**TITLE PAGE**

**What is the concept of Surgical Never Event? Perceptions of Interdisciplinary Professionals**

**Running title: Surgical Never Events and Perceptions of the definition**

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TITLE: **What is the Concept of Surgical Never Event? Perceptions of Interdisciplinary Professionals**

Running title: **Surgical Never Events and Perceptions of the definition**

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**ABSTRACT**

**Introduction:** Never Events are preventable medical errors with serious patient safety consequences, characterized by significant morbidity and mortality, some of the defined Never Events are surgical ones. Despite the development of a consensus formal definition and extensive efforts to eliminate serious surgical Never Events, they persist. The surgical interdisciplinary team should share mental model in regards to their role and situation to function collaboratively.

**Design:** This qualitative design study aimed: a) to assess the perceptions of the definition of Never Events among operating room clinicians and risk managers, and b) to assess the implications of their perceptions for practice.

**Methods:** 25 Operating Room professionals and risk managers from Israeli hospitals and Ministry of Health undergone a semi-structured interview according to the guide that was developed by experts' panel. The transcripts from the interviews were analyzed using a 6-phase inductive thematic analysis approach.

**Results:** The views and perceptions of a Never Event varied by profession while physicians described the incidents as rare compared to the nurses who saw them as a common. While agreeing such events are severe, mental models about preventability were mixed, with surgeons and nurses thinking that training and/or safety standards could prevent them, and anesthesiologists and risk managers considering them to be unpreventable.

**Conclusion:** Interprofessional Operating Room clinicians have different mental models about the definition and preventability of a Never Event. Nurses play a key role in identifying potential risks and preventing errors.

**Clinical relevance:** While a consensus definition of Never Events exists worldwide, different perceptions of professionals may lead to increased risk to patient safety and the efforts to reduce the events. Our findings suggest the definition should be modified according to the professional role and that the team perceptions should be assessed and addressed in order to encourage a shared mental model to improve teamwork and practice.

**KEYWORDS:** Never event, surgery, patient safety, mental model, nurses, physicians

**INTRODUCTION**

Adverse medical events can lead to significant morbidity and mortality and increase healthcare expenditures (Kjellberg et al., 2018). Never Events are preventable medical errors with serious consequences that were first defined by the National Quality Forum in 2001, as an outcome of voluntary stakeholder consensus process (Kizer & Stegun, 2005). Although the definition has varied somewhat and has evolved over time in different countries, several elements are typically present in all definitions (Joice et al., 2013, Robert et al., 2015). Jung et al. (2019) suggested an additional concept of unintended and unanticipated events caused by medical teams and not by the patient’s underlying conditions. Surgical Never Events, a subset of Never Events, include performing surgery on the wrong site or the wrong patient, performing the wrong surgical procedure, and unintended retention of a foreign object in a patient’s body after surgery, intraoperative or immediately postoperative death in otherwise healthy patients (NQF, 2021).

Multiple efforts have been undertaken to prevent surgical Never Events worldwide, beginning with the surgical safety checklist developed by the World Health Organization (WHO, 2009; Stawicki et al., 2009; Kumar & Raina, 2017). Other efforts include quality improvement training, root cause analysis, and team huddles. One of the important elements among organizational strategies for eliminating never events are efforts to promote a patient safety culture (Moppet & Moppet, 2016), an effort that includes listening and relating to employee voices (Martin et al., 2020), and encouraging effective interprofessional teamwork, intraoperative communication, and ability to manage disruptions (Mathew et al., 2018). An additional attribute of high functioning teams are shared mental models in relation to safety (Aveling, et al., 2017).

Mental models are individually held knowledge structures comprised of the attributes of content, similarity, accuracy, and dynamics. In the context of teams, shared mental models can help team members to function collaboratively (McComb & Simpson, 2014).

A literature search revealed that a few studies have analyzed interprofessional mental models in the Operating Room (Brown et al., 2012, Aveling et al., 2018), but have not directly probed views on the fundamental definition of Never Events. Brown et al. (2017) found that variability in mental models hampered communication among members of a cardiac perioperative team at critical care transition points. Schiff et al. (2018) determined that uptake of a training tool for improving teamwork was hampered by variable mental models among members of a surgical gynecology team. A study of Göras et al (2020) notes that mental models are created by shared planning to improve safety. However, their study did not explore the underlying characteristics of varying mental models. Perhaps most relevant is the work of McComb, et al. (2017) which found that physicians and nurses have significantly different mental models, as reflected in their divergent views on who is responsible for a number of activities closely related to patient safety, including patient advocacy, identifying errors and near misses, and medication reconciliation.

Generally, clinicians choose their actions during surgical procedures based on their knowledge and practice (Flug et al, 2018). Little is known about the perceptions of professionals and their mental model in regards to the concept of Never Events. This study aims to assess the perceptions of the concept of Never Events among Operating Room clinicians and risk managers in order to achieve a better understanding of their mental model and its implication on practice.

**DESIGN**

We conducted a qualitative study based on data from semi-structured, in-person interviews with the 25 Operating Room professionals (see Table 1). The interviewees were selected using a purposive recruitment (Cheung et al., 2019) from different general hospitals. Inclusion criteria were participants with an administrative role who had frontline and systemic views of Never Events in the OR. Exclusion criteria were participants who are trainees or staff members without an administrative role. In-person interviews were conducted at participants’ settings from September to December 2019 by one of the study’s authors (DA) and were recorded and transcribed verbatim. The interviews lasted, 20 minutes each on average.

**MATERIALS & METHODS**

The semi-structured interviews were performed according to a literature-based guide that was developed by the authors and validated by surgery and risk management experts (Thiels et al., 2015). The guide included open-ended questions specifically intended to explore the participants’ mental model with regard to aspects of the definition of perioperative surgical Never Events (see Table 3). To evaluate the guide, two pilot interviews were performed, resulting in an omission of one question. The data from the pilot study were added to the final analysis. Field notes were taken during and immediately after each interview. The interviewers described the participants’ familiarity with components of the Never Events definition and recorded any nonverbal reactions such as anger or discomfort during the interview.

**Data Analysis**

The researchers entered manually an information from the transcripts into Microsoft Excel, (version 16.0), using the 6-phase inductive thematic analysis approach as described by Braun and Clarke (2006): (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 of the study’s authors read and reread the entire data set and systematically, and independently, coded the transcripts. Codes were then grouped into emergent themes after iterative reading and discussion with two different authors. The entire team met several times throughout the analysis process to discuss disagreements and refine and label the themes descriptively and interpretatively ((Lindgren, Lundman & Graneheim, (2020).

**RESULTS**

***Participants***

The participants were employed at nine diverse Israeli hospitals or at the Israeli Ministry of Health. Although all subjects currently hold administrative positions, 19 of the 25 have also worked (currently or previously) in Operating Rooms. The risk managers from hospitals and the Ministry of Health have a role in risk assessment in the OR and policy development accordingly. The hospitals included four large urban trauma centers (>800 beds); three medium-sized (400-800 beds) rural centers, one of which was also a trauma center; and two small centers (<400 beds), one rural and the one urban, providing only surgical care.

***Main themes***

Two main themes were identified: professionals’ perceptions of the formal definition of Never Events; and perceptions around various characteristics of the definition of Never Events.

***Professionals’ perceptions of the formal definition of Never Events***

The participants shared their perceptions on the definition of Never Events. Risk managers endorsed the formal definition, whereas most of the Operating Room clinicians suggested modifying the definition. These clinicians suggested a broader definition to include any event that puts the success of the surgery at risk, but this was based on their own professional role in the surgery. For example, 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 a Never Event: “For me, a ‘never event’ is non-sharpened scissors.” And a majority of the anesthesiologists defined a Never Event as a surgery with an unexpected occurrence of events, including “unexpected death during surgery,” “wrong blood transfusion,” “wrong organ anesthesia,” and “wrong medication administration.”

Risk managers related to the formal regulatory definition of Never Events with a modification to patient's harm—for example, “There is a definition [from] the Ministry of Health,” and “In the Operating Room, there are three types of ‘never events’: error in patient identification, wrong site surgery, [and] surgery to the wrong patient” and suggested adding "Loss of tissue should be included in the definition….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’.”

***Perceptions of Various Characteristics of the Definition***

Incidence and Measurability of Never Events

Perceptions of incidence of Never Events varied among nurses and physicians. Nurses perceived these events as common: “In my opinion, they are very common, especially with regard to their severity,” and “…common events. There are patients [who] fall, burns during surgery, and problems with surgical counts.” Surgeons perceived the events as rare and related to the implementation of safety standards in the Operating Room: “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 “[A Never Event is] very rare; it might happen [once] every few years.” Anesthesiologists thought that the events are rare but unpredictable and thus hard to measure due to the dynamic work environment in the Operating Room: “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.”

Risk managers thought that some characteristics of the surgery might increase the incidence of Never Events. These characteristics challenge the measurability of an incident since they consider some errors to be unpredictable. One noted that 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.” Another pointed out that, “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, one starts creating shortcuts and doing things automatically.”

Severity and Preventability characterizing the Definition of Never Events

All participants described their perceptions of two characteristics of the definition of Never Events: severity and preventability, as shown in the Table 2. Severity was explained as the potential for severe patient harm from Never Events. There was a consensus among nurses and physicians that severity is an essential element of the definition and is related to the complexity of the surgery and the work environment in the Operating Room. An anesthesiologist further described the importance of the anesthesiologist’s role in quickly decreasing the severity of an occurring event with a rapid response. Moreover, a surgeon stated that a surgical Never Events indicates a serious safety hazard in the Operating Room that resulted in severe patient harm. Even though, there was a consensus regarding the severe outcome of Never Events, a risk manager thought that these events can be graded by their potential severity.

Preventability was referred to as the possibility of preventing these events through increased awareness, training, and work protocols, or as the possibility that these events are unpreventable due to human errors or characteristics of the surgery. Nurses thought that Never Events should be prevented by using tools such as training, awareness, and work protocols*.* For example, they referred to the importance of adhering to safety standards as a tool for preventing errors. However, they thought that some errors cannot be prevented by safety standards alone, owing to human errors.

Among the surgeons, a few thought that proper training could help prevent Never Events, whereas others said that some events are not preventable due to the inherent risks in some procedures, such as the combination of electricity and oxygen that can lead burns. Anesthesiologists thought that not all Never Events 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.

**DISCUSSION**

Since the initial definition of 'Never Events' by the NQF at 2001 (Kizer, 2001), other health care organization worldwide and in Israel adopted a similar definition and it has become a consensus definition (National Patient Safety Agency, 2010; World Health Organization, 2009). This study aimed to assess perceptions of professionals to the definition of surgical Never Events, since different perceptions may influence the efforts to reduce them. We found different perspectives in regard to the scope of a Never Event, its definition and characteristics, suggesting that the participants in surgery, particularly the nurses and physicians, do not share mental model in this concept. This is significant to effective interprofessional teamwork that includes components of communication, trust, respect, mutual acquaintanceship and more – all of which are related to the existence of shared mental models related to the tasks and the environment in which collaboration happens (Karam et al., 2018).

Other studies showed that initial perception of a definition is based on its literal meaning (Flug et al., 2018); however, in our study the clinicians modified the literal definition based on their role in a surgical procedure (surgeons in performing, anesthesiologists in stabilizing, and nurses in coordination and assistance). This is likely to be the result of ensuring a successful and safe surgery. Hence, studies find that surgeons care about economy, efficiency, and quality of care, while anesthesiologists and nurses care mostly about employee satisfaction (Hoeper et al., 2017; Eriksson et al., 2020; Booij, 2007). Little is known about perceptions of risk managers in this issue. In our study, they focused more on potential risks for patient harm. This view may be explained by their role as promoters of patient safety and error preventers (Koppenberg, 2012; Card, 2016; Carroll, 2016).

The incidence of Never Events was perceived differently by Operating Room clinicians with physicians stating that Never Events are rare, and nurses saying that Never Events are common. The variation in their mental models might be explained by dynamic work environment that affects the occurrence of Never Events (Göras, 2020; Vowels et al., 2012;), when mostly they are described rare (Moppett, 2016; Cohen et al., 2021). Thus, nurses’ mental model might be explained by perceiving the risks in the Operating Room that can lead to occurrence of Never Events as common (Haugen et al., 2013).

Participants viewed the events as severe, as defined by many international organizations (Joice et al., 2013, Robert et al., 2015). Although agreeing on the importance of severity to the definition, they had different opinions about whether all Never Events are actually preventable. Studies showed that teamwork is essential for their prevention ((Fry et al., 2010) evolving from implementation safety checklists (Urbach, 2014; Moppett, 2016) and from characteristics of the surgery itself. Effective teams have a shared understanding of the complexity of a clinical situation, make appropriate decisions, and act efficiently (Mitchell et al., 2011).;).

Measurability of Never Events is required to assess their incidence, consequences, improvement efforts (Cohen et al., 2021). However, measurability is dependent on staff reporting on the events, which is influenced by professional’s views toward adverse events that are conditioned by social norms, awareness, and perception of the event itself (Haim et al., 2018). Our study showed that lack of shared mental model might affect their measurability due to the characteristics of the surgery in which the event can be perceived as unexpected consequences and not as an error..

**CONCLUSION**

* Our study aimed to assess perceptions of professionals to the concept of surgical Never Events with the aim of achieving a better understanding of the implication of different mental models for practice. We revealed various mental models around the definition of Never Events and its characteristics. Since nurses play such a key role in identifying potential risks and preventing errors in the Operating Room, their advocacy for addressing the existence of divergent mental model and providing solutions.is especially important. Such efforts include: Enhance interprofessional and collaborative teamwork by evaluating the discrepancies in the team's mental model and planning a specific intervention to encourage their mutual agreement about the most important characteristics of a Never Event;
* Tailor a broader definition of Never Events that reflects the multiple roles of interprofessional teams and characteristics of the surgery;
* Offer a standardized, interprofessional training around the definition and prevention of errors; and
* Define a core of information that must be shared by all clinicians participating in the surgery to improve communication and teamwork.

Further research would benefit from the inclusion of more individuals who hold frontline surgical positions. Such a study could explore not only interprofessional differences, but also assess the impact on mental models of the norms of the participating organization, including any national or cross-cultural differences. Also, because this study was qualitative, the perceptions expressed may not statistically represent the entire population of health care professionals but can be used as the basis for a follow-on survey.

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**Table 1. Characteristics of Study Participants**

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| **Characteristic** | **Respondents, No. (%) (N = 25)** |
| Age, y  35–44  45–54  55–64  65–75 | 3 (12) 10 (40) 10 (40) 2 (8) |
| Sex  Male  Female | 10 (40) 15 (60) |
| Profession  Operating room clinician  Anesthesiologist  Surgeon  Nurse  Risk manager (physician)  Risk manager (nurse) | 6 (24) 3 (12) 9 (36) 3 (12) 4 (16) |
| Administrative role  Yes  No | 25 (100)  0 |
| Experience in profession, y  10–19  20–29  30–39  40–50 | 5 (20) 7 (28) 10 (40) 3 (12) |
| Experience in current position, y  0–4  5–9  10–14  15–19  20–25 | 9 (36) 9 (36) 2 (8) 1 (4) 4 (16) |

**Table 2. Perceptions of clinicians and risk managers regarding aspects of the formal “never event” definition**

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| **“Never events” are severe events that cause patient harm**   * “In my opinion, [a] ‘never event’ is an event that included [a] patient’s harm, occurred during routine surgery, or [was a] procedure that must not happen.”**–** a nurse * “Based on the fact that most ‘never events’ occur or may occur in the OR, it is an important issue that should be related to as severe events.” – a risk manager * “A safety event with severe patient harm or even death in a way that was preventable…It is not related to the elements that I operated [on in] the patient, and he was severely sick and then he passed and a harm occur[red]. It is an event of [a] retained foreign object such as pad/sponge, [or] major harm such as damage to a vital organ.”– a surgeon   **The severity of events can be graded and depends on the rapidity of response**   * “I would define the type of event such [as a] burn occurring during surgery at the same severity level as retention of [a] foreign object during surgery and definitely not as wrong [as a] blood transfusion that caused [a] patient’s death” – a risk manager * “Since the patient care we provide is one on one, it is easier for us to decrease the severity of events. If we give wrong medication, we can immediately recognize the error and provide care in five second[s] [to] decrease the potential severity.” – an anesthesiologist |
| ***Preventability***  **Surgical “never events” are preventable by increased awareness, training, and following work protocols**   * “Since all ‘never events’ have a risk for patient harm, we should prevent their occurrence in the OR.”– a nurse * “We count items during the surgery exactly by the rules; it is important to prevent errors.”– a nurse * “I think that they are all preventable. Everybody has awareness for preventing them and proper training for such awareness.”– a surgeon * “The types of surgeries with their special characteristics, like long surgeries with addition of absorbing materials/gauzes; in such surgeries, the surgical count should be done very carefully.”– a risk manage**r**   **Some events cannot be prevented owing to human errors and force majeure**   * “There is certain rate of human errors; we are unable to reach zero with these errors…with attention and proper standards, we can prevent all events except events that are related to [an] unknown factor/condition of the patient that you are not aware [of].”– a nurse * “Most ‘never events’ are preventable, but [a] large amount of them are not.”– an anesthesiologist * “The patient was restrained to the surgical bed and somehow the bed broke and he fell.”– an anesthesiologist   **The characteristics of the surgery affect the ability to prevent “never events”**   * “Performance of surgery in an airway [or] close to an airway created risk for catching fire in that area”– a nurse * “You use oxygen, you use electricity, and together it can lead to a surgical burn.”– a surgeon |

**Table 3. 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? |