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Registration and Management of "Never Events" in Swiss Hospitals—The Perspective of Clinical Risk Managers

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Background: In Switzerland, there is no mandatory reporting of "never events." Little is known about how hospitals in countries with no "never event" policies deal with these incidents in terms of registration and analyses.
Objective: The aim of our study was to explore how hospitals outside mandatory "never event" regulations identify, register, and manage "never events" and whether practices are associated with hospital size.
Methods: Cross-sectional survey data were collected from risk managers of Swiss acute care hospitals.
Results: Clinical risk managers representing 95 hospitals completed the survey (55% response rate). Among responding risk and quality managers, only 45% would be formally notified through a designated reporting channel if a "never event" has happened in their hospital. Averaged over a list of 8 specified events, only half of hospitals could report a systematic count of the number of events. Hospital size was not associated with "never event" management. Respondents reported that their hospital pays "too little attention" to the recording (46%), the analysis (34%), and the prevention (40%) of "never events." All respondents rated the systematic registration and analysis of "never events" as very (81%) or rather important (19%) for the improvement of patient safety.
Conclusions: A substantial fraction of Swiss hospitals do not have valid data on the occurrence of "never events" available and do not have reliable processes installed for the registration and exam of these events. Surprisingly, larger hospitals do not seem to be better prepared for "never events" management.

Key Words: never events, mandatory reporting, patient safety

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Despite increasing engagement in patient safety, devastating events, such as wrong-site surgery or wrong route medications, continue to happen. A specific subset of such serious adverse events have been named "never events." They result in serious harm of patients, are clearly defined, and are deemed largely preventable if well-established safety precautions are implemented. They are thus thought to be "completely eliminable," at least in theory. As sentinel events, "never events" may also flag system vulnerability related to more frequent but less dramatic events. The term "never event" has been criticized for various reasons, e.g., because these events will keep happening more or less at random and would not reflect system safety, and because of the consequences of the term for involved professionals.[1–3] The term "never event" is related to the concept of "zero harm," which has also been controversially debated as being either unattainable and placing burden on healthcare workers or on the other side as accepting defeat.[4,5] However, the precise description of constellations of error, harm, and preventability makes the term intuitive and attractive to policy makers and the general public.

"Never events" are very rare on an individual provider level but affect a considerable number of patients on the population level. For example, in the United Kingdom, the risk of a surgical "never event" was estimated as 1 in 16,423 operations.[6] Current estimates for wrong-site surgery and retained surgical items are 1 event per 100,000 and 1 event per 10,000 procedures, respectively.[7,8] An Egyptian study reports that among 55,000 different urological interventions during a period of 10 years, 61 patients were involved in wrong surgery events, and 39 cases of retained surgical items occurred (together approximately 10 events per year).[9,10] Detailed rates of nonsurgical "never events" are currently lacking. Several "never event" lists exist internationally (e.g., the National Quality Forum List of Serious Reportable Events).[11] Some countries have established mandatory reporting systems for "never events," namely, the UK and some U.S. states, often combined with the obligation to investigate the contributing causes and to derive actions for prevention of future events. In some health care systems, "never event" data are publicly reported. Regardless of the term itself, mandatory "never event" reporting systems have been questioned, e.g., because of underreporting, lack of transparency, and poor quality of investigations.[12] In addition, it has been argued that mandatory reporting of "never events" would inhibit a positive safety culture, learning from and reflection on the events because of fears for being publicity denounced or experiencing medicolegal or financial penalties.[1] This critique, however, applies to all mandatory reporting systems for poor outcomes, not only "never events," and is grounded in the question whether compulsory measures encourage or inhibit learning.

In Switzerland, incident reporting systems are widely implemented in acute care hospitals. In 2010, 86% of Swiss hospitals reported to have a local incident reporting system.[13] Some cantons impose requirements on the management of incident reporting systems that must be met by publicly funded hospitals. Local incident reporting systems are usually managed by clinical risk managers or—in smaller hospitals—by hospital quality managers. Large variation exists in whether, how, and by whom reports are analyzed. Only 48% of Swiss hospitals in 2010 reported to systematically analyze incidents according to a standardized procedure.[13] Incident reporting systems are used for voluntary, anonymous reporting by staff and predominantly cover nonharmful errors and near misses. As these systems and the filed reports are not protected by law and thus can be used for malpractice claims, national organizations recommend not to use them for reporting of serious adverse events and events in which significant harm is expected.[14,15] Thus, in Switzerland, incident reporting systems explicitly do not cover "never events."

As in many other European countries, there is no mandatory reporting of "never events" to public or governing agencies in Switzerland. In addition, there are no formal enquiries required by regulation except for "unexpected patient deaths," which have

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to be reported to police or prosecution and of which only a fraction is resulting from error. There is also no rule, statutory requirement, law, or guideline for providers on the management of "never events" in terms of recording, documentation, and exam. Thus, no national data are available on the prevalence and types of never events, their underlying causes, or the conclusions drawn. Simply speaking, currently nobody knows how frequently such events occur and which factors contributed to them. Still, valid and systematic "never event" data may silently exist in individual hospitals. However, nothing is known about how hospitals in countries with no "never event" policies deal with these incidents in terms of registration and analyses. Unregulated health care systems are suitable to study how hospitals respond to "never events" on their own initiative.

The main aim of our study was thus to explore how hospitals outside mandatory "never event" regulations identify, register, and manage "never events." We were particularly interested in learning whether reliable local data exist reflecting the occurrence of "never events." As the prevalence of "never events" is likely to be directly related to hospital size, one could expect that larger hospitals have better defined and coordinated processes for the registration and management of "never events" as compared with smaller hospitals. We therefore investigated whether "never event" registration and management practices are associated with hospital size. Hospitals' clinical risk and quality managers were deemed the appropriate population to report their hospitals "never event"–related activities.

METHODS

This study was a cross-sectional survey study conducted among risk managers of Swiss acute care hospitals in 2019.

Survey Instrument

The survey instrument was developed based on the literature and 8 in-depth interviews with clinical risk managers from diverse hospitals. It was pilot tested by 10 risk/quality managers. The survey contained several questions about the current practice in registration and management of never events, the processes established, and the responsibilities and roles of the involved staff. At the center of the survey, we presented 8 specific never events in random order, 3 related to invasive procedures, 3 related to medication and blood products, and 2 related to general care (Table 3). This list was composed of 6 rather "classic" never events (e.g., unintended retention of a foreign object).[11] We also included 2 serious adverse events that have been discussed as never events but are not included currently on existing never event lists.[16,17] These events were "serious injury or death due to failure to respond to a deteriorating patient on a general care ward" and "serious injury or death due to spinal hematoma after elective epidural or spinal anesthesia with insufficient hemostasis." Survey participants were asked 4 specific questions after each of the 8 events: whether they could give a count on how frequently such an event occurred in their hospital in the past year; if a count would be available, whether they had confidence in the correctness of this figure; whether the event is a reportable or editable event in their hospital; and whether they had been informed about the occurrence of such an event at least once during their current employment at their hospital. We chose the approach to target these questions to specific events rather than the entity of "never events" to make the situation as explicit and precise as possible. We aimed to avoid that respondents would answer with very different ideas about different "never events" in mind or would average over their own experiences. Five additional questions addressed respondents' opinions about the importance attached to never events in their hospital, the importance of having precise counts of never event occurrence, and attitudes toward never event reporting systems. Finally, few questions addressed personal and hospital characteristics.

Sample

The sample consisted of all acute care hospitals in Switzerland, except specialty clinics, e.g., psychiatric hospitals and rehabilitation clinics (n = 174). As informants about local "never event" reporting and management, hospitals' clinical risk and quality managers were deemed most qualified as they are responsible for management of reporting systems. Clinical risk and quality management departments are commonly organized as supporting units directly reporting to hospital leadership. They usually have no authority to issue directives to clinical staff. In many smaller hospitals, quality and risk management functions are combined. In larger hospitals, clinical risk management is a dedicated function or even unit. For each hospital, the head of risk management, or, if unavailable, the head of quality management was invited to participate in the survey per e-mail with a personalized access code. Two reminders were sent. The study was considered exempt from ethical approval from the Cantonal Ethics Committee Zurich (BASEC-Nr. Req-2019-00448) on the basis of the Swiss Legislation (Human Research Act, HRA), as data assessment was anonymous, and no patient-related data were gathered.

Data Analysis

Descriptive statistics were used to report survey responses. χ^2 and Fisher exact tests were used to test for associations between survey responses and hospital size. A P value of less than 0.05 was considered statistically significant.

RESULTS

Of the 174 invited hospital representatives, 95 persons completed the survey (55% response rate). Table 1 presents personal and hospital characteristics. Most participants self-defined as quality managers. Participants can be regarded as experienced and established professionals with an average of 9 years of professional experience in clinical risk management and 12 years of working in the current hospital. The distribution of hospitals in terms of hospital size is representative for Swiss acute care hospitals excluding rehabilitation, psychiatric and geriatric hospitals ($P = 0.062$). Most respondents self-reported to be familiar (70%) or somewhat familiar (13%) with the concept of "never events." Related to their everyday work, participants reported that "never events" have central (35%) or major (38%) relevance, whereas 27% responded that they have only minor or no relevance at all. Respondents most frequently stated to be considerably involved in deriving consequences/measures from "never events" and communication with involved staff (Fig. 1). A substantial fraction (19%) reported to be not involved at all in any task related to "never events." The type of reported involvement was unrelated to hospital size of the respondent.

Current Practices of "Never Event" Registration and Management

Only half of responding risk and quality managers said that they would be formally notified if a "never event" has happened in their hospital, e.g., via a designated reporting channel (45%). Contrary, 15% responded that they would learn about the event rather informally, i.e., not because of their function as risk manager but rather through spontaneous, personal conversation. A large fraction felt that whether they would get to know about the event would depend strongly on the clinics involved (sometimes

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TABLE 1. Respondents' Personal and Hospital Characteristics

	n (%)
Respondent's sex	
Female	61 (64)
Respondent's function	
Head, clinical risk management	14 (18)
Staff, clinical risk management	5 (6)
Patient safety officer	4 (5)
Quality manager	41 (52)
Other	15 (19)
Respondent's educational background	
Nurse	30 (38)
Physician	10 (13)
Economist	10 (13)
Physiotherapist	4 (5)
Pharmacist	1 (1)
Other	23 (29)
Years of professional experience in clinical risk management, mean (SD)	8.7 (5.8)
Years of work in this hospital, mean (SD)	12.0 (10.7)
Human resources available for clinical risk management, in FTE mean (SD)	1.1 (1.9)
Hospital type	
University hospital	4 (5)
General hospital 125–500 beds	31 (39)
General hospital <125 beds	25 (32)
Specialized clinic (incl. children's hospital)	19 (24)
Hospital ownership	
Public	41 (52)
Private	38 (48)

formal, sometimes informal, sometimes not at all; 38%). Responses were not associated with hospital size (P = 0.477). Sixty-nine percent of respondents reported that there is a defined process in their hospital how "never events" are managed, especially clarified responsibilities and roles, but 30% said that there is no such clear process. Existence of a defined process was not associated with hospital size (P = 0.527). For example, 2 of the 4 university hospitals each reported (not) having a defined process for "never event" management. Related to the analyses of "never events," 64% of respondents reported that all "never events" at their hospital are examined professionally (i.e., for the underlying causes, independent of the legal processing), 25% reported that none or only few "never events" are analyzed, and 12% responded that they did not know (no association with hospital size, P = 0.592).

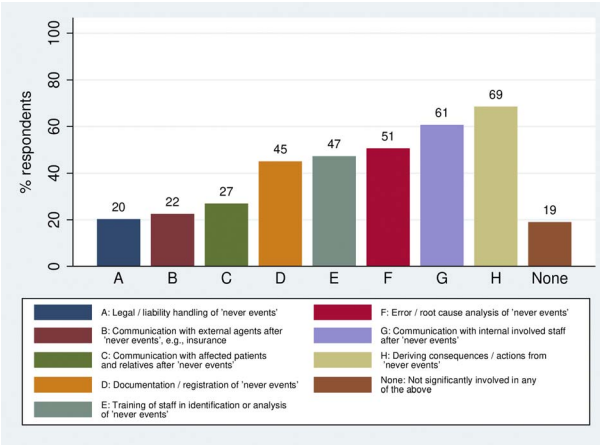

FIGURE 1. Self-reported "significant involvement" in activities related to "never events."

Table 2 reports which members of staff were considered primarily responsible for the analysis/root cause analysis of "never events." Responsibility of central risk management was more frequently reported by respondents from larger general hospitals (P = 0.007), whereas members of hospital management were more frequently mentioned by respondents from smaller hospitals (P = 0.004). When asked who *within the hospital* would be regularly informed after the occurrence of a "never event," hospital management was most frequently indicated (69%), followed by the medical and nursing heads of the affected clinic (43% each),

TABLE 2. Primary Responsibility for the Analysis/Root Cause Analysis of "Never Events"

Response Options (Multiple Choice)	n (%)
Clinical staff	27 (31)
Central risk manager	16 (18)*
Department-level quality/risk manager	30 (34)
Members of hospital management	43 (49)*
Other	19 (22)

*Significantly associated with hospital size.

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TABLE 3. Survey Responses to Eight Specific "Never Events"

Specific "Never Event"	n (%)										
	Systematic Count Available			Confidence in the Correctness of the Count*			Reportable Event			Occurrence of at Least 1 Event	
	Do Not Know	Yes	No	Cannot Tell	Yes	No	Do Not Know	Yes	No	Yes	No
Perioperative care											
1. Wrong site surgery (executed incision), e.g., wrong patient, wrong procedure, wrong site or side	16 (22%)	39 (53)	19 (26)	4 (10)	34 (87)	1 (3)	3 (4)	69 (88)	6 (8)	37 (47)	41 (53)
2. Unintended retention of a foreign object in a patient after a surgical/invasive procedure, e.g., swabs, needles	15 (20)	41 (55)	19 (25)	9 (22)	31 (76)	1 (2)	6 (8)	66 (84)	7 (9)	35 (44)	44 (56)
3. Serious injury or death due to spinal hematoma after elective epidural or spinal anesthesia with insufficient hemostasis	24 (34)	29 (41)	18 (25)	3 (11)	25 (89)	0	8 (11)	62 (82)	6 (8)	6 (8)	70 (92)
Medication and blood products											
4. Serious injury or death due to administration of medication by the wrong route, e.g., IV instead of epidural	16 (21)	39 (51)	21 (28)	13 (33)	25 (64)	1 (3)	5 (6)	68 (86)	6 (8)	36 (46)	42 (54)
5. Serious injury or death due to overdose of insulin	25 (33)	31 (41)	19 (25)	6 (19)	25 (81)	0	7 (9)	64 (81)	8 (10)	13 (17)	65 (83)
6. Serious injury or death due to transfusion or transplantation of ABO-incompatible blood components or organs	10 (14)	59 (82)	3 (4)	7 (12)	49 (86)	1 (2)	3 (4)	72 (92)	3 (4)	14 (18)	63 (82)
General patient care											
7. Serious injury or death associated with the use of physical restraints (bedrails, straps), e.g., strangulation	11 (16)	38 (55)	20 (29)	6 (16)	32 (84)	0	5 (6)	66 (85)	7 (9)	14 (18)	63 (82)
8. Serious injury or death due to failure to respond to a deteriorating patient on a general care ward	20 (26)	23 (30)	34 (44)	4 (17)	19 (83)	0	11 (14)	55 (70)	13 (16)	42 (54)	36 (46)
Mean across events	**137 (23)**	**299† (51)**	**153 (26)**	**52 (17)**	**242† (81)**	**5 (2)**	**48 (8)**	**522† (83)**	**56 (9)**	**197† (32)**	**424 (68)**

For exact question wording, see methods. Data are presented as n (%).

*Of those who responded that there is a systematic count available for this event.

† Significantly associated with hospital size.

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with no association with hospital size. When asked which *external bodies* are regularly informed after the occurrence of a "never event," the liability insurance was mentioned by 27%, the cantonal physician was mentioned by 12%, and the cantonal health directorate was mentioned by 10% of respondents (no association with hospital size). Approximately one-third reported that no external bodies are regularly informed.

Knowledge About the Occurrence of 8 Specific "Never Events"

For each of the 8 specified "never events," respondents answered 4 questions (Table 3). The events for which a systematic count would be most likely be available for were "transfusion of ABO-incompatible blood components" (82%), "unintended retention of a foreign object," (55%) and "injury/death associated with the use of physical restraints" (55%). Across all events, an average of 23% of respondents did not know whether a systematic count was available at their hospital. Confidence in the correctness of the count was highest for "spinal hematoma after elective epidural or spinal anesthesia with insufficient hemostasis" (89%) and "transfusion of ABO-incompatible blood components," (86%) whereas it was lowest for "administration of medication by the wrong route" (64%). "Wrong site surgery" (88%) and "transfusion of ABO-incompatible blood components" (92%) were most likely to be reportable events in the hospitals represented by respondents. Among all events, participants had most frequently information about the occurrence of at least 1 instance of serious "patient deterioration" (54%) and "wrong-site surgery" (47%). Averaged over all 8 events, a systematic count would be available in 51% of hospitals and 81% of respondents would have trust in the correctness of this count. The "count availability" measure averaged over the 8 events (51%) was highest among large general hospitals (55%) and lowest among university hospitals (44%; $P = 0.01$). On average over events, 32% survey participants reported that they had been informed about the occurrence of a certain event at least once during their current employment at their hospital. The average occurrence rate over the 8 events was associated with hospital size ($P < 0.001$). It was highest among representatives from large general hospitals of whom a mean of 43% reported to have experienced occurrence of at least anyone event.

Attitudes

A considerable fraction of respondents reported that their hospital pays "too little attention" to the recording (46%), the analysis (34%), and the prevention (40%) of "never events" (not associated with hospital size). No participant claimed that their hospital would pay "too much attention" to either the recording, analysis, or prevention of "never events." Most respondents rated it rather (38%) or very important (38%) for a national health system to know the exact, national incidence of "never events" (not associated with hospital size). All respondents rated the systematic registration and analysis of "never events" as very (81%) or rather important (19%) for the improvement of patient safety (not associated with hospital size). A *mandatory* reporting for hospitals about "never events" to a neutral agency if data protection and confidentiality were guaranteed was approved by 45% and disapproved by 47% of respondents, the remainder being neutral (not associated with hospital size). A *voluntary* reporting for hospitals about "never events" to a neutral agency if data protection and confidentiality were guaranteed was approved by 62% and disapproved by 29% of respondents (not associated with hospital size), the remainder being neutral.

DISCUSSION

This study is the first to explore "never event" registration and management practices in a health care setting without a national policy or mandatory reporting system. If "never events" were reliably registered on the local level, such decentralized data could be collected, merged, and beneficially used for system-wide analyses, maybe after anonymization. In our study, many of the participating risk managers reported that they had been informed about the occurrence of at least 1 of 8 specified "never events" during their current employment, indicating that these serious incidents do occur with nonnegligible frequency. The finding that respondents from larger hospitals were more likely to report occurrence of specific past events confirms our expectations that incidence is related to hospital size. This also validates responses as a correlation between never event frequency and patient volume or surgical caseload has been documented.[6]

However, our results clearly show that a substantial fraction of Swiss hospitals do not have valid data on the occurrence of "never events" available and do not have reliable processes installed for the registration and exam of these events. Surprisingly, larger hospitals do not seem to be better prepared for "never event" management. Nearly half of hospitals do not have designated reporting channels for "never events" that involve clinical risk managers. Even for established and rather well-defined events such as wrong-site surgery, only half of participants confirmed that the hospital would be able to provide a systematic, reliable count. This is even more alarming as we explicitly specified in the survey question that "zero" would be regarded a count if the absence of any case had been verified. We are thus quite confident that survey responses are not a product of misunderstanding the question, i.e., nonoccurrence of events in the past, but reflect unsystematic internal reporting and documentation correctly. This interpretation is supported by the subjective view of many risk managers that their hospital pays too little attention to the recording of never events. Irrespective of systematic event registration, it is concerning that one-third of hospitals reported that not all "never events" are analyzed for causes and contributing factors. This may be due to lack of resources or expertise at the hospitals. However, in combination with the nonexistence of a central reporting and investigation body, this means that many serious incidents simply go uninvestigated and are neither used for local nor accessible for system-wide learning and corrective action. Experiences from countries with system-wide "never event" reporting show that analyses of such events can indeed initiate questioning of current and the development of new, hopefully, safer practices. For example, the occurrence of severe injury due to misplacement of nasogastric tubes, a defined "never event," has led to several investigations, and development and evaluation of new practices addressing real-time image interpretation issues among radiographers in the United Kingdom.[18–20] Including wrong tooth extraction explicitly as a subcategory of wrong-site surgery lead to an increase in professional activity related to "never event" definition and prevention in dentistry.[21,22] Professional activities are motivated and strengthened if it is clear that serious events continue to happen, abstracted from the singular event at a single hospital. In contrast, having single hospitals carrying out their own analysis in isolation, learning from them, and deriving purely local measures seems unrealistic and not promising, in particular in small countries.

Our study shows that under unregulated conditions, "never events" not only are untracked on a national level but also receive relatively little attention at the local level and commonly no mechanisms are installed to learn from them systematically. The idea of hospitals addressing these events successfully individually "in silence" is misguided in many instances. Even if all events would be

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thoroughly analyzed locally, the conclusions drawn may be misleading. Systematic constellations and contributing factors common to a set of events may not be identified in single, detached rare events. Misinterpretation as "human failure" may be more likely when analyzing a single local event rather than when seeking communalities in a set of events. Aligning corrective, effective action to system problems is complex and cannot be expected from single institutions without the required expertise and resources available.[23] However, without any reliable data available, "never events" seem not to exist at the national level. Not all "never event" data need necessarily be acquired through a dedicated national "never event" reporting system. For some "never events," other data sources, such as clinical registries, may be more suitable for identification. For example, Odgaard et al[24] investigated the incidence of accidental high-risk component incompatibility in hip and knee arthroplasty based on the Nordic arthroplasty registry. However, such approaches may not be available for most "never events" at least in the near future. In addition, clinical registries and hospital statistics will usually not provide substantial information surrounding the incident making such data often useless for analysis.

It is striking that most surveyed risk/quality managers agreed on the importance for a national health system to know the exact, national incidence of "never events" but less than 50% supported a mandatory reporting system. We can only speculate on the reasons underlying this obvious divergence. For example, lack of support for a mandatory "never event" reporting system could be based on experiences with the few mandatory reporting systems existing in Switzerland, e.g., pharmacovigilance. Shedding more light on the reluctance toward mandatory reporting systems even when their purpose to generate reliable data is well supported remains a target for future research.

LIMITATIONS

Our study has 2 main limitations: first, with the response rate of 55%, we cannot rule out response bias with respondents interested in "never events" may have been more likely to participate. This, for example, may have affected responses to the attitude questions. In terms of hospitals size, the sample is representative. For example, 4 of the existing 5 Swiss university hospitals participated in our study. Second, our informants were clinical risk and quality managers. It is possible that they are unaware of specific processes and policies related to "never events" as such incidents may be entirely managed by liability officers (large hospitals) or hospital management (smaller hospitals). However, the average respondents in our sample held many years of expertise and employment in their hospital, and it seems unlikely that these persons would not have valid information about a well-established "never event" management in their hospital if this existed. It seems more plausible that respondents correctly and honestly reported about the lack of stringent procedures of "never event" management. In particular, in larger, academic hospitals, serious adverse events may be identified and reviewed through various processes with little consistency and coordination,[25] for example, in mortality and morbidity conferences, which are quite well established in Switzerland.[26] The explicit example events we presented included typical "never events," e.g., wrong-site surgery, and events not specifically included on existing "never event" lists, e.g., patient deterioration on a general care ward. The different response patterns to these types of events strengthens our trust in the capability of surveyed risk managers to give a realistic account of never event management in their hospitals. For example, serious deterioration of patients was the event most commonly reported to have occurred at least once but at the same time is the event for which the lowest percentage of respondents could report a systematic count. This seems to accurately resemble the fact that these events occur more frequently than other "never events" but are hard to define precisely and unambiguously.[16]

CONCLUSIONS

To the best of our knowledge, this is the first study to report about hospitals' practices related to "never events" in a healthcare system without mandatory reporting or regulation of event management. Our results reveal that under such conditions, many hospitals do not have reliable processes installed for the registration and exam of "never events." It is of particular concern that one-third of hospitals do not analyze all "never events" for causes and contributing factors. Although many hospitals try to learn locally from their "never events," risk managers feel that too little attention is attached to "never events." As no systematic data on the occurrence of "never events" exist on the local level, currently, no national data would be available for monitoring of system safety and many opportunities for improvement are lost. Every national health system should have an estimate of the frequency of devastating, largely preventable serious events and a robust strategy to ensure that system-wide investigation and learning occurs. Based on the data we obtained in this study, we are not convinced that leaving this entirely up to the individual hospital is such a strategy.

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