Accepted author's manuscript. Published in final edited form as: International Journal for Quality in Health Care 2022 (in press). Publisher DOI: 10.1093/intqhc/mzac064

Perspective

Public expectations on regulatory requirements for management of hospital "never events" in Germany

David Schwappach[1,2], Hardy Müller[3], Beate S. Müller[4]

1 Swiss Patient Safety Foundation, Asylstrasse 77, 8032 Zurich, Switzerland

2 Institute of Social and Preventive Medicine (ISPM), University of Bern, Mittelstrasse 43, 3012 Bern, Switzerland

3 Techniker Krankenkasse, Bramfelder Str. 140, 22305 Hamburg, Germany

4 Institute of General Practice, Goethe University Frankfurt, Frankfurt am Main, Germany

Corresponding author:

Prof. David Schwappach

email: david.schwappach@ispm.unibe.ch

Perspective

Public expectations on regulatory requirements for management of hospital “never events” in Germany

Background

Patient safety is an important public health issue for health care systems worldwide. While the majority of medical errors lead to only minor or moderate harm, there is also a subset of serious incidents, commonly termed “never events”. Never events are specific, clearly defined events, which cause serious patient harm and are deemed largely preventable if well-established safety precautions are implemented. Wrong side surgery and wrong route applications of high risk drugs are typical “never events”. Australia, some states in the US (e.g., Maryland, Minnesota), and countries in Europe, like the UK and France, have established mandatory reporting systems for all or for specific severe patient-harm incidents. In other countries, like Germany and Switzerland, there are no general requirements or policies to report and analyze “never events” for learning purposes or to derive and establish prevention efforts. A “never event” in Germany would commonly be subject to civil liability or criminal legislation, or both. After a “never event”, hospitals would not formally be required to investigate how the incident happened, to report to an official body, to derive action from the error to prevent recurrence, or to involve the police. Health care providers are required by law to inform patients about an suspected error if the patient /next of kin asks or if the event requires additional medical treatment. All hospitals are required to have a local, anonymous incident reporting system, but these are mainly intended for non-major incidents. Recent research suggests that under such circumstances and no formal requirements, , no reliable data about the occurrence of “never events” are available and there is wide variation between and within hospitals how such events are managed (1). On the other side, there is also strong evidence that patients and the public expect health care systems to disclose incidents to patients, to report serious incidents to external agencies and to reliably learn

from serious events (2). We thus assume that the lack of any formal requirements for management of “never events” is not known widely by the public and does not meet its expectations. Major disparities between public expectations and reality in management of “never events” are important because they have the potential to erode trust in the accountability of system, namely, that lessons are learned from severe incidents and that this learning is not only “nice to have”.

Public expectations about “never event” management

To investigate common assumptions about the consequences of “never events” for hospitals, we used the “TK Monitor Patientensicherheit”, an annual representative survey study among the German general public (see results of the first survey round for an overview of other survey components (3)). Three survey questions (items) were specifically developed to address public expectations towards never event management. These items were pilot-tested and included in the third round of the survey in summer 2021. The nationwide survey is conducted by a professional opinion polling institute by telephone. Data are weighted to represent the German population above 18 years. Participants (n=1’000) were informed “*In rare occasions, patients can be severely harmed when receiving hospital care. For example, they have surgery on the wrong site or receive a massive overdose of a high-risk medication. When something like this happens in a hospital* ….”. Participants were then asked (item 1) “… *which of the following actions do you think <u>are mandatory and must take place</u>?*” and (item 2) “*And what do you think <u>should be done</u>? Which of the following do you expect to happen after such an incident?*” Participants were given six specific response options, a “none of the above” and a “do not know” option. Item 3 asked “*In your view, are the following institutions and stakeholders in Germany doing everything reasonable to prevent such serious incidents?*” with response options “*yes; rather yes; rather no; no; do not know*” for each of five specific stakeholders.

Responses to the first two questions are combined in figure 1. The vast majority of the German general public believes that there are mandatory requirements for actions that must

take place after a "never event" in hospital. More than 80% of survey participants assume that hospitals are required to conduct an incident investigation, disclose the event to patients, report the incident to an official body and derive action to prevent future occurrences. More than three quarters (77%) believe an investigation of the incident by an official body is mandatory. The expectation of what should happen (rather than what is mandatory) in the aftermath of a “never event” was even stronger for each potential action. Only a minority thinks the police must (29%) or should be involved (37%). Most responders agreed that hospitals (81%) and medical offices (91%) do everything reasonable to prevent “never events”, considerably less believed that for the statutory health insurance (63%) and industry (56%). The smallest group (42%) agreed that health care policy is sufficiently engaged to prevent serious incidents.

Towards transparent accountability after “never events”

The results of our study provide first evidence that the general public strongly overestimates the mandatory requirements for hospitals in the aftermath of “never events” in the German health care system. The widely held expectation, that serious events are reported, investigated and preventive actions derived is currently clearly not met. We expect that comparable results would be obtained in countries with similar lack of regulation or policies. Our results are preliminary and need further and deeper investigation but highlight a misconception which cannot simply put aside. An accountable, “learning health care system” that strives to prevent future incidents is one the main – though often only implicit – promises of the patient safety movement and fundamental to a cooperative safety culture, including patients and the public. Patients who experienced a severe incident have a strong desire to know what the hospital did to prevent recurrences of the event, but usually do not receive information about this (4). If the public looses trust in this “learning and prevention promise”, we will remain stuck in a system of confrontation, hiding and blaming. There are different ways how transparent reporting and learning from severe incidents can be approached. For example, the UK and Norway established independent national bodies for the investigation of

serious events, HSIB (https://www.hsib.org.uk/) and UKOM (https://ukom.no/), which operate learning-oriented, systemwide and independent from the legal system (5). These safety investigation bodies will probably also serve as a "moderator" in a dialogue between the general public and the health care system about safety. Other countries with different cultures and legislation may choose other approaches than Norway and the UK. But despite specific operationalizations, we argue that all health care systems should establish an accountable reporting and investigation policy on the national level with transparent rules that meet expectations of the public and protects health care providers from blaming and legal risks. Such a policy would extend the idea of a "just culture", which surprisingly usually refers only to health care professionals and health care organizations, and does not include patients and the public, when defining the "space of justice" (6). Under such a policy, different needs and perspectives on "justice" in the aftermath of a serious "never event" would have to be sensitively balanced (7). From our perspective, procedural fairness would be central to gain acceptance by health care providers, patients and the public. Given the large differences between reality and public expectations about "never event management", we believe that without any clear, fair and transparent rules, the promise of systemwide learning after severe incidents made to the public will no longer hold.

References

1. Schwappach DLB, Pfeiffer Y. Registration and management of "never events" in swiss hospitals—the perspective of clinical risk managers. J Patient Saf. 2021;17(8):E1019–25.

2. O'Connor E, Coates HM, Yardley IE, Wu AW. Disclosure of patient safety incidents: A comprehensive review. Int J Qual Heal Care. 2010;22(5):371–9.

3. Müller A, Sawicki OA, Müller H, Schwappach D, Wendt P, Ploeger C, et al. Patient perspectives on patient safety: Results of a population-based survey in Germany. Z

Evid Fortbild Qual Gesundhwes. 2021 Oct 1;165:13–20.

4. Moore J, Bismark M, Mello MM. Patients' experiences with communication-and-resolution programs after medical injury. JAMA Intern Med. 2017;177:1595–603.

5. Wiig S, Macrae C. Introducing national healthcare safety investigation bodies. Br J Surg. 2018;105(13):1710–2.

6. Marum S Van, Verhoeven D, Rooy D De. The Barriers and Enhancers to Trust in a Just Culture in Hospital Settings : A Systematic Review. J Patient Saf. 2022;00(00):1–9.

7. Cribb A, O'Hara JK, Waring J. Improving responses to safety incidents: we need to talk about justice. BMJ Qual Saf. 2022;31(4):327–30.

Author Statements

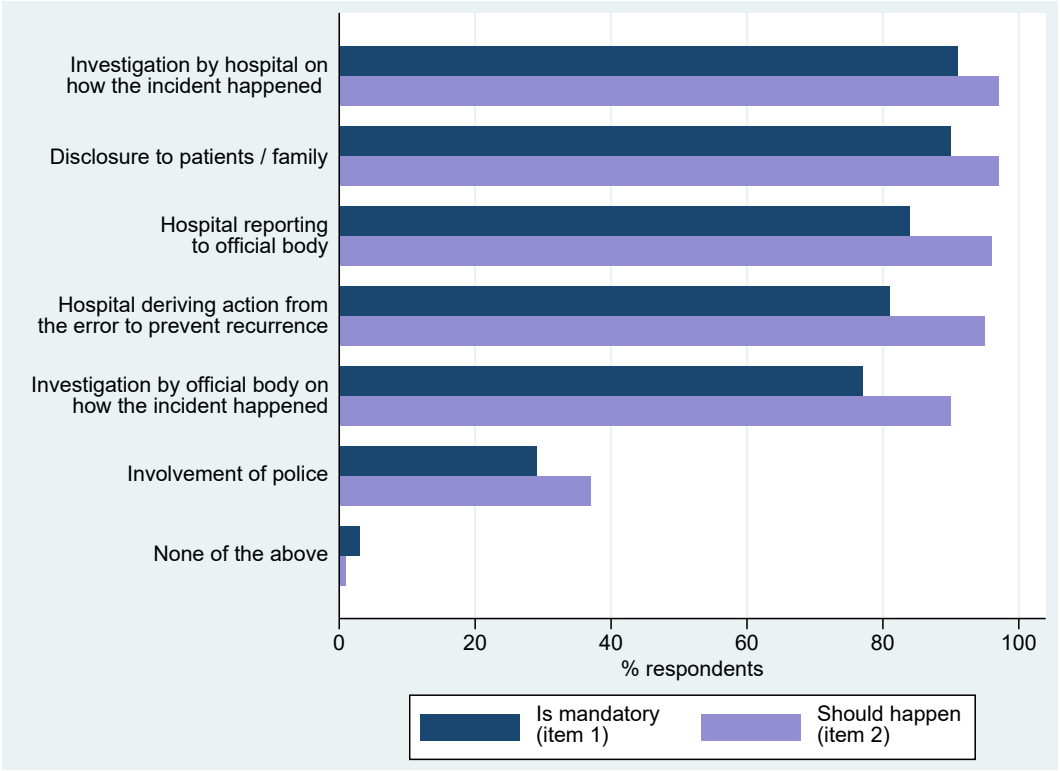
General public survey studies are not required to undergo ethical review in Germany. The polling institute which conducted the survey signed the international ethics code for public opinion research (ICC/ESOMAR Code).

The survey is conducted and funded by the Techniker Krankenkasse Germany. The funding source had no influence on the decision to publish this manuscript or on the interpretation of the data.

Figure legends

Figure 1: Respondents' assumptions about what is mandated and what should happen after a "never event" in hospitals (see text for wording of items 1 and 2)

Figure 1:


Investigation by hospital on how the incident happened
Disclosure to patients / family
Hospital reporting to official body
Hospital deriving action from the error to prevent recurrence
Investigation by official body on how the incident happened
Involvement of police
None of the above
0
20
40
60
80
100
% respondents
Is mandatory (item 1)
Should happen (item 2)

1