

Patient perspectives of being informed about iAEs

Prof. Tanja Krones, MD MS



















You are the treating neuro-surgeon of a 28 year old patient, working as a model and is suffering from meningeoma, which could be resected in toto. For fixing the sterile covering of the patient you had used a sharp clamp. When the cover was removed, the surgical nurse assistant discovers that the clamp went through the root of the nose and has injured the patient, now having two wounds at the right and left side of the nose



A 58 year old patient on ECMO is referred to the operation theatre for a lung surgery intervention. After anaesthesia (the patient was awake during ECMO since 1 week) the perfusionist has to change an adapter within the system due to a leak. Yet the new one does not fit into the system resulting in a heavy blood loss, need of mass transfusion and a short mechanical resuscitation of the patient. The operation goes well and the patient has seemingly and luckily not incured serious consequences.



Salome Dell-Kuster, ^{1,2,3} Nuno V Gomes, ^{1,3} Larsa Gawria, ^{2,4} Soheila Aghlmandi, ² Maame Aduse-Poku, ⁵ Ian Bissett, ⁶ Catherine Blanc, ⁷ Christian Brandt, ⁸ Richard B ten Broek, ⁴ Heinz R Bruppacher, ⁹ Cillian Clancy, ¹⁰ Paolo Delrio, ¹¹ Eloy Espin, ¹² Konstantinos Galanos-Demiris, ¹³ I Ethem Gecim, ¹⁴ Shahbaz Ghaffari, ¹⁵ Olivier Gié, ¹⁶ Barbara Goebel, ¹⁷ Dieter Hahnloser, ¹⁶ Friedrich Herbst, ¹⁵ Ioannidis Orestis, ¹³ Sonja Joller, ¹⁸ Soojin Kang, ⁵ Rocio Martín, ¹² Johannes Mayr, ¹⁷ Sonja Meier, ⁵ Jothi Murugesan, ¹⁹ Dairdes Nalli, ¹⁰ Manales Goeslik, ²⁰ Her Bassel, ²¹ Cimana Babasse, ²²

BMJ: first published as 10.11

Table 1 | ClassIntra version 1.0 classification of intraoperative adverse events. The classification defines intraoperative adverse events as any deviation from the ideal intraoperative course occurring between skin incision and skin closure. Any event related to surgery and anaesthesia during the index surgery must be considered and should be rated directly after surgery.* A requirement is that the indication for surgery and the interventions conform to current guidelines

Grade	Definition	Examples
Grade 0	No deviation from the ideal intraoperative course	-
Grade I	Any deviation from the ideal intraoperative course: • Without the need for any additional treatment or intervention • Patient with no or mild symptoms	 Bleeding: bleeding above average from small calibre vessel, self-limiting or definitively manageable without additional treatment than routine coagulation Injury: minimal serosal intestinal lesion, not requiring any additional treatment Cautery: small burn of the skin, no treatment necessary Arrhythmia: arrhythmia (eg, extrasystoles) without relevance
Grade II	Any deviation from the ideal intraoperative course: • With the need for any additional minor treatment or intervention • Patient with moderate symptoms, not life threatening, and not leading to permanent disability	 Bleeding: bleeding from medium calibre artery or vein, ligation; use of tranexamic acid Injury: non-transmural intestinal lesion requiring suture(s) Cautery: moderate burn requiring non-invasive wound care Arrhythmia: arrhythmia requiring administration of antiarrhythmic drug, no haemodynamic effect
Grade III	Any deviation from the ideal intraoperative course: With the need for any additional moderate treatment or intervention Patient with severe symptoms, potentially life threatening or potentially leading to permanent disability	 Bleeding: bleeding from large calibre artery or vein with transient haemodynamic instability, ligation or suture; blood transfusion Injury: transmural intestinal lesion requiring segmental resection Cautery: severe burn requiring surgical debridement Arrhythmia: arrhythmia requiring administration of antiarrhythmic drug, transient haemodynamic effect
Grade IV	Any deviation from the ideal intraoperative course: With the need for any additional major and urgent treatment or intervention Patient with life threatening symptoms or leading to permanent disability	 Bleeding: life threatening bleeding with splenectomy; massive blood transfusion; stay at intensive care unit Injury: injury of central artery or vein requiring extended intestinal resection Cautery: life threatening burn injury by cautery leading to fire requiring intensive care treatment Arrhythmia: arrhythmia requiring electroconversion, defibrillation, or admission to intensive care
Grade V	Any deviation from the ideal intraoperative course with intraoperative death of the patient	_







1. Would you tell the patient what happened? 🔲	
Yes	
○ No	
2. Would most of your colleagues tell the patient what happened?	
Yes	
○ No	
3. Would your institution clearly recommend to tell the patient what happened?	
Yes	
○ No	





Physician-Patient Communication

A Key to Malpractice Prevention

From the Departments of Medic Sciences University, Portland, Or Corresponding author: Wendy 22nd Ave, Portland, OR 97210.

Patient and Family Involvement

J



The Journal of Emergency Medicine, Vol. 51, No. 5, pp. 605–609, 2016 © 2016 Elsevier Inc. All rights reserved. 0736-4679/\$ - see front matter

http://dx.doi.org/10.1016/j.jemermed.2016.06.048





IN SUPPORT OF THE MEDICAL APOLOGY: THE NONLEGAL ARGUMENTS

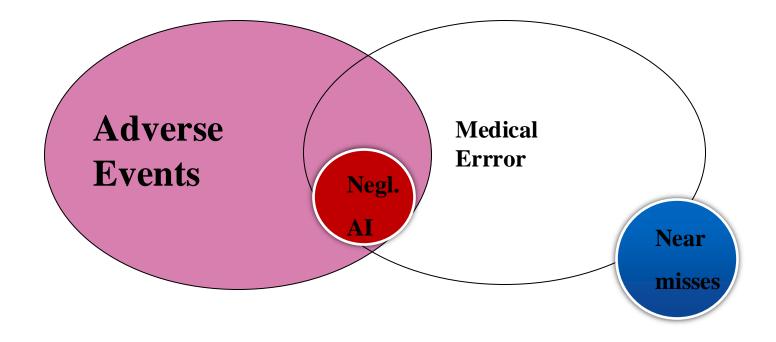
Heather A. Heaton, MD,* Ronna L. Campbell, MD, PHD,* Kristine M. Thompson, MD,† and Annie T. Sadosty, MD*

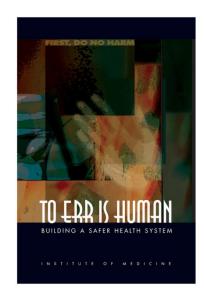
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Medical Error, Adverse Events, Near Misses







Medical Error in grey zones

«A medical error is «an act or an omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgable peers at the time it ocurred»

Wu, et al. To tell the truth: ethical and practical issues in disclosing medical mistakes to patients. J Gen Intern Med 1997; 12:770-775.



Principal Relevant Objectives and Framework for Integrated Learning and Education in Switzerland

Bern, March 15th 2017

9. Contribute to a culture of safety and improvement [linked roles: EXP/COM/COL/ADV/SCH/PRO]

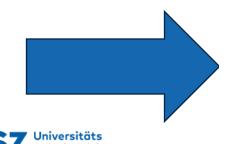
EPA	9.1	Identify actual and potential ("near miss") errors in care; speak up in case of real
		or potential errors, and use error reporting systems if available
EPA	9.2	Empower team members to "stop the line" if they discover a significant safety breach
EPA	9.3	Admit and disclose one's own errors, reflect on one's contribution and develop an
		improvement strategy
EPA	9.4	Address situations in which a patient could have been the victim of a medical error
EPA	9.5	Understand existing safety/quality procedures, their vulnerabilities and the con-
		cept of accountability
SSP	246	errors or misconduct of a co-worker or other healthcare professional

Principal Relevant Objectives and Framework for Integrated Learning and Education in Switzerland

Bern, March 15th 2017

A new era for the practice of medicine and a challenge for medical faculties

Over the last decades, the sectors of health and medicine have changed dramatically and will continue to do so. This evolution is on one hand linked to the transformation of medical practice, and on the other hand to demographic changes that are occurring in the population itself and within the medical profession. Both should influence the way in which medical students and doctors must be trained [3-8]. Indeed, physicians nowadays find themselves in an environment that is becoming increasingly technical and which involves imaging techniques or genetic and biological tests, which are becoming more and more sophisticated and available even to lay people. In high income countries in particular, patients are increasingly literate in the area of health (9), and this is radically transforming the nature of the patient-doctor relationship; the concept of shared decision-making is a good example (10, 11). Moreover, many countries increasingly emphasize the issue of professionalism, including issues such as patient safety, adequate reactions to potential errors (12) and attention to cost-ef-





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Improving communication skills--a randomized controlled behaviorally oriented intervention study for residents in internal medicine.

Psychosomatic Medicine. 60(3):268-76, MAY 1998

W A Langewitz; P Eich; A Kiss; B Wössmer show less



Interventions to Improve the Breaking of Bad or Difficult News by Physicians, Medical Students, and Interns/Residents: A Systematic **Review and Meta-Analysis**

Judith Johnson, PhD, ClinPsyD, and Maria Panagioti, PhD

Abstract

Purpose

To assess the effectiveness of news delivery interventions to improve observer-rated skills, physician confidence, and patient-reported depression/anxiety.

MEDLINE, EMBASE, CINAHL, PsycINFO, and Cochrane Register of Controlled Trials databases were searched from inception to September 5, 2016 (updated February 2017). Eligible studies included randomized controlled trials (RCTs), non-RCTs, and controlled before-after studies of interventions to improve the communication of bad or difficult news by physicians, medical students, and residents/interns. The EPOC risk of bias tool was used to

conduct a risk of bias assessment. Main and secondary meta-analyses examined the effectiveness of the identified interventions for improving observerrated news delivery skills and improving physician confidence in delivering news and patient-reported depression/anxiety. respectively.

Results

Seventeen studies were included in the systematic review and metaanalysis, including 19 independent comparisons on 1.322 participants and 9 independent comparisons on 985 participants for the main and secondary (physician confidence) analyses (mean [SD] age = 35 [7] years; 46% male), respectively. Interventions were associated with large, significant

improvements in observer-rated news delivery skills (19 comparisons: standardized mean difference [SMD] = 0.74; 95% CI = 0.47-1.01) and moderate, significant improvements in physician confidence (9 comparisons: SMD = 0.60: 95% CI = 0.26-0.95). One study reported intervention effects on patientreported depression/anxiety. The risk of bias findings did not influence the significance of the results.

Conclusions

Interventions are effective for improving news delivery and physician confidence. Further research is needed to test the impact of interventions on patient outcomes and determine optimal components and length.

Physicians frequently break bad or difficult news to patients. Research into the delivery of bad or difficult news originated in oncology services, where it was found that news communication practices can have a strong and lasting impact on patients' subsequent symptoms

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Acad Med. 2018:93:1400-1412.

First published online June 5, 2018 doi: 10.1097/ACM.00000000000002308 Copyright @ 2018 by the Association of American Medical Colleges

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of depression, anxiety, and posttraumatic stress disorder and can influence their treatment choices.1-5 Studies have since investigated the delivery of bad and difficult news in a range of health care settings, including pediatrics,6 emergency medicine,7,8 and obstetrics services.9,10 Together, this body of research has identified several challenges that physicians may face in scenarios where they have to deliver bad or difficult news, such as when the news occurs suddenly and without warning (e.g., in emergency settings), when there is limited time for physicians to prepare to deliver the news (e.g., in obstetric ultrasound settings), or when the news itself is uncertain because the diagnosis or prognosis is unclear. It has also highlighted the negative impact that these events can have on the physicians involved, including increased stress and burnout.8,11

A range of interventions that aim to improve the communication skills and confidence of physicians in delivering bad or difficult news have been described. These interventions vary in length and format but share some similar components; for example, most include

elements of didactic teaching, role-playing or simulation,9 group discussions,12 or the viewing of instructional videos.13 The interventions are often designed to enhance fidelity to existing guiding frameworks for bad or difficult news delivery. SPIKES14 is the most widely used of these frameworks; it proposes six steps, from which the acronym is derived, to improve news delivery events. These steps are (1) setting up the interview, (2) assessing the patient's perception of the situation, (3) obtaining the patient's invitation to deliver the news, (4) giving knowledge and information to the patient, (5) addressing the patient's emotions empathically, and (6) providing a summary and discussing prognosis and treatment options.14 Similarly, the more recently proposed SHARE15 protocol suggests that health care staff should follow four steps, which taken together form the acronym. These steps are (1) create a supportive environment, (2) consider how to deliver the news, (3) discuss additional information that patients would like to know, and (4) provide reassurance and emotional support.15

Academic Medicine, Vol. 93, No. 9 / September 2018

Rapid Learning of Adverse Medical Event Disclosure and Apology

Daniel B. Raemer, PhD. Steven Locke, MD. Toni Beth Walzer, MD. Roxane Gardner, MD. MPH. DSc. Lee Baer, PhD, and Robert Simon, EdD

Introduction: Despite published recommended best practices for full disclosure and apology to patients and families after adverse medical events, actual practice can be inadequate. The use of "cognitive aids" to help practitioners manage complex critical events has been successful in a variety of fields and healthcare. We wished to extend this concept to disclosure and apology events. The aim of this study was to test if a brief opportunity to review a best practice guideline for disclosure and apology would improve communication performance.

Methods: Thirty pairs of experienced obstetricians and labor nurses participated in a 3-part exercise with mixed-realism simulation. The first part used a standardized actor patient to meet the obstetrical team. The second part used a high-fidelity simulation leading to an adverse medical event (retained sponge), and the third part used standardized actors, patient, and husband, who systematically move through stages of grief response. The participants were randomized into 2 groups, one was provided with a cognitive aid in the form of a best practice guideline for disclosure and apology and the other was only given time to plan. Four blinded raters working in pairs scored subjects on a 7-point scale using a previously developed assessment instrument modified for this study.

Results: Pooled ratings of the disclosure and apology discussion for the intervention group (n = 167, mean = 4.9, SD = 0.92) were higher than those from the control group (n = 167, mean = 4.3, SD = 1.21) $(P \le 0.0001)$. One specific element was rated higher for the intervention group than the control group; posture toward the patient (n = 27, mean = 5.1, SD = 0.82 versus n = 28, mean = 4.3, SD = 1.33) (P = 0.020). The elements of dealing with anger, dealing with depression, dealing with denial, bargaining, and acceptance were not different.

Conclusions: Experienced practitioners performed better in a simulated disclosure and apology conversation after reviewing a cognitive aid in the form of a best practice guideline than a control group that was only given time to prepare.

Key Words: apology and disclosure, patient safety, medical error,

(J Patient Saf 2016;12: 140-147)

Adverse medical events are an unfortunate part of healthcare. 1,2

A number of guidelines from health-care organizations and specialty societies, including obstetrics and gynecology, promote appropriate and prompt disclosure of medical errors and adverse events to patients and families.^{3–5} Despite available guidelines for the process, 6-8 studies of disclosure have shown gaps between the recommended and actual practice.9-14 A variety of reasons have been identified for these gaps, including fear of litigation, professional repercussions, and concern that disclosure and apology will not benefit the patient and, clinicians being

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This study was supported by Grant no. 9600674 from The Physicians

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uncomfortable with difficult conversations or with the emotional expressions of patients' feelings. 15-17 Patients and families report experiencing a variety of negative emotions upon learning of an adverse event, including feeling sad, anxious, depressed, or traumatized.18 They are sometimes angry and frustrated as well as guilty for not avoiding the incident themselves. 19 Uncertainty about current policies and best practices may also affect the willingness to provide full and open disclosure and apology.²⁰

To close the performance gap, it has been suggested that educating clinicians on best practices and encouraging effective disclosure and apology should be part of successful patient safety programs. 21,22 A variety of educational programs, curricula, and methods have been used to provide all or parts of this learning. 23-31 Most studies of educational practice for this topic are descriptive, involve only trainees, and there is little guidance as to the most effective approach for experienced practitioners. 10,32,33 The use of cognitive aids (A cognitive aid is a checklist, manual, or guideline that is immediately available in printed or electronic form to assist a clinician in performing a procedure, follow an algorithm, or help diagnose or treat a condition.) has been successful for improving management of medical crises. 34-36 We wondered if this would apply to difficult conversations for disclosing and discussing adverse medi-

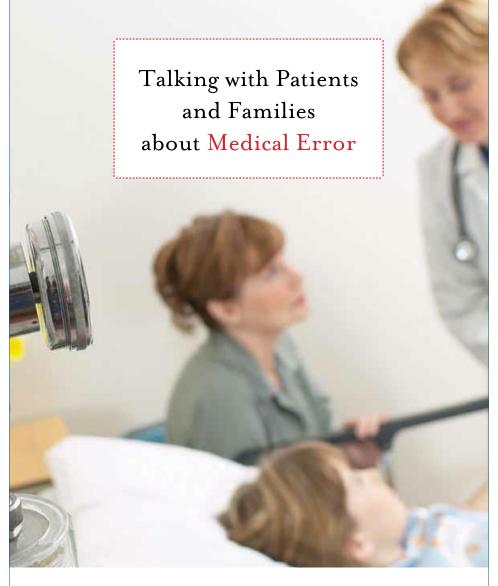
Simulation has been used successfully for the past 10 years at our institution with Labor and Delivery clinicians for learning crisis resource management as well as teamwork skills.37 Similar courses have been developed at other institutions with the aim of improving teamwork and crisis response for Labor and Delivery teams. Studies have shown that simulation training for obstetrical teams can be effective to develop and refresh skills, even among experienced teams, and improve patient outcomes. 38-40

We used a mixed-realism combination of an encounter with a standardized actor patient, then a high-fidelity simulation case using a mannequin, followed by an encounter with standardized actor patients.26 High-fidelity simulation using mannequins has been used most recently to raise the engagement of the participants in the adverse outcome itself. 27,41,42 The use of standardized patients for studying disclosure practice has long been used in a number of settings. 24,29,43-45 Because of its repeatable presentation of situations and the requirement that subjects declare actual rather than espoused actions, simulation is an important patient safety research technique.

To depict a wide spectrum of plausible emotional responses of patients and their families, to elicit a broad range of the clinician's disclosure skills, and to standardize the issues raised during the disclosure discussion, a structured process for the disclosure and apology discussion was chosen, wherein the standardized patients would enact all five stages of the grief response described by Kübler-Ross.42

We wanted to observe how experienced obstetricians and labor nurses would handle informing a patient and family about an avoidable surgical mishap. Furthermore, we sought to assess whether reviewing a cognitive aid in the form of a brief

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A GUIDE FOR EDUCATION AND PRACTICE

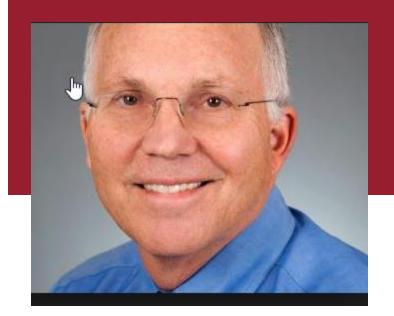


Robert D. Truog, M.D., David M. Browning, M.S.W., B.C.D., F.T., |udith A. |ohnson, |.D., and Thomas H. Gallagher, M.D.

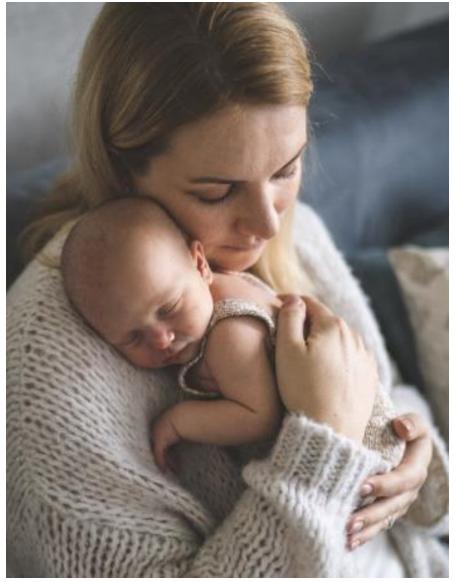
Foreword by Lucian L. Leape, M.D.

Things Wrong

RESPONDING
TO ADVERSE EVENTS











What is the "red line" for communicating an (preventable) adverse event?

Unexpected adverse events must be communicated if:

 You would yourself want to know about the incident, if you yourself or a family would have been in the same situation ("Application of the Golden Rule")

or

 The problem results or could result immediately or later in a change of the treatment or care plan



What should be told?

Facts should always be told and – generally the sooner the better ...

...But

The initial story is in most cases incomplete and sometimes totally wrong

Avoid the natural wish to draw a «complete picture», summarizing the initially few known facts

For these questions, a skillfull experienced coach can be extremely helpful



TRACK





Central communication skill and attitude	Definition	What should reach the patient
Transparency	Attitude of being open and honest	I get timely access to the information I need
		I was perceived and treated as an individual person
Accountabilty	The art of being available and responsive	The right persons have taken responsibility for their actions
Continuity	The commitment of continuous relatedness and caring, shared time span	The treatment I receive is comprehensible, without interruptions (I do not feel surrendered and abandoned) and makes sense to me
Kindness	The skill to act attentively, kindly and cordially	I was treated with respect, empathy and full attention

A possible "sequence" of the conversation



- ✓ Recapitulation of facts
- ✓ Clear, authentic, honest expression of apology
- ✓ Steps to adequately take care for the patient
- ✓ Steps being planned to investigate the incident and prevent another occurrence of the same situation
- ✓ Offer of multifaceted individualized support for patient/family
- √ Who is talking next to patient/family and when
- ✓ Close with an honest, serious expression of support, sympathy and deep interest in the situation of the affected/injured person



When and how to apologize

Two meanings of «I'm sorry"-

- Expression of compassion and solidarity— "I am so sorry that this has happened" (German "Es tut mir leid")
- Expression of responsibility and accountability "We know that what has happened was a preventable adverse event and I want to truly apologize" (German "ich möchte mich dafür aufrichtig entschuldigen")

The first "sorry" is always adequate

The second form of apology is only adequate, when a preventable medical error has occurred



How apologogies fail...

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"I apologize for everything that has happened..."
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"If a mistake has happened..."

"There was a mistake, but ..."

"This happens to the **best** physicians..."

"The mistake has **for sure not changed the outcome** of your treatment ..."

Quote of a (very experienced) surgeon: "I know, I know, for you it is uncomfortable, terrible, but believe me, for me it is devastating»



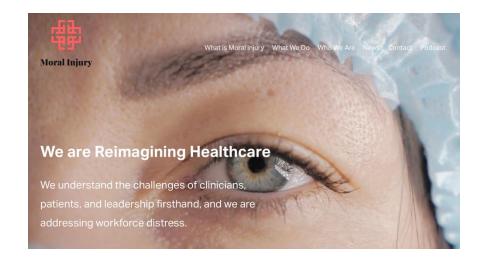
First/Second/Third Victim

⇔ SBB CFF FFS





Physicians aren't 'burning out.' They're suffering from moral injury By Simon G. Talbot and Wendy Dean July 26, 2018 Reprints

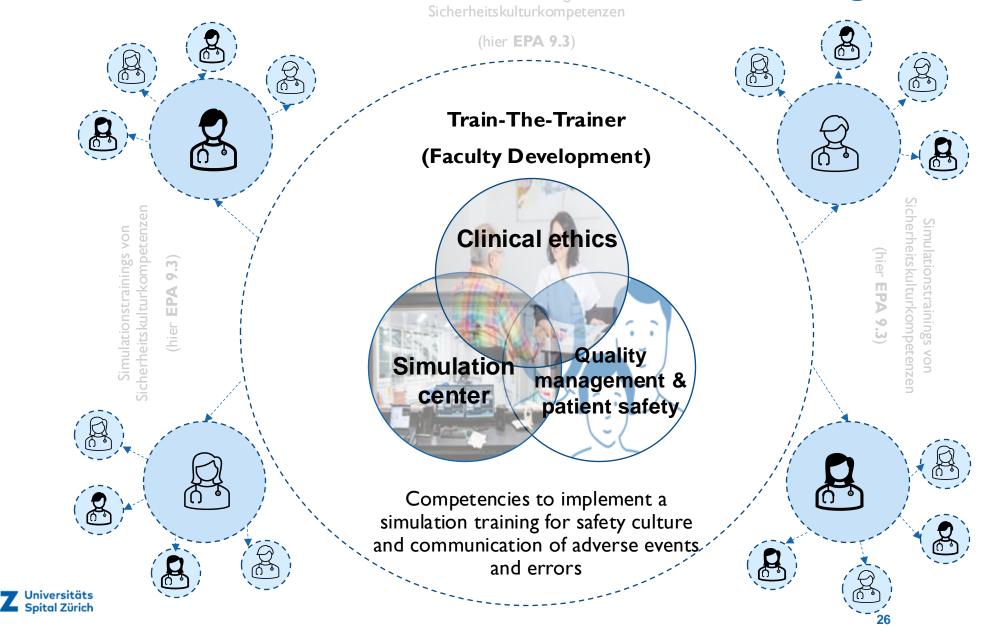


Moral injury occurs when clinicians are repeatedly expected, in the course of providing care, to make choices that transgress their long standing, deeply held commitment to healing.

It reframes the challenge of distress from "burnout", which suggests a lack of resilience on the part of clinicians, to one that more accurately locates the source of distress in a conflict ridden healthcare system.



SIWF awarded communication instructor/ Coaching course



	Day 1	Day 2
08:30 - 09:00	Introduction & Relevance	SimSession for Disclosure & Apology after a
09:00 - 09:30		preventable adverse event according to TRACK
09:30 - 10:00		& Observation & Feedback
10:00 – 10:30		
10:30 – 11:00	Disclosure & Apology after a preventable adverse event according to TRACK Break	
11:00 – 11:30		SimSession for Disclosure & Apology after a preventable adverse event according to TRACK & Observation & Feedback
11:30 – 12:00		
12:00 – 12:30		
12:30 – 13:00		
13:00 – 13:30	Disclosure & Apology after a preventable adverse	Breack
13:30 – 14:00	event according to TRACK	
14:00 – 14:30	& observation	SimSession for Disclosure & Apology after a
	- With simulated persons-	preventable adverse event according to TRACK
14:30 – 15:00		& Observation & Feedback
15:00 – 15:30	Disclosure & Apology after a preventable adverse event according to TRACK & observation - With simulated persons-	
15:30 – 16:00		
16:00 – 16:30		Take Aways, next Steps & Evaluation
16:30 – 17:00		

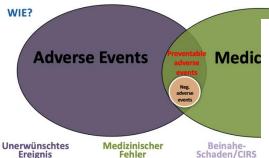


"Fehler"- Definitionen

Unterscheidungen, Überschneidungen von verschiedenen, die Patient:innensicherheit WAS? gefährdenden Ereignissen¹

WOZU?

- ✓ Je nach Sachverhalt sind unterschiedliche Herangehensweisen adäguat²
- ✓ Es ist wichtig, überschiessende Reaktionen («jede Abweichung muss kommuniziert werden») ebenso zu vermeiden, wie das Übersehen relevanter Abweichungen («es ist ja
- ✓ Reflexion über Definitionen und Grenzfälle erhöht die Sensibilität und fördert eine aktive, hilfreiche Fehlerkultur 1,2



Fehler Ereignis

("preventable") oder

Beispiel: Ein Patient erhält Penicillin und entwickelt eine allergische Hautreaktion ngl.: Error

ine Handlung oder ein Interlassen, bei dem a) ine Abweichung vom Plai) ein falscher Plan oder o ein Plan vorliegt. Ob araus ein Schaden ntsteht, ist für die Definition des Fehlers

Beispiel: Bestellung des falschen Patienten in den OPS

Eine Situation, Ereign oder Fehler ohne

Schaden, der zu einen Schaden hätte führen können.

Engl. Near

Miss/Critical Incident

Beispiel: Aufgrund eines Lieferkettenengpasses wird Temesta knapp (Situation/Ereignis)

Second Victim und Coaching

WAS? Beschreibung der Reaktionen und Bedürfnisse der «Second Victims», d.h. der Betroffenen des Behandlungsteams, und angemessene Unterstützungsstratgier¹

WOZU?

WIE?

Wie und warum ist das nur passiert?

INTRUSIONEN/ZWEIFEL/

U

√ Offene, angemessene Fehlerkommunikation und bedarfsgerec können das Risiko einer schweren und anhaltenden Traumatisi



SUIZID...

Bin ich die richtige für si einen Job? Bin ich

überhaupt etwas werti

DAS LEE

SUCHE NA

und O

PSYCHOLOGIS

EMOTIONALE

WIE?

√ Ermöglicht tieferes Verständnis der «äusseren» und «inneren Gründe» für eine offene und empathische Mitteilung 1-5

✓ Ordnet die Kommunikation medizinischer Fehler als wichtigen Teil einer aktiven Sicherheits- und Fehlerkultur (Entrustable Professional Activity EPA 9) ein 4,6

√ Selbstreflexives, vertieftes Lernen, Stärkung der «Advocacy»⁵



2020: Interprofessionelle gemeinsame ethische Grundlagen 2010: Verinnerlichte

USZ Simulationszentrum

Faculty Development

Prinzipien der Fürsorge und Beziehung 2000: Grundprinzip "Do not

1990: Weniger

Haftpflichtfälle

Gründe der offenen Mitteilung: Historische Entwicklung



Bsp: Wo suchen Führungskräfte die Ursachen für Fehler?

¹ Truog , R. D., Browning, D. M., Johnson, J. A., Gallagher, T. H., & Leape, L. L. (2011). Talking with patients and families about medical error: A guide for education and practice. Baltimore: Johns Hopkins University Press ² Levinson W (1994) Physician-Patient Communication: A Key To Malpractice Prevention, JAMA, 272: 20

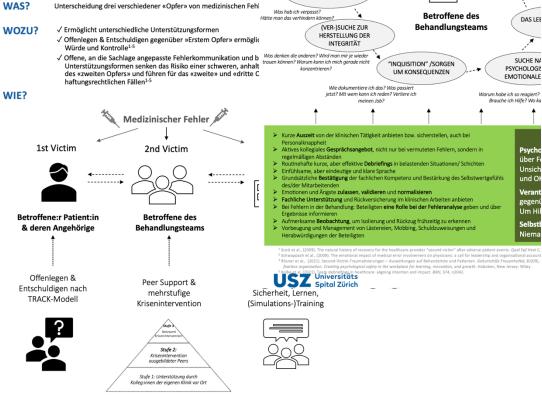
3 Heaton HA, Campbell RL, Thompson KM, Sadosty T (2016) In Support of the Medical Apology: The nonlegal arguments . The Journal of Emergency Medicine, 51(5) Institute of Medicine (2000): To Err is Human Building a Safer health System, Washington, National Academies Press

Doherty , RF (2021) Ethical Dimensions in the Halth Professions. 7th edition. Elsevier, St. Louis.

⁶ Michaud PA, Jucker-Kupper P, and members of the Profiles working group

PROFILES; Principal Objectives and Framework for Integrated Learning and Education in Switzerland. Bern: Joint Commission of the Swiss Medical Schools; 2017.







First, Second & Third Victim

Truog et al. (2011). Talking with patients and families about medical error: A guide for education and practice. Baltimore: Joi Ozeke et al. (2019). Second victims in health care: current perspectives. Advances in Medical Education and Practice, 10(null), 593-603.



