Les doses non-administrées en fonction des politiques écrites, telles que des procédures de radiographie, ne sont pas comptées comme des erreurs d'omission. Une erreur d'administration de médicament non autorisé est l'administration d'une dose de

	amount ordered; the range of allowable deviation is based on each organization's definition. (Aspden)	médicament non autorisé à ce patient. Les cas de « marque ou la substitution de marque ou de traitement » sont comptés comme des erreurs de médication non autorisée seulement lorsqu'interdit par la politique de l'organisation. Une erreur de mauvais dosage de médication se produit quand un patient reçoit une quantité de médicament qui est supérieure ou inférieure à la quantité prescrite ; le niveau de déviation permis est basé sur la définition de chaque organisation.
	Any preventable event (i.e., professional practice, drug products, procedures, systems, prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use) that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer.[281]	•Tout événement évitable (c.-à-d., pratique professionnelle, produits pharmaceutiques, procédures, systèmes, prescription, communication de la prescription, étiquetage / emballages / nomenclature des produits, composition, préparation, distribution, administration, l'éducation, la surveillance et utilisation) qui peut causer ou entraîner l'utilisation inappropriée de médicaments ou de nuire au patient pendant le traitement est sous le

	A deviation from an interpretable written prescription or medication order, including written modification of the prescription made by a pharmacist following contact with the prescriber or in compliance with the pharmacy policy [or] any deviation from professional or regulatory references, or guidelines affecting dispensing procedures. (CoE)	contrôle d'un professionnel de la santé, du patient ou du consommateur. • Un écart par rapport à une prescription écrite interprétable ou d'une ordonnance de médicaments, y compris la modification écrite de l'ordonnance faite par un pharmacien ayant pris contact avec le prescripteur ou en conformité avec la politique de la pharmacie [ou] toute déviation de références professionnelles ou réglementaires, ou des lignes directrices touchant les procédures de distribution.
Erreur par omission (error of omission)	Erreur par omission : lorsque l'on ne fait pas quelque chose que l'on aurait dû faire (Brami) Failing to provide the patient with a medical intervention from which the patient would have likely benefited (Aspden)	• Ne pas fournir au patient une intervention médicale dont le patient aurait probablement bénéficié.

	The failure to administer an ordered dose to a resident by the time the next dose is due, assuming there has been no prescribing error. Exceptions would include a resident's refusal to take the medication and failure to administer the dose because of recognized contraindications. (Khoja)	• L'incapacité à administrer une dose prescrite à un patient au moment où la dose suivante est due, en supposant qu'il n'y ait pas eu d'erreur de prescription. Des exceptions pourront inclure le refus d'un patient de prendre le médicament et l'échec à administrer la dose en raison de contre-indications reconnues.
Erreur par Commission (error of commission)	Quand, pendant la planification ou l'exécution d'une action, l'on fait quelque chose qu'il ne fallait pas faire (Brami) An error that occurs as a result of an action taken[282]	• Une erreur qui se produit à la suite d'une mesure prise.
Événements critiques (Critical Event)	En particulier, les incidents graves, indicateurs potentiels d'un dysfonctionnement grave du système, qui pourraient engendrer un préjudice grave pour le patient voire son décès et entraîner une perte de confiance des citoyens à l'égard des services de santé. (EU)	
Evènement Indésirable (Adverse event)	Adverse events are untoward incidents, therapeutic misadventures, iatrogenic injuries or other adverse	• Les événements indésirables sont les incidents fâcheux, mésaventures thérapeutiques, blessures

	occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic or other facility. Adverse events may result from acts of commission or omission (e.g., administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment, etc.)[61]	iatrogènes ou autres événements indésirables directement associés aux soins ou aux services fournis au sein de la juridiction d'un centre médical, clinique externe ou autre établissement. Les événements indésirables peuvent résulter d'actes commis ou omis (par exemple, l'administration du mauvais médicament, omission de faire un diagnostic en temps opportun ou d'instaurer l'intervention thérapeutique appropriée, les effets indésirables ou les résultats négatifs du traitement, etc.)
	Il s'agit d'un événement non désiré et imprévisible, susceptible de causer un préjudice. C'est la nature du préjudice (conséquence) qui détermine la classification de l'événement et sa gravité. (CHUM)	
	An injury that was caused by medical management or complication instead of the underlying disease and that resulted in prolonged hospitalization or disability at the time of discharge from medical care, or both.[283]	• Une blessure qui a été causée par la direction ou complication médicale la place de la maladie sous-jacente et qui a abouti à une hospitalisation

		prolongée ou un handicap au moment de la sortie des soins médicaux, ou les deux.
	An undesired patient outcome that may or may not be the result of an error.[269]	• Un résultat indésirable pour le patient qui peut ou pas être le résultat d'une erreur.
	An event or omission arising during clinical care and causing physical or psychological injury to a patient.[284,285]	• Un événement ou omission survenant pendant les soins cliniques et causant des blessures physiques ou psychologiques à un patient.
	A negative consequence of care that results in unintended injury or illness which may or may not have been preventable.[286]	• Une conséquence négative des soins qui se traduit par une blessure ou une maladie imprévue qui peut ou peut ne pas avoir été évitable.
	Event means a discrete, auditable, and clearly defined occurrence. Adverse describes a consequence of care that results in an undesired outcome. It does not address preventability.[288]	• Evènement signifie une occurrence discrète, vérifiable et clairement définie. Indésirable décrit la conséquence de soins qui se traduit par un résultat indésirable. Il ne traite pas l'viabilité.

	An injury that was caused by medical management and that results in measurable disability.[287]	• Une blessure qui a été causée par la gestion médicale et qui résulte en une invalidité mesurable.
	An injury caused by medical management (rather than by the underlying disease) which prolongs hospitalization, produces a disability at the time of discharge, or both; . . . AEs are caused by drug complications, wound infections, and technical complications, and those due to negligence [caused by] diagnostic mishaps, therapeutic mishaps, and events occurring in the emergency room. (Segen)	• Une blessure causée par la gestion médicale (plutôt que par la maladie sous-jacente) qui prolonge l'hospitalisation, produit un handicap au moment de la décharge, ou les deux ; . . . Les EI sont causés par des complications du médicament, des infections de plaies et des complications techniques, et celles qui sont dues à la négligence [provoquée par] des mésaventures diagnostiques, des mésaventures thérapeutiques, et les événements qui se produisent dans la salle d'urgence.
	An undesirable event occurring in the course of medical care that produces a measurable change in patient status.[288]	• Un événement indésirable survenant dans le cadre de soins médicaux qui produit un changement mesurable de l'état du patient.

	An event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient. (Aspden)	• Un événement qui donne lieu à des dommages involontaires au patient par un acte de commission ou d'omission plutôt que par la maladie sous-jacente ou l'état du patient.
	An unintended injury caused by medical management rather than by a disease process.[289]	• Une blessure involontaire causée par le traitement médical plutôt que par un processus de la maladie.
	Any injury caused by medical care (AHRQ)	•Toute blessure causée par les soins médicaux.
	An incident in which harm resulted to a person receiving healthcare[290]	•Un incident dont résultent des dommages pour la personne recevant des soins.
	Situation qui s'écarte de procédures ou de résultats escomptés dans une situation habituelle et qui est ou qui serait potentiellement source de dommages. Il existe plusieurs types d'événements indésirables : les dysfonctionnements (non-conformité, anomalie,	

	défaut), les incidents, les événements sentinelles, les précurseurs, les presque accidents, les accidents[291] An adverse event shall mean an event that occurs in connection with health professional activity, including pre-hospital activity or in connection with supply of and information about medicines. Adverse events comprise known and unknown events and errors that are not caused by the patient's disease, and which either are harmful or could have been harmful had they not been avoided beforehand or for other reasons did not occur.[292]	• Un événement indésirable désigne un événement qui se produit dans le cadre de l'activité professionnelle de la santé, y compris l'activité préhospitalière ou en relation avec l'offre de et l'information sur les médicaments. Les événements indésirables comprennent des événements et des erreurs connus et inconnus qui ne sont pas causés par la maladie du patient, et qui sont soit nuisibles ou soit auraient pu être nuisibles s'ils ont pu être évités au préalable ou qui ne sont pas survenus pour d'autres raisons.
Evènement indésirable grave (Serious Adverse Event)	[An event] that leads to or prolongs a hospitalization, contributes to or causes death, or is associated with cancer or a congenital anomaly.[293] An event that results in death or loss of a body part or disability or loss of bodily function lasting more than	• [Un événement] qui conduit à une hospitalisation ou la prolonge, contribue ou provoque la mort, ou qui est associée à un cancer ou une anomalie congénitale. • Un événement qui entraîne la mort ou la perte d'une partie du corps ou d'invalidité ou de perte de fonction corporelle qui dure plus de sept jours

	seven days or still present at the time of discharge from an inpatient healthcare facility or, when referring to other than an adverse event, an event whose occurrence is grave. (NQF) Unexpected occurrences involving death or serious physical or psychological injury. Any adverse event (AE) that is fatal, life-threatening, or permanently Disabling, or that results in new or prolonged hospitalization. (Khoja)	ou encore présent au moment de la sortie d'un établissement de soins de santé en milieu hospitalier ou, en se référant à autre qu'un événement indésirable, un événement dont la survenance est grave. • Evénements inattendus ayant entraîné la mort ou une blessure physique ou psychologique grave. Tout événement indésirable (EI) qui est mortelle, met la vie en danger, ou handicape de façon, ou qui résulte en une hospitalisation nouvelle ou prolongée.
Evènement Indésirable Grave Evitable (Never Event)	Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.[286]	• Les évènements indésirables graves évitables sont des incidents de sécurité graves, en grande partie évitables, qui ne se seraient pas produits si les mesures préventives disponibles avaient été mises en œuvre.
Evènement Indésirable Sans Préjudice (No-Harm Event)	When an error does not result in an adverse event for the patient and the absence of injury is owed to chance. This differs from a near miss, in which injury is absent because the error was “caught.”[294.]	• Quand une erreur ne se mue pas en évènement indésirable pour le patient et que l’absence de dommage est dû à la chance. C’est différent des

		« presque incidents » pour lesquels il n'y a pas de préjudice puisque l'erreur a été évitée.
Incident (Incident // Occurence) Synonyme d'évènement indésirable	Une action ou une situation qui n'entraîne pas de conséquences sur l'état de santé ou le bien-être d'un usager, du personnel, d'un professionnel concerné ou d'un tiers, mais dont le résultat est inhabituel et qui en d'autres occasions, pourrait entraîner des conséquences. (CHUM) An event that, under slightly different circumstances, could have been an accident. (Aspden)	• un événement qui, lors de circonstances légèrement différentes, aurait pu être un accident.
Incident Potentiel (No Harm Event)	Une grave erreur ou un grave incident qui peut éventuellement causer un incident, mais ne le fait pas en raison du hasard ou parce que l'erreur est constatée à temps (aussi appelé « quasi-incident »). (EU)	
Infraction / Violation (Violation)	Une infraction implique le non-respect délibéré d'une procédure, d'une norme ou d'une règle. (WHO)	
Médecine Humanitaire (Humanitarian Medicine)	Médecine qui s'adresse à des populations marginalisées, éprouvées par une crise ou privées	

	d'accès aux soins. Celle qui s'exerce sans autre objectif que de se rendre utile.[231]	
	A set of medical or public health practices whose sole intent is to selflessly accommodate and address the tension created between compelling health needs and the ongoing deprivation of resources in a given population or community.[19]	• Un ensemble de pratiques médicales ou de santé publique dont le but unique est d'accueillir et de répondre, de manière désintéressée, à la tension créée entre les besoins de santé incontestables et la privation continue d'accès aux ressources pour une population ou une communauté donnée.
	While all medical intervention to reduce a person's sickness and suffering is in essence humanitarian, Humanitarian Medicine goes beyond the usual therapeutic act and promotes, provides, teaches, supports, and delivers people's health as a human right, in conformity with the ethics of Hippocratic teaching, the principles of the World Health Organization, the Charter of the United Nations, the Universal Declaration of Human Rights, the Red Cross Conventions and other covenants and practices that ensure the most humane and best possible level of	• Alors que toute intervention médicale pour réduire la maladie et la souffrance d'une personne est par essence humanitaire, la médecine humanitaire va au-delà de l'acte thérapeutique habituelle et favorise, fournit, enseigne, soutient, et délivre la santé des gens en tant que droit de l'homme, en conformité avec l'éthique l'enseignement d'Hippocrate, les principes de l'Organisation mondiale de la Santé, de la Charte des Nations Unies, la Déclaration universelle des

	care, without any discrimination or consideration of material gain.[295]	droits de l'homme, les conventions de la Croix-Rouge et d'autres conventions et pratiques qui garantissent le niveau le plus humain et le meilleur de soins possible, sans aucune discrimination ou considération de gain matériel.
	Humanitarian medicine is made up of a wide range of practices with few obvious connections between them. Battlefield medicine and surgery, rural dispensaries in remote areas, campaigns to raise awareness about health problems in poor countries, emergency teams in disaster situations, vaccination campaigns, health education, help for marginalised groups in affluent countries and public health advice are just some examples of actions that fall within the scope of “humanitarian medicine” when they are carried out by organisations and in circumstances that can be classified as “humanitarian”. The field is defined not by a particular set of techniques but by the setting in which the action takes place and the stated aim of those involved. This may appear inadequate as a definition insofar as it combines some	• La médecine humanitaire est constituée d'un large éventail de pratiques avec quelques connexions évidentes entre elles. La médecine et chirurgie du champ de bataille, les dispensaires ruraux dans les zones reculées, des campagnes de sensibilisation sur les problèmes de santé dans les pays pauvres, les équipes d'urgence dans les situations de catastrophe, les campagnes de vaccination, l’éducation à la santé, l'aide aux groupes marginalisés dans les pays riches et les conseils de la santé publique ne sont que quelques exemples de actions qui entrent dans le champ d'application de la «médecine humanitaire» quand ils sont effectués par des organisations et dans des circonstances qui peuvent être classés comme «humanitaire». Le

	very different areas under a single heading, both from the point of view of the context in which the action takes place and the status of the organisations involved. Heterogeneity, however, is a defining characteristic of humanitarian medical practice.[296]	champ est défini non pas par un ensemble particulier de techniques, mais par le contexte dans lequel se déroule l'action et l'objectif déclaré de ceux qui y sont impliqués. Cela peut paraître insuffisant comme une définition dans la mesure où il combine des domaines très différents sous une seule rubrique, tant du point de vue du contexte dans lequel se déroule l'action et le statut des organisations impliquées. L'hétérogénéité, cependant, est une caractéristique déterminante de la pratique médicale humanitaire.
	La médecine humanitaire se définit comme « la médecine pour ceux qui n'y ont pas accès »[232] La médecine humanitaire n'est pas une pratique à la marge de la biomédecine et de la santé publique, mais une tentative de répondre aux attentes de populations qui en sont privées alors que leur poids démographique est parfois considérable.[297]	

Mésaventure médicale (Medical Misadventure) Terme juridique en Nouvelle Zélande jusqu'en 2005. Remplacé depuis par « Blessure de traitement » (Treatment Injury)	Personal injury that is caused by medical error or medical mishap. Medical misadventure required the injury suffered by the claimant to be caused by fault on the part of the health professional providing treatment (medical error), or for the injury resulting from properly given treatment leading to an adverse consequence to be both rare and severe (medical mishap).[298] An accident or unintentional act, as in an occupation-related "homicide by misadventure"; in medicine, the term has become an elegant euphemism for a therapeutic error, as in a surgical misadventure in which the wrong leg was amputated. (Segen)	• Dommage causé par une erreur médicale ou une mésaventure médicale. Une mésaventure médicale nécessite que le préjudice subi par le plaignant soit causé par une faute de la part du professionnel de santé qui fournit le traitement (erreur médicale), ou soit le préjudice résultant du traitement dûment donné menant à une conséquence négative étant à la fois rare et grave (accident médical). • Un accident ou acte involontaire, comme un « homicide accidentel » lié à la profession ; en médecine, le terme est devenu un euphémisme élégant pour une erreur thérapeutique, comme dans une mésaventure chirurgicale dans laquelle la mauvaise jambe a été amputée.
Négligence/Faute (Medical negligence)	An incident causing harm, damage or loss is the result of doing something wrong or failing to provide a reasonable level of care in a circumstance in which one has a duty of care.[299]	• Un incident, causant des lésions, dommages ou pertes, est le résultat du fait de faire quelque chose de mal ou de ne pas fournir un niveau de soins raisonnable dans une situation où l'on a une obligation de soins.

	Manque de soin, de vigilance. Manque de precaution. (CHUM)	
	In law, negligence refers to a breach of a duty of care owed by one person or entity to another, which if breached, results in foreseeable and compensable harm to that other, or to some interest of his or hers.T132 FPT More narrowly, negligence can refer to one element of the cause of action for negligence, i.e. whether the defendant's conduct met the standard of care.[107]	• En droit, la négligence se réfère à un manquement à une obligation de soins dû par une personne ou entité à une autre, qui, si manquée, entraîne des dommages prévisibles et indemnisables à cette autre, ou à un intérêt des siens. Plus étroitement, la négligence peut se référer à un élément de la cause de l'action pour négligence, à savoir si la conduite du défendeur a respecté la norme de soins.
	The [British] law of medical negligence operates on two principles: that the patient must agree to treatment and that treatment must be carried out with proper skill by the doctors involved. But it holds doctors and other healthcare professionals liable only for that subset of iatrogenic injury that occurs when there is a breach of the duty to use reasonable care and, as a consequence, the patient experiences an	• Le droit [britannique] de la négligence médicale fonctionne sur deux principes : le patient doit accepter le traitement et le traitement doit être effectué avec la compétence voulue des médecins impliqués. Mais il tient les médecins et les autres professionnels de santé pour responsables de ce sous-ensemble de dommage iatrogène qui se produit quand il y a une violation de l'obligation

	injury... In principle, adverse outcomes consistent with “normal” risk must be borne by the patient.[300]	de soins raisonnable et qu’en conséquence, le patient encourt un dommage. . . En principe, les résultantes défavorables cohérentes avec un risque « normal » doivent être supportées par le patient.
	Care provided failed to meet the standard of care reasonably expected of an average practitioner qualified to care for the patient in question. (COE)	• Les soins fournis ne répondent pas à la norme de soins raisonnablement attendue d'un praticien moyen qualifié pour soigner le patient en question.
	The failure (usually on the part of a physician or other healthcare professional) to exercise ordinary, reasonable, usual, or expected care, prudence, or skill (that would usually or customarily be exercised by other reputable physicians treating similar patients) in the performance of a legally recognized duty, resulting in foreseeable harm, injury; or loss to another; negligence may be an act of omission (i.e., unintentional) or commission (i.e., intentional), characterized by inattention, recklessness,	• L'échec (habituellement de la part d'un médecin ou d’un autre professionnel de la santé) d'exercer des soins raisonnables, ordinaires, habituels ou attendus, de la prudence, ou de compétences (ce qui serait normalement ou habituellement fait par d'autres médecins réputés qui traitent des patients similaires) dans l'exécution d'une obligation légalement reconnue, ce qui entraîne un préjudice prévisible, un dommage; ou une perte à un autre; la négligence peut être un acte

	inadvertence, thoughtlessness, or wantonness; in healthcare, negligence implies a substandard deviation from the “standard of medical practice” that would be exercised by a similarly trained professional under similar circumstances. (Segen)	d'omission (c.-à-d. non-intentionnelle) ou de la commission (c.-à-d. intentionnelle), caractérisée par l'inattention, l'imprudence, l’inattention, l'insouciance ou la sauvagerie; dans les soins de santé, la négligence implique une piètre déviation des «standards de la pratique médicale» qui seraient appliqués par un professionnel qualifié de manière équivalente dans des circonstances similaires.
	Care that fell below the standard expected of physicians in their community. Care provided failed to meet the standard of care reasonably expected of an average practitioner qualified to care for the patient in question. The failure of an individual to exercise the ordinary degree of care that would be expected from a reasonable and prudent person acting in the same situation, under the same or similar circumstances. This term is generally synonymous with malpractice. A legal conclusion that is reached when it has been determined that: (1) the defendant owed a duty of care to the plaintiff; (2) the defendant breached the	• Soins tombé en dessous de la norme attendue de médecins dans leur communauté. Les soins fournis n’atteignent pas la norme de soins raisonnablement attendue d'un praticien moyen, qualifié pour soigner le patient en question. L'échec d'un individu à exercer le degré de soins ordinaire qui serait attendu d'une personne raisonnable et prudente agissant dans la même situation ou dans des circonstances similaires. Ce terme est généralement synonyme de faute professionnelle. Conclusion juridique atteinte quand il a été déterminé que : (1) le défendeur

	duty of care; (3) the plaintiff was injured. as a result of the breach of the duty of care; and (4) legally cognizable damages resulted from the injury. (Khoja)	avait une obligation de diligence envers le demandeur ; (2) le défendeur transgresse le devoir de soins dus au plaignant ; (3) le plaignant a eu des dommages à la suite de la violation de l'obligation de soins ; et (4) un préjudice est reconnu par la loi à la suite des dommages.
Presque incident // Quasi incident // Echappée belle (Near miss // Close call // No harm incident)	An event or situation that did not produce patient injury, but only because of chance. This good fortune might reflect robustness of the patient (e.g., a patient with penicillin allergy receives penicillin, but has no reaction) or a fortuitous, timely intervention (e.g., a nurse happens to realize that a physician wrote an order in the wrong chart). This definition is identical to that for close call. (AHRQ) An error of commission or omission that could have harmed the patient, but serious harm did not occur as a result of chance. ([263], Aspden, IOM)	• Un événement ou une situation qui n'a pas produit de blessure au patient, mais seulement parce que dû au hasard. Cette bonne fortune pourrait refléter la robustesse du patient (par exemple, un patient atteint d'allergie à la pénicilline reçoit la pénicilline, mais n'a pas de réaction) ou d'une intervention fortuite rapide (par exemple, une infirmière arrive à se rendre compte que le médecin a écrit un ordre dans le mauvais tableau). Cette définition est identique à celle « d'échappée belle ». • Une erreur de commission ou d'omission qui aurait pu nuire au patient, mais le préjudice grave ne se produit par chance.

	Un « quasi-incident » est une erreur ou un accident grave qui peut éventuellement causer un incident, mais qui ne le cause pas par hasard ou parce que l'erreur a été constatée à temps. (EU) Un incident qui n'a pas provoqué d'atteinte (WHO) An event or situation that could have resulted in an adverse event but did not, either by chance or through timely intervention. (VA)	• Un événement ou une situation qui aurait pu conduire à un événement indésirable, mais n'a pas, par hasard ou à la suite d'une intervention en temps opportun.
Qualité des Soins	Degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. (Kohn) Quality of care is the kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of	•Degré auquel les services de santé pour les individus et les populations augmentent la probabilité de résultats souhaités en santé et qui sont conformes aux connaissances professionnelles actuelles • La qualité des soins est le type de soins qui devrait maximiser une mesure inclusive du bien-être patient, après que l'on a tenu compte de

	expected gains and losses that attend the process of care in all its parts.[301]	l'équilibre des gains et des pertes attendues qui participent au processus de soins dans toutes ses parties.
	Healthcare that uses the available and appropriate resources in an efficient way to equitably contribute to the improvement of the health of the populations and patients. This implies that provision of care is consistent with current professional knowledge, focuses on the needs and goals of individuals, their families and communities, prevents and avoid harm related to care, and involves persons/patients as key partners in the process of care.[302]	• Les soins de santé qui utilisent les ressources disponibles et appropriées d'une manière efficiente pour contribuer équitablement à l'amélioration de la santé des populations et des patients. Cela implique que la fourniture de soins est conforme aux connaissances professionnelles en cours, se concentre sur les besoins et les objectifs des individus, de leurs familles et des communautés, prévient et évite les dommages liés aux soins, et implique les personnes / patients en tant que partenaires-clés dans le processus de soins.
	Quality of care is the level of attainment of health systems' intrinsic goals for health improvement and responsiveness to legitimate expectations of the population.[303]	• La qualité des soins est le niveau de réalisation des objectifs intrinsèques des systèmes de santé pour améliorer la santé et la réactivité aux attentes légitimes de la population.

	The degree of conformity with accepted principles and practices (standards), the degree of fitness for the patient's needs, and the degree of attainment of achievable outcomes (results), consonant with the appropriate allocation or use of resources. The phrase quality of care carries the concept that quality is not equivalent to "more" or "higher technology" or higher cost. The degree of conformity with standards focuses on the provider's performance, while the degree of fitness for the patient's needs indicates that the patient may present conditions that override strict conformity with otherwise prescribed procedures.[281]	• Le degré de conformité avec les principes et les pratiques acceptées (standards), le degré d'adaptation aux besoins du patient, et le degré de réalisation des objectifs réalisables (résultats), conforme avec l'attribution ou l'utilisation des ressources appropriées. La phrase « qualité des soins » soutient l'idée que la qualité n'est pas équivalente à « plus » ou « plus haute technologie » ou à un coût plus élevé. Le degré de conformité avec les standards se concentre sur la performance du prestataire de soins, tandis que le degré d'adéquation aux besoins du patient indique que le patient peut présenter des conditions qui outrepassent le strict respect des procédures prescrites autrement.
	Healthcare that is effective, safe and responds to the needs and preference of patients. Other dimensions of quality of care, such as efficiency, access and equity	• Les soins de santé qui sont efficaces, sûrs et répondent aux besoins et aux préférences des patients. D'autres dimensions de la qualité des soins, tels que l'efficacité, l'accès et l'équité sont

	are seen as being part of a wider debate and are being addressed in other fora.[304]	considérés comme faisant partie d'un débat plus large et sont traitées dans d'autres enceintes.
	La qualité des soins de santé signifie la prestation des meilleurs soins qui soient et l'atteinte des meilleurs résultats possibles chaque fois qu'une personne a recours au système de soins de santé ou utilise ses services. Il s'agit essentiellement de faire le meilleur travail possible en fonction des ressources disponibles.[305]	
	[quality is] the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. The Institute of Medicine has identified six dimensions of healthcare quality. These state that healthcare must be: safe, effective, patient-centred, timely, efficient and equitable. (IOM)	• [La qualité est] le degré par lequel les services de santé aux individus et aux populations augmentent la probabilité de résultats souhaités en santé et sont conformes aux connaissances professionnelles en cours. L'Institute of Médecine a identifié six dimensions de la qualité des soins de santé. Ceux-ci affirment que les soins de santé doivent être : sûrs, efficaces, centrés sur le patient, rapides, efficients et équitables.

	Quality of care is defined by the proportion of potential health gain actually delivered by a healthcare organization for its set of patients. It reflects the gap between what can be achieved and what actually happens. When the gap is small, quality is achieved, if gap large, bad quality.[15] (Vincent) La qualité a un périmètre plus large que la sécurité car touche à d'autres aspects que ce qui est directement lié au soin comme l'accueil, l'hôtellerie…. Cela étant chaque action dans la démarche qualité est à la fois plus locale et procédurale : chaque action porte sur une cause supposée d'un incident et corrige le problème par la mise en place d'une nouvelle procédure spécifique. Or souvent les causes sont multiples… (Brami)	• La qualité des soins est définie par la proportion de gain potentiel en matière de santé effectivement délivré par un organisme de soins de santé pour l'ensemble de ses patients. Il reflète l'écart entre ce qui peut être accompli et ce qui se passe réellement. Lorsque l'écart est faible, la qualité est atteinte, s'il y a un grand écart, elle est de mauvaise qualité.
Sécurité du Patient (Patient Safety)	The avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of healthcare. These events include	• L'évitement, la prévention et l'amélioration des résultats ou des dommages indésirables découlant des processus de soins de santé. Ces événements

	“errors,” “deviations,” and “accidents.” Safety emerges from the interaction of the components of the system; it does not reside in a person, device, or department. Improving safety depends on learning how safety emerges from the interactions of the components. Patient safety is a subset of healthcare quality.[88]	comprennent des "erreurs", "déviations" et "accidents" de sécurité. La sécurité émerge de l'interaction des composants du système. Elle ne réside pas dans une personne, dispositif ou un département. Améliorer la sécurité dépend de l’apprentissage de comment la sécurité émerge des interactions entre composants. La sécurité des patients est un sous-ensemble de la qualité des soins de santé.
	Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur. (Kohn et[306])	• L’absence de dommages accidentels ; assurer la sécurité du patient implique la mise en place de systèmes et processus opérationnels qui minimisent la probabilité d'erreurs et de maximisent la probabilité de les intercepter quand elles se produisent.
	Actions undertaken by individuals and organizations to protect healthcare recipients from being harmed by the effects of healthcare services. (Vincent)	• Les actions menées par des individus et des organisations pour éviter aux bénéficiaires de soins de santé d'être lésés par les effets des services de soins de santé.

	Freedom from accidental injuries during the course of medical care; activities to avoid, prevent, or correct adverse outcomes which may result from the delivery of healthcare. (CoE)	• L'absence de dommages accidentels au cours de soins médicaux ; activités pour éviter, prévenir ou corriger les effets indésirables qui peuvent résulter de la prestation des soins de santé.
	The identification, analysis and management of patient-related risks and incidents, in order to make patient care safer and minimize harm to patients. (CoE)	• L'identification, l'analyse et la gestion des risques et incidents liés au patient, afin de rendre les soins aux patients plus sûrs et de minimiser les dommages pour les patients.
	The reduction and mitigation of unsafe acts within the health-care system, as well as through the use of best practices shown to lead to optimal patient outcomes. (Davies)	• La réduction et la réduction des actes dangereux au sein du système de soins de santé, ainsi que l'utilisation de pratiques exemplaires qui donnent des résultats optimaux aux patients.
	The prevention and mitigation of harm to patients. (NQF) La sécurité du patient est définie comme l'absence, pour un patient, d'atteinte inutile ou potentielle associée aux soins de santé. (WHO)	• La prévention et la réduction des risques pour les patients.

	The prevention of harm caused by errors of commission and omission. (Aspden, IOM)	• La prévention des dommages causés par les erreurs et les omissions.
	Patient safety refers to freedom from accidental or preventable injuries produced by medical care. Thus, practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events. (AHRQ)	• La sécurité des patients se réfère à l'absence de dommages accidentels ou évitables générés par les soins médicaux. Ainsi, des pratiques ou des interventions qui améliorent la sécurité des patients sont celles qui réduisent la survenue d'événements indésirables évitables.
	The process by which an organisation makes patient care safer. This should involve risk assessment, the identification and management of patient-related risks, the reporting and analysis of incidents, and the capacity to learn from and follow-up on incidents and implement solutions to minimise the risk of them recurring. The term 'patient safety' is replacing 'clinical risk', 'non-clinical risk' and the 'health and safety of patients'. (NHS)	• Le processus par lequel une organisation rend les soins aux patients plus sûrs. Cela devrait inclure une évaluation des risques, l'identification et la gestion des risques liés aux patients, l'analyse et le reporting des incidents, et la capacité d'apprendre de et de suivre les incidents et de mettre en œuvre des solutions pour minimiser le risque de leur reproduction. Le terme « sécurité du patient » remplace les termes « risque clinique », « risque de non-clinique » et la « santé et la sécurité des patients ».

	La sécurité du patient se définit comme la réduction de tout risque de préjudice évitable subi par le patient (HAS)	
	Avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare. (Vincent)	• L'évitement, la prévention et l'amélioration des résultats ou dommages indésirables découlant du processus des soins de santé.
	Patient safety is the sustained, proactive process of identifying, avoiding and rapidly resolving errors, omissions, mishaps and miscommunications that could affect a patient's healing, health or well-being at any point, at any time, in any care setting. (Khoja)	• La sécurité du patient est le processus proactif visant à identifier, éviter et résoudre rapidement les erreurs, les omissions, les accidents et les malentendus qui pourraient affecter la guérison, la santé ou le bien-être d'un patient, à tout moment, en tout temps et dans tous les structures de soins.
	A discipline in the healthcare sector that applies safety science methods toward the goal of achieving a trustworthy system of healthcare delivery. Patient safety is also an attribute of healthcare systems; it	• Une discipline dans le secteur des soins de santé qui applique les méthodes scientifiques de sécurité en vue de parvenir à un système de soins fiable. La sécurité du patient est aussi un attribut

	minimizes the incidence and impact of, and maximizes recovery from, adverse events.[14]	des systèmes de soins de santé ; il minimise l'incidence et l'impact des événements indésirables et en maximise la récupération.
Situation dangereuse/Risque (Hazard)	A situation or event that introduces or increases the probability of an adverse event arising from a danger or peril, or that increases the extent of an adverse event. (JCHAO) The potential source of harm (e.g., a hazard can be an error in the system itself or a misuse of the system).[307] Le risque est la probabilité qu'un événement causant ou pouvant causer des dommages se produise. Lorsque cet événement se produit, on dit alors que le risque s'est réalisé. (CHUM) Any threat to safety, e.g. unsafe practices, conduct, equipment, labels, names. (WHO, 2005)	• Une situation ou un événement qui introduit ou augmente la probabilité d'un événement indésirable découlant d'un danger ou péril, ou qui augmente l'étendue d'un événement indésirable. • La source potentielle de dommages (par exemple, un risque peut être une erreur dans le système lui-même ou le détournement du système). • Toute menace à la sécurité, par exemple pratiques, conduite, équipement, étiquettes, noms dangereux.

	A set of circumstances or a situation that could harm a person's interests, such as their health or welfare.[308] Anything that can cause harm. (NQF) Le risque est la probabilité de survenue d'un incident (WHO Delphi) Both active and latent failures exist that create a hazard increasing the risk of harm (Forum of End Stage Renal Disease Networks) The chance of something happening that will have an impact on individuals and/or organisations. It is measured in terms of likelihood and consequences. (NHS)	• Un ensemble de circonstances ou une situation qui pourrait nuire aux intérêts d'une personne, comme leur santé ou leur bien-être. • Tout ce qui peut causer des dommages. • Il existe à la fois des défaillances actives et latentes qui créent un danger d'augmentation du risque de préjudice. • La chance de quelque chose qui se passe d'avoir un impact sur les individus et / ou organisations. Elle est mesurée en termes de probabilité et de conséquences.
Standard de Soins (Standard of Care)	Les principes et les pratiques reconnues par les professionnels de la santé pour un état de santé	

	donné dans des circonstances données. Les standards de soins sont des consensus d'experts basés sur des recherches spécifiques. (CHUM)	
	A set of characteristics or quantities that describes features of a product, process, service, interface, or material. The description can take many forms, such as the definition of terms, specification of design and construction, detailing of procedures, or performance criteria against which a product, process, and other factors can be measured (National Research Council, 1995). (Aspden)	• Un ensemble de caractéristiques ou de quantités qui décrit les caractéristiques d'un produit, processus, service, interface, ou matériel. La description peut prendre de nombreuses formes, telles que la définition des termes, la spécification de la conception et de la construction, le détail des procédures ou des critères de performance par lesquels un produit, un processus, ainsi que d'autres facteurs peuvent être mesurés. (National Research Council, 1995).
	A level of competence in performing medical tasks that is accepted as reasonable and reflective of a skilled and diligent healthcare provider, which obliges a physician to confine his practice of medicine only to those areas of his expertise; such standards may be delineated by a hospital's medical staff bylaws or the standards published by a specialty college. (Segen)	• Un niveau de compétence dans l'exécution des tâches médicales qui est accepté comme raisonnable et reflétant un prestataire de soins de santé qualifié et diligent, qui oblige un médecin de limiter sa pratique de la médecine uniquement aux domaines de sa compétence ; ces standards peuvent être délimitées par les statuts du

		personnel médical d'un hôpital ou les normes publiées par un collège de spécialité.
	The principles and practices that have been accepted by a healthcare profession as expected to be applied for a patient under ordinary circumstances. Standards of care are developed from a consensus of experts, based on specific research (where such is available) and expert experience. “Under ordinary circumstances” refers to the fact that a given patient may have individual conditions that are overriding; absent such considerations, a medical staff or nursing staff quality review committee will expect the generally accepted principles and practices to be carried out. (Slee)	• Les principes et les pratiques qui ont été acceptés par une profession des soins de santé comme étant attendu à appliquer pour un patient dans des circonstances ordinaires. Les standards de soins sont développés à partir d'un consensus d'experts, basés sur des recherches spécifiques (si telles sont disponibles) et de l'expérience d'experts. "Dans des circonstances ordinaires" se réfère au fait qu'un patient donné peut avoir des conditions individuelles qui sont prépondérantes ; en dehors de telles considérations, un comité du personnel médical ou infirmier d'examen de la qualité escompte que les principes et pratiques généralement acceptées soient mises en œuvre.
	Generally, in healthcare law, the degree of care that a physician, who possesses average skills and practices in the same or similar locality, should exercise in the same or similar circumstances. In cases involving specialization, however, certain courts have	• En général, en droit de la santé, le degré de soin qu'un médecin, qui possède les compétences et les pratiques moyenne dans la même localité ou une localité similaire, devrait exercer dans les circonstances identiques ou similaires. Dans les

	disregarded geographical considerations, holding that in the practice of a board-certified medical or surgical specialty, the standard should be that of a reasonable specialist practicing medicine or surgery in the same special field. If a physician's conduct falls below the standard of care, he or she may be liable for any injuries or damages resulting from that conduct. (Aspden)	cas impliquant une spécialisation, cependant, certains tribunaux ne tiennent pas compte des considérations géographiques, estimant que dans la pratique d'une spécialité médicale ou chirurgicale certifiée par un Conseil, la norme doit être celle d'un spécialiste raisonnable pratiquant la médecine ou la chirurgie dans le même domaine de spécialité. Si la conduite d'un médecin tombe en dessous des standards de soins, il ou elle peut être tenu responsable des blessures ou dommages résultant de ce comportement.
	The principles and practices which have been accepted by a health-care profession as expected to be applied for a patient under ordinary circumstances. (Davies)	• Les principes et les pratiques qui ont été acceptées par une profession de soins de santé comme étant à appliquer pour un patient dans des circonstances ordinaires.
	That standard of care is as found in a policy, or clinical guideline, or in common practice — a set of steps that would be followed or an outcome that would be expected. The standard of care may vary by	• Cette norme de soins est, comme on le trouve dans une politique ou une directive clinique, ou dans la pratique courante, un ensemble d'étapes qui seraient suivies ou un résultat qui serait

	community (eg, due to resource constraints). When the term is used in the clinical setting, the standard of care is generally felt not to vary by specialty or level of training. In other words, the standard of care for a condition may well be defined in terms of the standard expected of a specialist, in which case a generalist (or trainee) would be expected to deliver the same care or make a timely referral to the appropriate specialist (or supervisor, in the case of a trainee). Standard of care is also a term of art in malpractice law, and its definition varies from jurisdiction to jurisdiction. When used in this legal sense, often the standard of care is specific to a given specialty; it is often defined as the care expected of a reasonable practitioner with similar training practicing in the same location under the same circumstances. (Khoja)	attendu. La norme de soins peut varier selon la communauté (par exemple, en raison de contraintes en termes de ressources). Lorsque le terme est utilisé dans le cadre clinique, la norme de soins est généralement estimée ne devant pas varier selon la spécialité et le niveau de formation. En d'autres termes, la norme de soins pour un état de santé peut ainsi être défini en termes de la norme attendue de la part d'un spécialiste, auquel cas il est attendu d'un généraliste (ou d'un stagiaire) de fournir le même soin ou de référer le patient en temps opportun au spécialiste appropriée (ou superviseur, dans le cas d'un stagiaire). La norme de soins est aussi un terme en droit de la responsabilité, et sa définition varie d'une juridiction à l'autre. Lorsqu'il est utilisé dans ce sens juridique, souvent la norme de soins est spécifique à une spécialité donnée ; elle est souvent définie comme le soin attendu de la part d'un praticien raisonnable, avec une formation pratiquent au même endroit et dans les mêmes circonstances.

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