‘Never Events in Surgery’: Mere Error or an Avoidable Disaster

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Abstract Never events in surgery is not an uncommon occurrence. It is difficult to find any surgeon who never had an experience of one or another kind of mistake, committed while delivering the surgical care to the patient. Whatever the reports come out through news media or other sources are just a tip of iceberg. Collectively, its results, not only as a huge suffering and financial burden for the patients but also its impact on the operating surgeon and sometimes to related institute, are very far reaching and extremely negative. In spite of all of this, every one of us thinks this as an individual problem or one of the anecdotal media coverage. The aim of this study is to create an awareness among surgeon’s fraternity and bring the attention of associations of surgeon bodies to this serious issue so that collective steps can be initiated to address it. In an attempt to find all the related information, an extensive search of literature in English language was performed using online search engines: PubMed NCBI database, Google search, and other digital sources available online. Error may be in the form of an act of commission, act of omission, error of planning, or error of execution, but whatever the reason, ultimate impacts are not less than disastrous, affecting individuals to global level. In addition to the enforcing authorities, all other stake holders should wake up and must take collective and comprehensive approach to create a safety system inside the health care organisations.

Keywords Never events · Wrong surgery · Patient safety · Medical error · Surgical negligence

Introduction

“Surgeon’s must be very careful when they take the knife! Underneath their fine incisions stir the culprits – Life!” -Emily Dickinson, C.1859.

We are all aware about this quote, but another fact is that regardless of what we do, our karma has no hold on us. We are free to choose our choice of action but even with best of our intention, we do not have the free choice to choose the consequence of our action thereafter. But what if such actions and consequences are involving precious human life or human suffering? What if it can destroy the so-called world or dream of a dependent family? And what if it can destroy whole career of the surgeon who is also a fallible human being. Then, we need to analyse and contemplate our action to the core and must try to bring those preventable errors to the zero level.

History of surgical errors and its adverse outcomes is dated back to 1795–1750 BC when it got mentioned in the ancient Mesopotamian Code of Hammurabi [1]. ‘First do no harm’ admonition of Hippocratic oath has always been a guiding principle for the medical fraternity world over [2]. In spite of that, it is well-known fact that as far as harm to the patients are concerned, no surgery is routine and no surgeon is immune. Now in modern era with advent of advance technology, health care delivery in surgery is becoming more complex and error prone. At the same time, expectation of modern society for error-free health care delivery has reached to a highest point where there is no scope for any compromise. To many extents,

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this may be attributed to growing public awareness as well as active pro-consumer journalism of news media [3].

First time in the year 2000, the serious impact of medical error and its magnitude were brought into the focus at international level by report of the Institute of Medicine (IOM) of USA. After comprehensive study on medical error and patient safety, IOM published a report titled ‘To Err Is Human: Building a Safer Health System’. This report shocked the world when it highlighted death between 44,000 and 98,000 and over 1 million injuries occurred each year in American hospitals due to medical error [4]. This drew much needed attention of international community towards this serious issue as medical error itself was found to be one among the top ten leading causes of death.

The term ‘never events’ was first coined in 2001 by the National Quality Forum (NQF), an important health organisation of USA that promotes and ensures patient safety and healthcare quality through measurement and public reporting [5]. As per definition by the NQF, ‘never events’ are errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients, and that indicate a real problem in the safety and credibility of a health care facility. Initially, in 2002, the NQF identified 27 events, which was updated in 2006 with addition of one new event. Recently, in 2011, it has been again revised and updated and now consists of 29 events grouped into seven categories: surgical, product or device, patient protection, care management, environmental, radiologic, and criminal [6].

According to the NQF, important example of never events are surgery performed on the wrong body part or on the wrong patient, wrong surgical procedure performed on a patient, unintended retention of a foreign object in a patient after surgery or other procedure, a mismatched blood transfusion, a major medication error, a severe ‘pressure ulcer’ acquired in the hospital, and intraoperative or immediately postoperative death in an ASA Class I patient.

Amidst all these concerns of unacceptable magnitude of medical error and compromised patient safety, World Health Organisation (WHO) came in to action. In October 2004, it launched the worldwide initiative to reduce the adverse consequences of unsafe health care. In 2009, in order to formulate worldwide recommendation, WHO issued a guideline on the subject of global patient’s safety challenge. Main motto of all these campaigns was ‘*Safe Surgery Saves Lives*’ [7].

Methods

In an attempt to find each and every information related to this review article, an extensive search of literature in English language was performed using online search engines: PubMed NCBI database, Google search, and other digital sources available online. For this study, we followed the Prisma’s

guideline as depicted below in the form of a flow chart (Fig. 1). Initially, any related article, found to be providing some specific and evidence-based information highlighting the issue of patient safety, was listed and screened. Out of 374 related studies from all sources, finally, at the end, 35 studies were selected for review and ultimate analysis. Criteria for inclusion were specific events related only to surgery, research articles based on large case series, articles that helped in formulating recommendations and guidelines, preferably free full text, and books or updates released by concerned organisations highlighting this issue comprehensively.

Results

Magnitude of the Problem Much before the report ‘To Err is Human ...’ published by IOM, which got worldwide recognition, in 1991, Leape et al. had published the report on the similar issue. It revealed 48% of all adverse events recorded in their study on 30,121 hospitalised patients was due to one or another mishap in respect to surgical operations [8]. In 1992, Gawande et al. in their cohort study (published in 1999) reported 66% of total adverse event in 15,000 non psychiatric patients was a result of surgical care, and out of which, 54% were preventable adverse events [9]. In 2011, a study published in British journal of surgery concluded that errors are common in surgery and far more common than that is near misses’ errors. So they advocated reporting of all such near misses to prevent major and serious consequences [10]. In October 2014, a study done exclusively in respect to intra operative adverse events (IAEs) reported shocking result of 277 I.E. (187 patients) in 9292 patients, and many of these were of serious nature which increased the morbidity of the patients significantly [11].

In developed countries, there are few studies reporting to some extent the magnitude of surgical adverse events, while in developing or under developed countries, no such data are available. Recently, in February 2015, a study involving 18 public hospitals conducted in Iran, which again found the highest frequency of medical error (42.3%), was related to surgical unit [12]. Whatever reports come out through news media or regulatory bodies are only the little tip of iceberg. If we compare the availability of hospital infrastructure, surgical instruments, doctor-patient ratio, lack of proper training, and awareness of people especially in remote areas of developing countries with those in the developed Western world, it is not difficult to assume the prevailing situation.

Identified Risk Factors

Error can happen in the form of adverse event; negligence; medication error; wrong-site, wrong-procedure, or

Fig. 1 Flow chart based on Prisma's guidelines for review study

wrong-patient surgery; and unintentional retention of a foreign body in a patient after surgery. Sometimes, all of a sudden in an unexpected manner, error can crop up. Many time, although error happens but does not result in patient harm, these are the near missed error [10, 13]. An errors in any form can happen at any stage of delivery of health care i.e. right from the time of admission in the form of clerical mistake, patient's assessment, investigations, diagnosis, and treatment to at the time of discharge in the form of wrong prescription. However, here, we are not including the error which can happens even outside the hospital e.g. in ambulances, at home by family members, or patient himself. Broadly, we can classify the risk factors contributing errors into the following:

Human error: At any stage, human can do mistake either in the form of *act of commission* (doing the wrong thing), *act of omission* (failing to act), *error of execution* (the correct action does not proceed as intended), and *error of planning* (the original intended action is not correct). Few example of these are failure in responding to the patient's call on time, failure in assessing the patient clinically, either inadequate investigations or investigations done on the wrong line, error in diagnosis, avoidable delay in treatment, or lack of training or experience in recognising the danger beforehand, overworked, time

constrain, and personal psychological distraction [14, 15].

Communication error: Surgical management involves teamwork at many level so proper communication and dialogue is very important aspect of safe delivery of surgery. Communication failure can happen at any level either among teams of surgeon themselves, between surgeon and anaesthetist, between surgeon and nursing staff or other paramedics, or most importantly between surgeon and the patient. It has been found that poor communication is major reason for unexpected error or sentinel events, for example wrong-site surgery [16].

System failure: System is basically an arrangement of required infrastructure, administrations, staff, people, and functions organised and managed to accomplish task or goal. Many time, system in which surgeon works does not support or provide proper environment to implement safe health care delivery. It may be in the form of administrative failure, inadequate staff, lack of proper infrastructure, lack of financial support, or absence of a system that reports, records, and reviews the adverse events for future correction.

Equipment failure: It can be in the form of sudden technical failure or lack of skill in a person who is responsible for its operation.

Ultimate Cost of an Errors

There cannot be anything worse than an error that results in human suffering and might even cost a precious human life. Such errors are so repetitive and occur almost everywhere in the world that their analysis can make the strongest of souls to feel wretched. Ultimate cost in terms of physical suffering, emotional trauma, and financial loss is not limited to patient and their family only but it immensely affects operating surgeon as well concerned institution in a very negative way. At the end, en bloc, it affects the productivity of whole society and nation. There had been many studies in past which tried to quantify the impact of never events in surgery [17–20]. One such study titled *Surgical never events in the United States*, published in year 2013, reported that 4082 surgical never event claims occur each year in the USA with claim settlement cost runs in billions of dollars [21].

Solutions Area

The issue of medical error and patient safety came into lime-light in the early part of twenty-first century. To address this issue, lot of agencies at national and international level came into action. Primary aim of these agencies was to find out the root of problems and formulate the universally applicable guidelines/recommendations that can minimise the medical error. Among those agencies most pertaining to mention here are Institute of Medicine (IOM), National Quality Forum (NQF), Joint Commission on Accreditation of Health Care Organisation, National Patient Safety Foundation (NPSF), and World Health Organisation (WHO).

On the basis of different universal recommendations and guideline, following pragmatic and evidence-based approach can be applied to improve the safety of the patient during surgical care. Ultimate aim of all of these suggestions is to create a safety system inside the health care organisations.

1. **Creating awareness:** In spite of many reports declaring never events as a significant public health concern, it is yet to get a proper recognition. In developing countries, situations are still bad to worse as they are still fighting for basic health care deliveries, and no relevance is there in respect to patient safety and quality of service. Unless it will get recognise and society becomes aware of this grave issue, remedial measures cannot be implemented.
2. **Mandatory and voluntary reporting:** In the absence of reporting and reviewing of the identified problems, it is impossible to find the solution, and most importantly, you cannot hold anyone accountable. Recommendation are as follows: mandatory reporting to government bodies to make health care provider accountable plus mandatory internal reporting for audit purpose and voluntary, and confidential reporting to an external group for purposes

of quality improvement. At the same time, it is also recommended that these sorts of reporting system should be legally protected so that no way any one can harass or threaten the job or position of a reporting surgeon [4]. A concept of root cause analysis and action (RCA²) to prevent further harm by learning from adverse events has been initiated by the National Patient Safety Foundation (NPSF) which has issued an update of its recommendation recently in January 2016 [22].

3. **Sound communication and team culture:** A good communication in clear and straightforward way is required among all surgical team members, anaesthetists, nurses, and paramedics at every stage of surgical care. Important example of establishing good communication is operating room *briefing* and *debriefing* which are sharing of all patient-related information preoperatively, intraoperatively, and postoperatively at the time of handing over [7, 23, 24]. Another useful example is a concept of ‘time out’ or ‘surgical pause’ which is a brief, less than 1-min pause in operating room immediately before incision; during this time, every one of the operating team whether surgeons, anaesthetists, nurses, or anyone verbally confirms the identity of the patient, the operative site, and the procedure to be performed. It is a means of ensuring clear communication among team members and avoiding ‘wrong-site’ or ‘wrong-patient’ errors. Another concept of ‘extended pause’, which is not only a confirmation of the identity of the patient and the surgical site but also a discussion by team members of the critical details of the operation to be performed, is found to be further helpful in reducing human error [7, 16, 25, 26].

Communication between surgeon and patient right from the beginning until discharge and follow-up is equally and even more important. Ability of the surgeon to explain the things in a humblest and gentle way also was found to reduce the litigation and claim in significant manner [27].

So many times, strict hierarchy of operating room, which intimidates the juniors or scrub nurse to speak up or personal preferences of senior team member, was found to be main reason for break in communication and never event [28]. So *individual surgeon autonomy must not be above the patient safety and institution*.

4. **Professional fitness and competency:** Surgery profession requires uncompromising level of competency and proficiency and to maintain that continued learning and update of skill development is of paramount importance [29]. For this purpose, *accreditation of health care organisation with transparent rating system can play an immense role* [16, 30].
5. **Oversight organisation:** Role of organisation to keep eyes over performances of health care institution, collect data,

and take steps to improve their quality, safety, efficiency, and effectiveness is very important. Lot of such organisations are active in developed countries and playing very important role in maintenance of patient safety. One such organisation is the Agency for Healthcare Research and Quality (AHRQ) of USA which advocates the use of quality indicators (the patient safety indicators, PSIs), to measure health care quality using readily available hospital inpatient administrative data.

6. Documentation: Many times, reason for error happens to be improper assumption of the thing by the health care personnel. Only way to prevent such accident is proper documentation at every step rather relying on just verbal communication. Important examples are documentation of *counting of surgical instruments, sponges, cotton swabs, needle, and side marking* before surgery [7, 31–33]. Other equally important is *correct labelling of surgical specimens* with the identity of the patient, the specimen name, and location (site and side) from which the specimen was obtained, by having one team member read the specimen label aloud and another verbally confirming agreement [7]. Surgical safety checklist recommendation of WHO which has got concept of chequing at time of entry in to operation theatre (*sign in*), before making an incision (*time out*), and at time of exit (*sign out*) was found to tremendously improve patient safety [7].
7. Implementation: Any of the safety measure recommendations or guidelines are not going to work unless concerned authorities, whether it is internal of hospital or external law enforcing regulatory bodies, take strong step to implement it.
8. Error disclosure: In any given circumstances, disclosure of error is not so easy. This is due to fear of loss of reputation, facing a lawsuit, losing the job along with immense stress, and feeling of guilt, which create a mental block situation. *That's why surgeon can be referred as a second victim and system need to take care of second victim too.* With experience, it is now recommended that honest confession with full explanation and informing about the future course of remedial action is the best bet. Sincere offer of regret or apology as appropriate to circumstances with taking full responsibility of patient care works in a most positive manner most of the time. Law of most of the nations also entails this [34, 35].

Discussions

Definition of 'Never Events' declares it as an identifiable and preventable medical 'Error' resulting in serious consequences for patients. Literal meaning of an 'Error' according to

advance English dictionary is a wrong action attributable to bad judgement or ignorance or attention. But when we look at the frequency, magnitude, and impact of this never event's 'Error' on the patient safety, it is difficult to digest it as a once in a while incidence pertaining to human error. It casts doubt on our system which just formally disposes off the case on the basis of anecdotal media coverage and then forgets it. Probably, this is the only reason that in spite of lot of action being taken against this problem in past decade, situation is not as good as it should be.

There are so many much higher risky organisations, for example aviation industry, nuclear reactors, and sub marines, which have comparatively much better safety record than our health care delivery organisations. Reason for their better safety record is that they are always in anticipation mode, follow strict code of conduct and strong leadership with cohesive team work, and *personality of organisation is much above than personality of individual.*

However, we cannot deny the fact that on a given day, even the best person can make the worst error, and we cannot make any action hundred percent free of error or free of accident. Also, the complex system of surgical management requiring multi-disciplinary approach with multiple level of intervention makes it more error prone. In such scenario, no magic pill can be expected to improve the patient safety but a comprehensive approach would only help to minimise this grave problem. Keeping in view of its magnitude and widespread universal root, strategic approach is required which can be applied right from institution to national and international level.

Conclusions

Whatever data is available with us, it is clear beyond doubt that the never events in surgery are the major cause among all the medical error, and these are totally preventable and avoidable. Keeping in view of its magnitude and impact, it can be very well concluded that not always the diseases itself but medical error can be the aetiology of human sufferings, and an urgent attention is required to put some brake on this. For effective implementation, we just cannot leave this on government or other enforcing agencies but associations of surgeons of different surgical discipline must come forward and play their important role.

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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed Consent Informed consent was not applicable in this case.

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