

1 Public expectations

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6 Perspective

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

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1 **Perspective**

2 **Public expectations on regulatory requirements for management of** 3 **hospital “never events” in Germany**

4 **Background**

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

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

7 **Public expectations about “never event” management**

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

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

1 take place after a "never event" in hospital. More than 80% of survey participants assume
2 that hospitals are required to conduct an incident investigation, disclose the event to patients,
3 report the incident to an official body and derive action to prevent future occurrences. More
4 than three quarters (77%) believe an investigation of the incident by an official body is
5 mandatory. The expectation of what should happen (rather than what is mandatory) in the
6 aftermath of a "never event" was even stronger for each potential action. Only a minority
7 thinks the police must (29%) or should be involved (37%). Most responders agreed that
8 hospitals (81%) and medical offices (91%) do everything reasonable to prevent "never
9 events", considerably less believed that for the statutory health insurance (63%) and industry
10 (56%). The smallest group (42%) agreed that health care policy is sufficiently engaged to
11 prevent serious incidents.

12 **Towards transparent accountability after "never events"**

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

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

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12 **Author Statements**

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

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

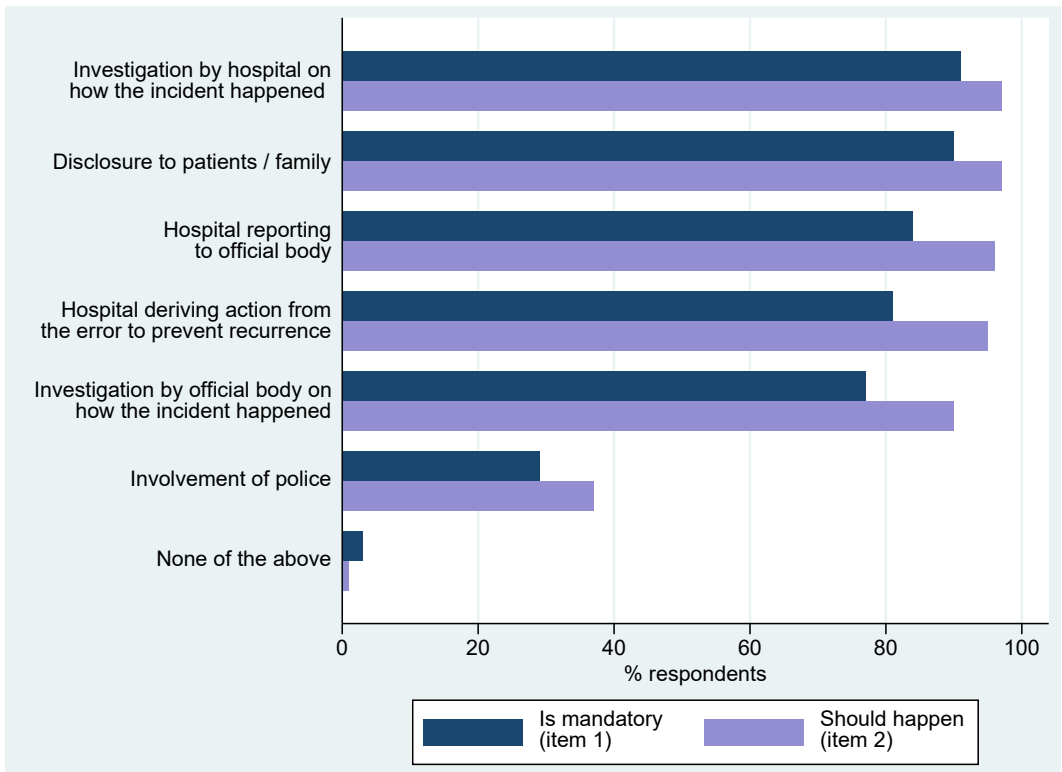
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20 **Figure legends**

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

23 Figure 1:

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