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Quality Improvement Initiatives In Surgery: Challenges And The Way Forward

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IMPORTANCE According to Abdul Latif Shaikh, President of Pakistan Society of Health-System Pharmacists (PSHP), at a press conference in Karachi Press Club in 2017, over half a million people die each year due to medication errors. More than 200 million surgeries are performed each year globally, and recent studies demonstrated a high rate of adverse events despite certain patient safety initiatives in the recent past.

Surgical errors include errors that occur before and after any surgical intervention and during perioperative care rather than a technical surgical mistake. These include but are not limited to, lack of communication amongst the surgical team, healthcare providers, patients, and their families, delay in diagnosis or failure to diagnose, and delay in treatment or failure to treat. Thus, we need to formulate processes that implement multiple layers of defense (Swiss Cheese Model) for surgical care, to ensure a proper defense mechanism against the potential harm that can be caused by an error. Errors within the system are like an opportunistic pathogen in the body. As the immune system of the body gets weaker, the pathogen wins. Similarly, as the processes of the organization lack its defense, the error wins.

Based on the number of research articles and as working Quality Professionals, we would suggest that the government, under the public and private partnership, develop a separate department for Surgical Improvement in Pakistan. This department will focus on developing key surgical measures, analyzing and sharing data on positive outcomes procedure, consultant and hospital-wise, and issue them for the public to choose from the best possible care available to them.

KEYWORDS Quality Initiatives, Surgical challenges, Way forward, Medical Errors, Failures, Donabedian Model

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Organizations with higher safety standards include the Aviation industry, Boeing, Airbus, Amusement Parks, Oil Industries, Nuclear plants, etc. These are organizations attributable to higher safety and quality standards because one error can lead to hundredths and thousands of deaths. One loophole may end up costing people their lives. These are high-risk organizations. Unfortunately, healthcare industries were very late to understand the gravity of their outcome on patients and are still a very high-risk organization. An indicator from the Source: Joint Commission's presentation in HMA 2004 at Bangkok, Thailand, shows the Deaths/100 Million Hours[1].

Medical errors play a considerable role in justifying the need to adopt a robust health system that can prevent avoidable deaths and incidents that lead to temporary or permanent loss of limb of a patient.

Joseph King, a 3-year-old child, died due to dehydration caused by a medication error in one of America's best hospital care centers. Betsy Lehman, a health reporter, died from an overdose of chemo. Willie King had become a victim of the wrong site procedure and got the wrong leg amputated. Eight years old Kolb died during surgery due to the wrong medication[2]. In 2009, Imanae Malik,a 3-year-old child, came in an emergency with a minor hand burn and died due to an overdose of a high alert medication. Nashwa, a 9-month-old infant, died due to an accidental overdose.

Deaths/100 Million Hours	
Being pregnant	1
Traveling by train	5
Working at home	8
Working in agriculture	10
Being in traffic	50
Working in construction	67
Commercial flying	100
Being hospitalized	2000

Source: Joint Commission's presentation in HMA 2004 at Bangkok, Thailand

All these cases are just the tip of an iceberg. Especially in the Lower Middle-Income Countries (LMIC), where no reporting culture exists, lie within the iceberg's submerged part, over half a million people who die each year due to medication errors. While in the west, a significant study was published in 1999 by the Institute of Medicine, called 'To Err is Human-Building a Safer Healthcare System,' which suggested that 45000 to 98000 people die each year due to preventable medical errors. According to this report, medical errors were the 8th leading cause of death at that time[2].

The study also cited that 2 out of every 100 admissions had become a victim to the preventable adverse events, which increased the in-patient hospital cost to about $2 billion for the nation as a whole in America. However, these incidents can be avoided by developing systems and taking initiatives that prevent caregivers from making inadvertent errors and encourage them to follow the processes diligently[2].

CHALLENGES:

The Harvard practice study group defines error and mistake, used interchangeably, in surgical practice as an adverse event or an unintended injury caused by surgical management rather than by the disease process resulting in death, disability, re-admission, or an increased length of hospital stay. A cognitive psychologist, James Reason, started research based on an incident that occurred during his everyday routine. One day he was making tea for himself and ended up pouring cat food in the tea instead of milk as his cat was clamoring around him. This absent-mindedness incident developed his interest in researching, in the late 1980 and early 1990s, with his team, where they analyzed 21 surgeons conducting multiple surgeries that took them to the edge of their abilities. He was surprised to discover that every procedure had an adverse event of one kind or another. Hence, he deduced that surgical excellence is different from what he imagined, not free of error after all. However, according to him, the most accomplished surgeons expected and detected the errors and compensated for them. They could be flexible and remained optimistic, which distinguished them from the less adaptive surgeons with had tunnel vision[4].

More than 200 million surgeries are performed each year globally, and recent studies demonstrated a high rate of adverse events despite certain patient safety initiatives in the recent past. These include the '100,000 Lives Campaign' (2005/2006) and subsequently '5 Million Lives Campaign' (2007/2008) by the Institute for Healthcare Improvement (IHI), the 'Surgical Care Improvement Project' (2006), and 'Universal Protocol' (2009) by the Joint Commission, and the WHO 'Safe Surgery Saves Lives' campaign accompanied by the global implementation of the WHO surgical safety checklist (2009). However surgical errors include errors that occur before and after any surgical intervention and during perioperative care rather than a technical surgical mistake. These include lack of communication amongst the surgical team, healthcare providers, patients, patients and their families, delay in diagnosis or failure to diagnose, and delay in treatment or failure to treat[5].

QUALITY IMPROVEMENT INITIATIVES:

"Every hospital should follow every patient it treats, long enough to determine whether or not the treatment has been successful, and then to inquire, 'if not, why not' to prevent similar failure in future." —Ernest Codman[6].

Quality Improvement Initiatives have had more than 100-year history, starting from a Hungarian Obstetrician named Dr. Ignaz Semmelweis, who prevented the spread of disease and other nosocomial infection through hand hygiene. Based on his research, today, hand hygiene is the single most effective technique to prevent Healthcare-Associated Infections, as declared by WHO.

Earnest A. Codman, an American surgeon, in 1910 -1913 proposed the "end result" system of hospital standardization and founded the American College of Surgeon – Hospital Standardization Program to maintain minimum quality standards during the surgical procedure and also gave the concept of mortality and morbidity review in the organization. Later in 1917 and 1918, the American College of Surgeon published their first Minimum Hospital Standards and started Hospital inspections for its implementation. In 1953, ACS officially transferred its Hospital Standardization Program to the Joint Commission on Accreditation of Hospital, which began providing accreditations to hospitals in the United States[6,7].

In 1966, Dr. Avedis Donabedian developed a model. This framework still has a remarkable implication during the modern healthcare quality: what we call a Donabedian Model, that lays out three key components for monitoring, analyzing, and improving the Quality of care outcomes; the structure, process, and outcomes. Each of these components helps the organizations to measure its intended outcome based on the processes it develops and the resources it provided. Hence, structures are the resources required to implement the processes for the desired outcomes[8].

The further initiative includes the National Surgical Quality Improvement Program (NSQIP), the use of selective referral

and centers of excellence, the Surgical Care Improvement Project, and the World Health Organization Surgical Safety Checklist[9].

American College of Surgeon's NSQIP is one of the most widely recognized programs developed by the Department of Veterans Affairs health system. This program was based on a Quality measurement system for non-cardiac surgeries and its core purpose is to enhance the quality of surgical care by focusing on the core processes and structure of care at the subspecialty level of surgical care and services rather than focusing on bad surgeons. The program works on the Donabedian framework of Structure, Process, and Outcome. Department of Veteran Affairs witnessed a 27% decrease in postoperative mortality and a 45% decline in postoperative morbidity, along with a decreased length of stay and a positive increase in patient satisfaction scores[9].

There is insufficient research in Pakistan to establish the challenges and medical errors affecting patient care outcomes during hospitalization apart from medical errors. Despite being a lack of research and reporting culture, medical errors in Pakistan are as high as half a million in a year. Recent studies showed that 134 million adverse events occur every year due to a lack of safe care in hospitals in Lower-Middle Income Countries (LMIC), which leads to 2.6 million deaths each year[10]. These statistics reveal that LMICs are way behind the developed contries in ensuring safe care in hospitals. For instance, ACS published its first "Minimum Standards" back in 1917. In Pakistan, the first of its kind, Minimum Service Delivery Standards for Hospitals, was published in 2013 and was only done in one province of Pakistan, i.e., Punjab. Before this, there were no such healthcare-related standards that focused on holistic care. However, these minimum service delivery standards still lack the framework required to implement these standards in true letter and spirit. As we have already discussed above, the actual surgical errors were the ones that occurred during pre- and post-operative surgical care. These include inadequate communication amongst the surgical team, healthcare providers, patients, and their families, delay in diagnosis or failure to diagnose, and delay in treatment or failure to treat[5]. One report from Joint Commission revealed that 80% of the medical error is caused by the lack of communication of one kind or another between care transitions[11]. Lack of an integrated approach between departments, inappropriate System Thinking, and the lack of a Donabedian approach also has a critical role in not achieving high-quality care. Due to a lack of education, training, and human resource development, the staff is rarely bothered to implement these standards. Some common failures that impede the Quality of care are listed but not limited to, the following:

1. Not prioritizing the Quality Improvement Activities as the first point agenda in Top Management Meetings.
2. Lack of emphasis in Documentation Control.
3. Improperly informed consent may cause miscommunication.
4. Improper Handoff communication between caregivers including doctors.
5. Transfer within the Hospital facility mostly undermines in many hospitals.
6. Improper Preoperative assessment.
7. Lack of follow up on specimen pathology after surgery.
8. Site marking and Time Out Process knowledge and implementation.

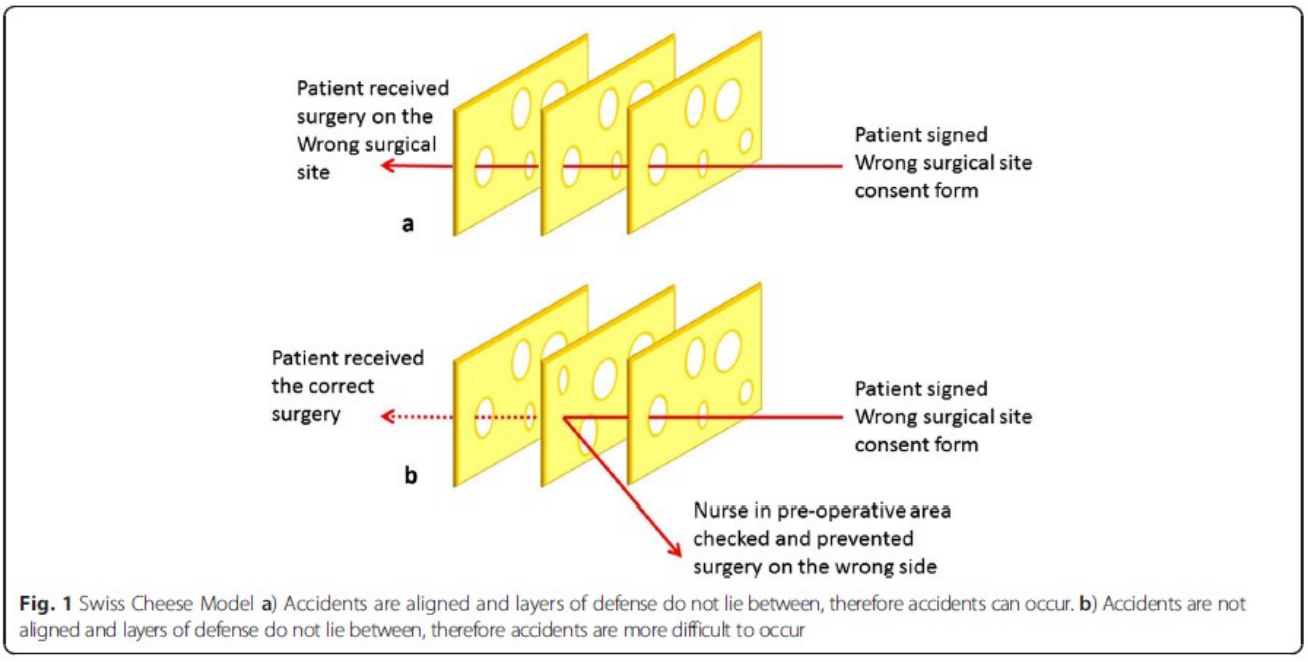

Fig. 1 Swiss Cheese Model **a**) Accidents are aligned and layers of defense do not lie between, therefore accidents can occur. **b**) Accidents are not aligned and layers of defense do not lie between, therefore accidents are more difficult to occur

9. Lack of preparation beforehand before elective cases.
10. Lack of implementation understanding of the Safe Surgery Checklist and its importance.
11. Improper monitoring of quality measures.
12. Proper Monitoring of Anesthesia Care.
13. Lack of labeled medications administered in Operating Rooms
14. Breach of Operating Room space by staff again and again during the procedure.
15. Ensuring the CSSD indicator before using the surgical instrument.
16. Proper Sign Out with swab and instrument count, etc.

In this overall scenario, it is imperative to understand that human beings may make errors. And errors are unavoidable, but having a well-established system for developing processes, keeping the outcomes in focus, and providing the right structure can prevent errors. This is illustrated in the Swiss Cheese Model, formally propounded by Dane Olandella and James R. Reason, where each hole, dispersed at random, denotes a varying degree of failure at every step and the slice represents the defense layer in the process. The alignment of the holes results in the patient being harmed.

Each layer in the process acts as a defense against the potential error, as depicted in figure below[5]:

Thus, we need to formulate surgical care processes with multiple layers of defense to ensure a proper defense mechanism against the potential harm caused by an error.

THE WAY FORWARD:

Given the various research articles and as working Quality Professionals, there is a dire need to develop a system under the public and private partnership i-e The Department for Surgical Improvement in Pakistan. This department's focus will be to conduct research and recommend improvements in General Surgery across Pakistan. The department will also focus on developing critical surgical measures, analyzing and sharing data on positive outcomes procedure, consultant and hospital-wise, and issue them for the public to choose from the best possible care available to them. These measures will also be available for national and international benchmarking. This will create a surge in the Surgeons and the Hospitals to measure, analyze, and improve their performance, as things which are not measured cannot be improved.

At the end but not least, the Avedis Donabedian Model should be utilized for the minimum service delivery standard's basic framework. As the outcomes cannot be achieved in the absence of processes, and implementation of processes cannot be achieved without a proper structure.

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