**Perceptions of Professionals on the Definition of Surgical 'Never Events'**

Dana Arad 1, 2, Adi Finkelstein 3, Ronen Rozenblum 4, 5, Racheli Magnezi 1

1. Bar Ilan University, Health System Management Department, Israel
2. Ministry of Health, Patient Safety Division, Israel
3. Department of Nursing, Jerusalem College of Technology, Israel
4. Brigham and Women’s Hospital, Boston, MA, USA
5. Harvard Medical School, Boston, MA, USA

\* Correspondence:
Dana Arad

Dana.arad@moh.gov.il

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Abstract

**Background:**

Surgical 'Never Events' have a formal definition, created by the National Quality Forum (NQF) and adapted by international health organizations. However, clinicians and risk managers may perceive this events differently compared to the formal definition.

**Objective:**To explore perceptions of Operating room's (OR) clinicians and risk managers of the formal definition of 'Never Events' and its aspects.

**Methods:**

Between September and December 2019, data was gathered through semi structured interviews with OR clinicians (physicians and nurses) and risk managers from hospitals and the Israeli Ministry of Health. The interviews were analyzed using the six phase's inductive thematic analysis approach (TA) to identify themes related to perceptions of the definition.

**Results:**

Data was gathered from 25 participants (19 OR clinicians and 6 risk managers). While Risk managers endorsed the formal definition, clinicians suggested to modify the definition based on their role in the surgery (Anesthesiologists as unexpected occurrence of events, surgeons as inappropriate preparedness, and nurses as preventable event that they are accountable for and risk mangers as event with patient's harm). While participants agreed that these events are severe, their perception of their preventability was mixed. Surgeons and nurses thought that they can be prevented by training or safety standards. Anesthesiologists and risk managers thought that they are unpreventable.
Perceptions of incidence varied when physicians viewed the events as rare and nurses as common. Unpredictability was suggested as an aspect of the definition due to the dynamic work environment in the OR and characteristics of the surgery.

**Conclusions:**

Clinicians and risk managers' voice is crucial in promoting safety. Our results show that these stakeholders have different perceptions of the formal definition what can suggest that they do not share the same mental model during the surgery. Therefore we suggest to re asses the definition and adjusting it according to type of surgery and the role of each clinician during the surgery. Such modification requires implementing team communication to maintain the shared mental model.

Introduction:

The first axiom to the potential medical errors that can occur because of the medical care is the Hippocratic injunction of *primum non nocere* (first, do no harm) (Smith, 2005). This axiom is being tested when 'Never Event' (NE) occurs.

NE was first defined by The National Quality Forum (NQF) in 2001 (Kizer & Stegun, 2005) as serious events that are largely preventable and of concern to public and to healthcare providers with a goal of reducing them by quality improvement (Kumar and Raina, 2017). The definition's process was voluntary consensus standards setting among stakeholders (Kizer & Stegun, 2005) and describes shocking medical errors that should never occur (Flug, Ponce et al, 2018).

The surgical NEs include surgery or invasive procedure performed on the wrong site, on the wrong patient, wrong surgical or invasive procedure performed, and unintended retention of a foreign object in a patient after surgery, intraoperative or immediately postoperative death in ASA (American Society of Anesthesiologists) class1patient serious reportable events in healthcare 2011).

In order to prevent surgical NE and perform a safe surgery, the participating team members should share a mental model in regards to perioperative risks and errors (Brown et al, 2017), (Shciff et al, 2018). Also, the perceptions of NEs should be based on mutual understanding of the situation during the surgery by the participating team (Stout et al, 1999 in Etherington et al, 2019, Goras et al, 2017, Fruhen et al, 2020). Thus, when team behaviors differ during the surgery, it indicates different and conflicting interpretations of the surgery what may affect its safety (Aveling et al, 2018).

When analyzing interpretation of the NQF definition, 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 wrong patient, wrong site, and wrong body part' (Rosenthal & Booth, 2003). Another study exploring showed that anesthesiologists were aware of the formal definition of NE but had their personal definition that related to the speed of onset of the event and potential severity (Smith, Goodwin, Mort & Pope, 2006).

In 2011 the NQF updated its definition and added the aspect of prevention of these events (Robert, Choi et al, 2015). The Center for Medicare and Medicaid (CMS) related to the definition as surgical events, in serious hospital-acquired conditions, also with aspect of prevention by implementation of standardized protocols (Joice et al, 2013)

A systemic review by Jung, Elfassy, Juni and Grantcharov (2019) showed that surgical NE added the concept of unintended and unanticipated event, caused by medical teams and not the patient's underlying conditions.

Our study aims to examine perceptions of Operating Room's (ORs) clinicians (physicians and nurses) and risk managers to the definition of surgical 'Never Events'. We chose to use qualitative methods as they elaborate the understanding of how and why people behave as they do, in addition to comprehensive answers regarding their interpretations of the definitions NE.

Methods:

*Design, Settings and Participants*

We conducted semi-structured interviews. Some participants were clinicians working in the OR such as physicians (anesthesiologists and surgeons) and nurses. The other participants were risk managers (physician and nurses) from general hospitals in various sized and locations and risk managers from the Israeli Ministry of Health (MOH), with regulatory role of policy makers. Table 1 describes the characteristics of participants. We performed a purposive recruitment of participants (Boet et al, 2020). The preference was for participants with administrative position that have a systemic view of 'Never Events' from hospitals varied in their type sizes and location.

*Study tool*

The interview guide was developed based on experts' opinion in surgery and risk management and causes of 'Never Events' based on literature review (Thiels et al, 2015). The semi-structured interview guide (Appendix 1) evaluated aspects of the definition of perioperative 'Never Events'. A literature search revealed that few studies analyzed aspects of such definition and no studies analyzed those aspects based on clinical profession. Thus, in order to pilot test the interview guide two pilot interviews were performed with two participants. One question was omitted as a result of the pilot interviews. The data from the pilot study was added to the final analysis.

*Interview process*

Interviews were conducted between September 2019 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 acquaintance of the participants to components of 'Never Events' definitions and their non-verbal reaction such as anger or discomfort. Participants provided verbal consent and received no compensation for their participation.

*Data analysis*

The researchers entered information from the transcripts into Excel (version 16.0; Microsoft Corp) manually. Using the six phase's inductive thematic analysis approach as described by Braun and Clarke (2006): 1) familiarizing 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 re-read through the entire data set and systematically coded the transcripts independently. Codes were then grouped into emergent themes after iterative reading and discussion with the two other authors (RM, RR). The whole team met several times throughout the analysis process to discuss disagreements and refine and label the themes and sub-themes.

*Research ethics*

Ethical approval was obtained from the Medical Research and Ethical Committee of the Israeli Ministry of Health (reference number MOH 032-2019 at 27.12.19).

Findings

Study Sample

The study captured a set of 25 participants (out of 25 participants approached): Clinicians from the OR that included physicians (anesthesiologists and surgeons) and nurses and risk managers (physicians and nurses) (Table 1). The reference to risk managers was one profession group whether they were physicians or nurses. Participants were from hospitals and the MOH. The hospitals are heterogeneous in size and location. Four hospitals were large (>800 beds), urban and were defined as trauma center, three hospitals were medium size (400-800 beds) and rural, one of them is also a trauma center, and two hospitals were small (<400 beds) when one of them was rural and one was urban and provided only surgical care.

Table 1: Characteristics of participants

|  |  |  |
| --- | --- | --- |
| **Characteristics** | **No. of respondents(N=25)** | **Percentage of respondents (%)** |
| Age (years)35-4445-5455-6465-75 | 310102 | 1240408 |
| GenderMaleFemale | 1015 | 4060 |
| ProfessionOR clinician:AnesthesiologistSurgeonNurseRisk manager:PhysicianNurse | 63835 | 2412321220 |
| Administrative roleYesNo  | 250 | 1000 |
| Years of experience in profession10-1920-2930-3940-50 | 57103 | 20284012 |
| Years of experience in current position0-45-910-1415-1920-25 | 99214 | 36368416 |

Main themes

Two main themes were identified: Perceptions of professionals to the formal definition of 'Never Event' and its aspects and perceptions regarding the probability of occurrence of 'Never Events' in regards to their incidence and unpredictability.

**Perceptions of professionals to the definition of 'Never Event'**

The perceptions of participants to the definition included their perceptions to the formal definition of the NQF and their perceptions to two main aspects in the definition: severity and preventability.

***Perceptions to the formal definition***

Risk managers endorsed the formal definition of 'Never Event' while most clinicians from the OR suggested to modify the definition based on their role during the surgery and the importance of errors to the success of the surgery.

OR physicians and nurses related to the literal concept of 'Never Events'. Nurses as *'Events that mustn't happen'* or *'Error that should never happen'*, a surgeon as *'Event that should never happen'* and an anesthesiologist as *'Event that mustn't happen that is why called 'Never Event'*. They suggested to modify the definition to an event that risks the success of the surgery based on their role in the surgery. For example, majority of anesthesiologists defined 'Never Event' as a surgery with unexpected occurrence of events, not routinely: *'Unexpected death during surgery, wrong blood transfusion, wrong organ anesthesia'*, *'Wrong medication administration'*. Nurses related to their role as accountability to 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*" and a surgeon viewed inappropriate preparedness to the surgery as an event: *'for me a 'Never Event' is non sharped scissors*'.

Risk managers related to the formal regulatory definition without modification. For example, *'MOH has a policy defining 'Never Events'*, *'There is a definition of the MOH. In the OR there are 3 types of 'Never Events: error in patient identification, wrong site surgery, surgery to the wrong patient'*. However, when related to the list of events in the formal definition, some risk managers suggested adding events with potential patient's harm: *'Loss of tissue, it mustn't happen to somebody who goes thorough a surgery in order to know if he has cancer or not'*, *'The issue of patient identification should be a critical aspect in 'Never Events' and should be expressed'*.

***Perceptions to the aspects of severity and preventability***

All participants described their perceptions in regards to two aspects of the formal definition of 'Never Events': severity and preventability as shown in Box 1.

There was a consensus, among most of participants, that severity is an essential aspect of 'Never Events' definition and is related to the complexity of the work environment ORs and to the surgery's characteristics. An anesthesiologist further described the impact of anesthesiologist's role to quickly decrease the severity of the event within its occurrence with a quick response.

 Moreover, a surgeon though that 'Never Events' in the OR indicates a serious safety hazard that resulted in severe event. However, one risk manager assumed that these events should be graded based on the different severity level evolves from each event.

Another aspect of the 'Never Events' in the definition is their preventability. The participants had different perceptions to this aspect. OR Nurses and risk managers agreed that the events should be prevented by using tools such as training, awareness and work protocols*.* For example, OR nurses referred to importance of adhering to safety standards as a tool to prevent the errors. However, they thought that some errors cannot be prevented by safety standards due to human errors.

Among surgeons, few thought that proper training can assist in preventing the events, while others said that some events are unpreventable due to the inherited risks in the procedure such as the combination of electricity and oxygen that can lead to a burn.

Anesthesiologists thought that not all 'Never Events' are preventable and described situations of 'force majeure' in which the events are not preventable*,* such as patient's fall and a surgical burn although standards were kept.

**Box 1: Perceptions of clinicians and risk managers to the aspects of the formal 'Never Event' definition**

***Severity***

**'Never Events' are severe events that cause patient harm**

* 'In my opinion 'Never Event' is an event that included patient's harm, occurred during routine surgery or 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 the patient and he was severely sick and then he passed and a harm occur. It is an event of retained foreign object such as pad/sponge, 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 burn occurring during surgery at the same severity level as retention of foreign object during surgery and definitely not as wrong blood transfusion that caused to 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 seconds what 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 due 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 to events that are related to unknown factor/condition of the patient that you are not aware to'- a nurse
* 'Most 'Never Events' are preventable but 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 of 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

**Perceptions to the probability of occurrence of 'Never Events'**

The perceptions of participants regarding the probability of occurrence of 'Never describe the relation between the perceived incidence of the events and the ability to predict them.

***Perceived incidence of 'Never Events'***

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', 'common events. There are patients' fall, burns during the 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 that was the major issue in these events…. Lack of following work protocols is very simple, it caused by distraction, working at night and burnout', 'Very rare, it might happen one every few years'.*

One risk manager thought that incidence of such events should not be taken into consideration: *'Enough that this event will occur once, there is no issue of prevalence'*. However, other risk managers described characteristics of surgeries in which there is a higher incidence of 'Never Events': *OBGYN (obstetrics and gynecology) is 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 '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 to the definition***

Unpredictability evolved from anesthesiologists and OR nurses as a suggested aspect that should be added to the definition in order to emphasize that not all 'Never Events' can be predicted or assumed to happen or not happen. Anesthesiologists describe the unpredictability as unplanned deviation from routine work process due to the dynamic work environment in the OR what is related to their perceptions of a incidence as a rare event: 'An adverse event that surprisingly occurs within our usual routine and is exceptional and unusual'. For example: 'Esophageal intubation, unidentified, that caused the patient severe harm. A case of unpredictable wrong use of equipment, that we did not notice of, during bronchoscopy that caused the patient harm'.
OR Nurses, that perceived these events as common thought that surgery's length is a contributing factor to the possibility to predict occurrence of 'Never Event'. Some thought that short surgeries are in high risk: 'In shorter surgeries like laparoscopic and eye surgery (such as cataract) the risk of retaining absorbing materials is less common', '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 'Never Events' can occur more in long surgeries: 'A long surgery can be calm and organized but when it requires multiprofessionals surgeons, errors can occur'. Surgeons did not related to this aspect of unpredictability as a required part of the definition.

Discussion

In the last decade there is a consensus regarding the formal definition of surgical NEs by international health organizations (National Patient Safety Agency, 2009/2010), (Kizer, 2001), (WHO, 2009). The definition was created as a consensus standard by a steering committee of stakeholders and policy makers (NQF, 2011) rather than relying on perceptions of direct health care providers.

Our study aimed to analyze perceptions of OR clinicians and risk managers to the definition of NEs. We assume that the characteristics of our participants (profession, years of experience, position and place of work) provide a wide range of systemic perceptions to the definition.

Studies show that listening to employee voices, is crucial to promote safety and thus should be taken into consideration (Martin, Chew, Dixon-Woods, 2020). For example, 345 Scottish general practice team members viewed NE as causing severe harm (or potential to) to a patient, is preventable, can be clearly and precisely defined, can be detected and is not the result of an unlawful act (Wet, O'Donnell and Bowie, 2014).

Surprisingly, our results show that there is no consensus regarding formal 'Never Events' definition among clinicians participating in the surgery, what suggests that they do not have a shared mental model in this issue. While other studies show that the initial perception of a definition is based on its literal meaning (Kumar & Raina, 2017), our results show that clinicians modified the definition based on their role in the surgery and its success (surgeons in performing, anesthesiologists in stabilizing and nurses in coordination and assistance). This can be explained by different importance goals of the participating professional groups: surgeons cared about economy, efficiency and quality of care, anesthesiologists cared about employee satisfaction and nurses about satisfaction as well (Hoeper et al, 2017), (Eriksson , 2002) (Booji, 2007). Another explanation is that people feel free to choose their choice of action best to their knowledge and practice in the situation of a surgery (Kumar & Raina, 2017).

Risk managers modified the formal definition as well, but their perception was directed to potential risks to patient safety adding aspect of potential harm to the definition. Their view is explained by their role as patient safety promoters and error preventers (Kooperberg, 2012), (Card, 2016), (Carroll, 2016).

The incidence of NEs was perceived differently by OR clinicians. While OR physicians assumed that they are rare, OR nurses thought that they are common. A systemic review of Hempel et al (2017) showed that the estimation of incidence for surgical NEs varies and can be influenced by the dynamic work environment in the OR (Goras et al, 2017), (Vowels et al, 2012), (Sexton et al, 2007).

Our results suggest adding an aspect of unpredictability to the definition as a contributing factor to occurrence of NEs. In general, NEs are hard to predict since they are rare with wide distribution. Also, safety standards were not found to predict their occurrence and is context related to the surgical specialty or hospital (Moppett & Moppett, 2015). An Analysis of Fry et al (2010) revealed that patient characteristics and procedural interventions can increase the occurrence of 6 of the 8 post procedural infections that are defined as infectious NEs.

Characteristics of the surgery can contribute to the occurrence of NEs as well. For example, urgent surgeries or head and neck surgeries as high risk surgeries for surgical burns. Length of surgery was found to be a contributing factor to their occurrence when interpretations regarding the specific length varied, maybe because affect partial compliance to the safety standards when the staff rush and 'skips' some of the phases of the standards (Rodziewicz et al, 2020). Risk managers also viewed additional risk factors of the surgery such as paired organ surgeries. Studies showed that when checklists are prospectively tailored to the context, they are more likely to be used and sustained in practice ([Gillespie](https://pubmed.ncbi.nlm.nih.gov/?term=Gillespie+BM&cauthor_id=26415946) & [Marshall](https://pubmed.ncbi.nlm.nih.gov/?term=Marshall+A&cauthor_id=26415946), 2015).

Our study has several limitations. First, we focused on clinicians and risk manager's perspectives with administrative role what may cause a bias compared to frontline position perspectives. Second, we were unable to get an in-depth understanding of cultural environment of the organizations what may affect the participants' perspectives. Third, since our study is qualitative it may not statistically represent the perceptions revealed.

Our study revealed that there is no shared mental model among team member participating in the surgery and risk managers dealing with 'Never Events' in regards to the definition of surgical NEs. Also, the definition is not tailored to surgery's characteristics, roles of participants and their mission during the surgery.

Therefore, we recommend to re assess the definition based on the perceptions raised in this study. For example, considering adding aspects of unpredictability to the definition and tailoring the definition in relation to characteristics of the surgery such as surgery's length, urgency and complexity. The tailored definition should be than mediated by dedicated team communication standard to maintain the shared mental model in relation to the definition.

A further research is needed. A quantitative study to statistically evaluate perceptions of professionals to the definition and a qualitative one to analyze the shared mental model and safety level in the operating rooms in regards to occurrence of 'Never Events'.

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# United States operating room nurses: work environment perceptions

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*Appendix 1: Interview guide*

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| --- | --- |
| Discussion topics | Examples of questions |
| Attitude towards ‘Never Events’ in the Operating Rooms in Israel | How would you define 'Never Events’ in the operating rooms? PROBE: Are there different types of 'Never Events’ in the operating rooms? PROBE: Preventable vs. Not Preventable |
| Personal experience with ‘Never Events’ in the operating room | Were you exposed to ‘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?  |