**Perceptions of Professionals About the Definition of Surgical “Never Events”**

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Acknowledgement:

This study was funded by grant #MOHIG 14-2019 from the Medical Research Fund for Health Services–Jerusalem.

Keywords: Never event, Definition, Surgery, Operating room, Patient safety, Profession

Abstract, 255 words

**Background:** Surgical “never events” (NEs) have a formal definition created by the National Quality Forum and adapted by international health organizations. However, clinicians and risk managers may perceive these events differently. This study explored perceptions held by operating room (OR) clinicians and risk managers about the formal definition and aspects of NEs.

**Methods:** From September to December 2019, data were gathered through semistructured interviews with OR clinicians (physicians and nurses) and risk managers from hospitals and the Israeli Ministry of Health. The interviews were analyzed using a 6-phase inductive thematic analysis approach to identify themes related to perceptions of the definition of NEs.

**Results:** Data were gathered from 25 participants (19 OR clinicians and 6 risk managers). Whereas risk managers endorsed the formal definition of NEs, clinicians suggested modified definitions (anesthesiologists suggested “unexpectedly occurring events”; surgeons, “inappropriate preparedness”; nurses, “preventable events for which they are accountable”; and risk managers, “events that harm patients”). Surgeons and nurses thought the events could be prevented by training or safety standards, whereas anesthesiologists and risk managers thought the events were unpreventable. Perceptions of incidence also varied; physicians viewed the events as rare and nurses as common.

**Conclusions:** The study’s results suggest that clinicians and risk managers may have different perceptions of the formal definition of NEs and might not share the same mental model during surgery. We recommend reassessing the definition of NEs and adjusting it according to surgery types and the roles of clinicians during surgery. Such modification requires implementing team communication to maintain a shared mental model.

Main article, 3508 words

The first axiom regarding potential medical errors that occur because of medical care is the Hippocratic injunction of *primum non nocere* (first, do no harm).1 This axiom is being tested when a “never event” (NE) occurs.

Never events were first defined by the National Quality Forum (NQF) in 20012 as serious events that are largely preventable and of concern to the public and to health care providers, with a goal of reducing them by quality improvement.3 The definition involved the setting of standards by voluntary consensus among stakeholders2 and described shocking medical errors that should never occur.4

Surgical NEs include surgery or invasive procedures performed on the wrong site or the wrong patient, performing the wrong surgical or invasive procedure, unintended retention of a foreign object in a patient’s body after surgery, and intraoperative or immediately postoperative death.5

To prevent surgical NEs and perform a safe surgery, the participating team members should share a mental model regarding perioperative risks and errors.6,7 Also, the perceptions of NEs should be based on a mutual understanding of the situation during the surgery among the participating team.8-11 Thus, when team behaviors differ during the surgery, it indicates different and conflicting interpretations of the surgery that may affect its safety.12

When analyzing interpretations of the NQF definition of NEs, a SAFER report showed that surgical NEs were rephrased implicitly or with variation by states and team members. For example, “wrong surgical procedure” was rephrased as surgery on the wrong patient, wrong site, or wrong body part.13 Another study showed that anesthesiologists were aware of the formal definition of NE but had their own personal definition that related to the speed of onset of the event and its potential severity.14

In 2011, the NQF updated its definition of NEs and added the aspect of prevention of these events.15 The US Center for Medicare & Medicaid Services interpreted the definition as surgical events and serious hospital-acquired conditions and also incorporated the aspect of prevention by implementation of standardized protocols.16 In addition, a systemic review by Jung and colleagues17 showed that the definition of surgical NEs included the added concept of unintended and unanticipated events caused by medical teams and not the patient’s underlying conditions.

The aim of this study was to examine perceptions of operating room (OR) clinicians (physicians and nurses) and risk managers regarding the definition of surgical NEs. We solicited comprehensive answers regarding the participants’ interpretations of the definition of NEs, and we used qualitative analysis methods because they inform the understanding of how and why health care professionals behave as they do.

**Methods**

*Design, settings, and participants*

Semistructured interviews were conducted with study participants from general hospitals of various sizes and locations and with risk managers from the Israeli Ministry of Health (MOH), who have the regulatory role of policy makers. Some of the study participants were clinicians who worked in ORs (such as physicians—anesthesiologists and surgeons—and nurses), and some were risk managers (physician and nurses). We performed a purposive recruitment of participants.18 The preference was for participants with an administrative position who had a systemic view of NEs, from hospitals that varied in type, size, and location. for the studyMOH, Participants provided verbal consent to participate and received no compensation for their participation. Characteristics of the study participants are described in the Table.

*Study tool*

A literature search revealed that few studies have analyzed aspects of the definition of NEs, and no studies were found that have analyzed those aspects based on clinical professions. The interview guide was developed based on opinions of surgery and risk management experts and on causes of NEs based on literature review.19 The semistructured interview guide (Appendix) evaluated aspects of the definition of perioperative NEs. To pilot test the interview guide, 2 pilot interviews were performed with 2 participants. One question was omitted as a result of the pilot interviews. The data from the pilot study were added to the final analysis.

*Interview process*

Interviews were conducted from September to December 2019 by a single team member (DA). The interviews were recorded and transcribed verbatim. All names of participants were changed to pseudonyms. The interviews were conducted in person at the participants’ offices and lasted, on average, 20 minutes each. Field notes were taken during and right after each interview and described the participants’ familiarity with components of the NE definition and any nonverbal reactions such as anger or discomfort.

*Data analysis*

The researchers entered information manually from the transcripts into Microsoft Excel, version 16.0 (Microsoft Corporation), using the 6-phase inductive thematic analysis approach as described by Braun and Clarke20: (1) familiarization with the data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing the report. Two investigators (DA, AF) read and reread the entire data set and systematically coded the transcripts independently. Codes were then grouped into emergent themes after iterative reading and discussion with 2 other authors (RM, RR). The whole team met several times throughout the analysis process to discuss disagreements and refine and label the themes and subthemes.

**Results**

*Study sample*

The study included 25 participants (out of 25 approached) from 9 hospitals. They included 17 OR clinicians (physicians [anesthesiologists and surgeons] and nurses) and 8 risk managers (physicians and nurses) (Table). Participants were from hospitals and the MOH. The hospitals were heterogeneous in size and location. Four hospitals were large (>800 beds) and urban and were defined as trauma centers; 3 were medium-sized (400-800 beds) and rural, 1 of which was also a trauma center; and 2 were small (<400 beds)—of these, 1 was rural and the other was urban and provided only surgical care.

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*Main themes*

Two main themes were identified: Professionals’ perceptions of the formal definition of NEs and its aspects and perceptions regarding the probability of occurrence of NEs in regard to their incidence and unpredictability.

*Professionals’ perceptions of the definition of NEs*

The participants’ perceptions of the definition of NEs included their perceptions of the formal definition as per the NQF and their perceptions of 2 main aspects of the definition: severity and preventability. Risk managers endorsed the formal definition of NEs, whereas most of the OR clinicians suggested modifying the definition based on their own role during surgical procedures and stressed that avoiding errors was important to the success of the surgery.

The OR physicians and nurses related to the literal concept of NEs—nurses as “events that must not happen” or “errors that should never happen” and surgeons as “events that should never happen.” An anesthesiologist said, “Events that mustn’t happen— that is why they are called ‘never events.’” These clinicians suggested modifying the definition to any event that risks the success of the surgery, but this was based on their own professional role in the surgery. For example, a majority of the anesthesiologists defined an NE as a surgery with an unexpected occurrence of events, not a routine surgery, including “unexpected death during surgery,” “wrong blood transfusion,” “wrong organ anesthesia,” and “wrong medication administration.” Nurses related to their role of being accountable for the patient’s safety: '”If I want the patient not to fall, I will stand next to him and make sure the stretcher is braked while he is being transferred.” One surgeon viewed inappropriate preparedness for the surgery as an NE: “For me, a ‘never event’ is nonsharpened scissors.”

Risk managers related to the formal regulatory definition of NEs without modification—for example, “[The] MOH has a policy defining ‘never events,’” “There is a definition [from] the MOH,” and “In the OR, there are 3 types of ‘never events’: error in patient identification, wrong site surgery, [and] surgery to the wrong patient.” However, regarding the list of NEs in the formal definition, some risk managers suggested adding events that create potential harm for patients: “Loss of tissue,” “It mustn’t happen [for] somebody [to go] through a surgery in order to know if he has cancer or not,” and “The issue of patient identification should be a critical aspect in ‘never events’ and should be expressed.”

*Perceptions of the severity and preventability of NEs*

All participants also described their perceptions of 2 aspects of the formal definition of NEs: severity and preventability, as shown in the Box. There was a consensus among most of the participants that severity is an essential aspect of the definition of NEs and is related to the complexity of the work environment in ORs and to the characteristics of each surgical procedure. An anesthesiologist further described the importance of the anesthesiologist’s role to quickly decrease the severity of an occurring event with a quick response.

 Moreover, a surgeon stated that an NE in the OR indicates a serious safety hazard that results in a severe event. However, 1 risk manager stated that these events should be graded based on the severity level of the individual event.

Another aspect of the definition of NEs is their preventability. The participants had different perceptions about this aspect. Operating room nurses and risk managers agreed that NEs should be prevented by using tools such as training, awareness, and work protocols*.* For example, OR nurses referred to the importance of adhering to safety standards as a tool to prevent errors. However, they thought that some errors cannot be prevented by safety standards alone owing to human errors.

Among the surgeons, few thought that proper training can assist in preventing NEs, whereas others said that some events are not preventable owing to the inherent risks in some procedures, such as the combination of electricity and oxygen that can lead to a burn.

Anesthesiologists thought that not all NEs are preventable and described situations of “force majeure” in which events are not preventable*,* such as a patient’s fall or a surgical burn, which can occur even if standards are upheld.

*Perceptions of the probability of NEs*

Regarding the probability of occurrence of NEs, participants described the relationship between the perceived incidence of the events and the ability to predict them. Perceptions of incidence varied among OR clinicians. Nurses perceived these events as common: “In my opinion, they are very common, especially in regards to their severity,” and “Common events. There are patients [who] fall, burns during surgery, and problems with surgical counts.” Surgeons and anesthesiologists perceived the events as rare and related to the implementation of safety standards in the OR: “The events are rare because everybody implemented correct signing, [which] was the major issue in these events…Lack of following work protocols is very simple; it is caused by distraction, working at night, and burnout,” and “Very rare; it might happen [once] every few years.”

One risk manager thought that the incidence of such events should not be taken into consideration: “[It is] enough that this event will occur once—there is no issue of prevalence.” However, other risk managers described characteristics of surgical procedures in which there is a higher incidence of NEs:

“OBGYN (obstetrics and gynecology) is [a] high-risk specialty since many surgeries are urgent…also trauma surgeries because the team skips the safety standards due to the urgency.”

“In general, when the surgery is more complicated, the chance for [a] ‘never event’ is higher because when one needs to give attention to so many details, he starts creating shortcuts and doing things automatically.”

“In paired organ surgery, the staff can replace by mistake the size of the organ operated.”

*Unpredictability* *as a suggested aspect of the definition*

Anesthesiologists and OR nurses suggested that unpredictability is an aspect that should be added to the definition of NEs to emphasize that not all such events can be predicted or assumed to happen or not happen. Anesthesiologists described unpredictability as unplanned deviation from a routine work process owing to the dynamic work environment in the OR, which was related to their perceptions of such incidents as rare events: “An adverse event that surprisingly occurs within our usual routine and is exceptional and unusual.” Another described an “esophageal intubation, unidentified, that caused the patient severe harm. A case of unpredictable wrong use of equipment, that we did not [take] notice of, during bronchoscopy that caused the patient harm.”

Nurses who perceived NEs as common thought that the length of surgical procedures contributes to the possibility of the occurrence of NEs. Some thought that short surgeries are associated with high risk: “In shorter surgeries like laparoscopic and eye surgery (such as cataract), the risk of retaining absorbing materials is less common,” and “The truth is, the reason for the fire was because they did not wait enough time for the chlorhexidine to dry, because in shorter surgeries, they rush.” Other nurses thought that NEs can occur more often in long surgeries: “A long surgery can be calm and organized, but when it requires [multiple] surgeons, errors can occur.” Surgeons did not relate to unpredictability as an essential part of the definition of NEs.

**Discussion**

During the past decade, there has been a consensus among international health organizations regarding the formal definition of surgical NEs.21-23 The definition was created as a consensus standard by a steering committee of stakeholders and policy makers5 rather than relying on perceptions of direct health care providers.

This study aimed to analyze perceptions of OR clinicians and risk managers regarding the definition of NEs. We assumed that the characteristics of the study’s participants (profession, years of experience, position, and place of work) would provide a wide range of systemic perceptions of the definition.

Studies show that listening to employee voices is crucial to promote safety and thus should be taken into consideration.24 For example, 345 general-practice team members in Scotland stated that NEs cause (or have the potential to cause) severe harm to a patient, are preventable, can be clearly and precisely defined, can be detected, and are not the result of an unlawful act.25

Surprisingly, we found no consensus regarding the formal definition of NEs among OR clinicians who participated in this study, which suggests that they do not have a shared mental model regarding NEs. Whereas other studies showed that the initial perception of a definition is based on its literal meaning,3 the results of this study showed that clinicians modified the definition based on their role in a surgical procedure and its success (surgeons in performing, anesthesiologists in stabilizing, and nurses in coordination and assistance). This may be explained by different importance goals of the participating professional groups: surgeons care about economy, efficiency, and quality of care; anesthesiologists care about employee satisfaction; and nurses care about satisfaction as well.26-28 Another explanation is that people feel free to choose their actions to the best of their knowledge and practice in the situation of surgical procedures.3

Risk managers modified the formal definition of NEs, as well, but their perception was directed toward potential risks to patient safety, adding the aspect of potential harm to the definition. Their view may be explained by their role as patient safety promoters and error preventers.29-31

The incidence of NEs was perceived differently by OR clinicians. Whereas OR physicians stated that NEs are rare, OR nurses said they thought NEs are common. A systemic review by Hempel et al32 showed that estimates of the incidence of surgical NEs vary and can be influenced by the dynamic work environment in the OR.33-35

This study’s results suggest adding an aspect of unpredictability to the definition of NEs as a contributing factor to their occurrence. In general, NEs are hard to predict, because they are rare and widely distributed. Also, safety standards have not been found to predict the occurrence of NEs and are a concept related to specific surgical specialties or hospitals.36 An analysis by Fry et al37 revealed that patient characteristics and procedural interventions can increase the occurrence of 6 of the 8 postprocedural infections that are defined as infectious NEs.

Characteristics of the surgical procedure can contribute to the occurrence of NEs as well. For example, urgent surgeries or head and neck surgeries are at high risk for surgical burns. Length of the surgery was mentioned by participants in this study as a contributing factor to the occurrence of NEs, although interpretations regarding the specific surgery length varied, perhaps because compliance with safety standards is affected when the staff rush and skip some of the steps of the standards.38 Risk managers in this study also mentioned additional risk factors for certain surgical procedures such as paired organ surgeries. Studies have shown that checklists, especially when prospectively tailored to a particular context, may be helpful and their use sustained in practice.39

This study has several limitations. First, we focused on clinicians’ and risk managers’ perspectives from their administrative role, which may have caused a bias compared with perspectives of individuals in frontline positions. Second, we were unable to obtain an in-depth understanding of the cultural environment of the participating organizations, which may have affected the participants’ perspectives. Third, because this study was qualitative, the perceptions revealed may not statistically represent the entire population of health care professionals.

This study revealed that there was no shared mental model among the participating OR team members and risk managers regarding the definition of surgical NEs. Also, the definition was not tailored to the characteristics of particular surgical procedures or to the specific roles and mission of the participants during surgical procedures.

Therefore, we recommend reassessing the definition of NEs based on the perceptions observed in this study—for example, tailoring the definition of NEs in relation to characteristics of surgical procedures, such as their length, urgency, and complexity, and considering the addition of aspects of unpredictability to the definition. The tailored definition should then be mediated by team communication dedicated to maintaining a shared mental model of the definition of NEs.

Further research is needed, including quantitative studies to statistically evaluate professionals’ perceptions of the definition of NEs and qualitative studies to analyze the shared mental model of NEs and the safety level in ORs regarding the occurrence of these events.

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|  | **R, No. (%)**  |
| ,  |  (12) (40) (40) (8)  |
| Sex  |  (40) (60) |
|  perating room     |  (24) (12) (32) (12) (20) |
|    |  (100) |
| E, y  |  (20) (28) (40) (12) |
| E, y  |  (36) (36) (8) (4) (16) |

Appendix: Interviewguide

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| Discussion topics | Examples of questions |
| Attitude toward “never events” in operating rooms in Israel | How would you define “never events” in operating rooms? PROBE: Are there different types of “never events” in operating rooms? PROBE: Preventable vs. not preventable |
| Personal experience with “never events” in the operating room | Have you been exposed to a “never event” in the operating room? If yes, can you please tell me what happened? PROBE: In your opinion, what were the main causes of the “never event” in this case? PROBE: Do you think the “never event” in this case was preventable? PROBE: Do you have any suggestions for how to avoid a case like that in the future? |