**Study Title: Surgical safety audit in India, or Lack thereof: An urgent need for national policy on wrong site surgery registry and research**

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*Abstract*

Multiple studies have analyzed the incidence of wrong site surgeries in developed countries. This study aims to find out information relevant to the incidence and pattern of WSS in India. Multiple sources like Medline, EMBASE, and the Global Health Library databases were searched for abstracts and citations in all languages published between Jan 1, 1975, and Dec 31, 2018, describing any WSS from India. After extensively searching the online databases only one case report related to WSS in India could be found. Zero incidences of WSS in general surgery from India seems fallacious and it is due to non-reporting of such events and Government of India should implement a national registry to maintain data on WSS which can lead to improved surgical care.

*Key words:* Wrong-site surgery, Surgical safety audit, Health policy, LMIC

*Introduction*

Healthcare has become one of India's largest sectors both in terms of revenue and employment. The industry is growing at a tremendous pace owing to its strengthening coverage, services and increasing expenditure by public as well as private players[1]. The total industry size is estimated to touch US$ 372 billion by 2022. The hospital industry in India stood at Rs 4 trillion (US$ 61.79 billion) in financial year (FY) 2017 and is expected to increase at a Compound Annual Growth Rate of 16-17 per cent to reach Rs 8.6 trillion (US$ 132.84 billion) by FY 2022 [1]. Patient safety is a crucial component of the quality of healthcare. This topic is attracting lawmakers and the general public in India as well. Wrong-site surgery (WSS) is one of the most devastating patient safety issue having implications beyond its effects on the patient. It has medical, legal and social implications. The Joint Commission sentinel event statistics database of North America ranks wrong-site surgery as the second most frequently reported event [2].

Multiple studies have analyzed the incidence of wrong-site surgeries in high income countries (HICs) mainly in the USA and Canada [3,4,5,6,7]. These research publications have identified wide variations in incidence, pattern, and prevention but they have sampled only a small proportion of world population undergoing surgeries leaving out low and middle income countries (LMICs). This study aims to find out information relevant to the incidence and pattern of WSS amongst patients undergoing general surgical procedures in India.

*Methods*

Single repository or one all-inclusive website providing information on wrong-site surgery does not exist in India. There is no national database for India, neither reporting of WSS is mandatory by health administration. Hence, multiple sources were used to extract data on WSS. We searched Medline, EMBASE, and the Global Health Library databases with the search terms “ wrong-site surgery India” “wrong side surgery India”, “wrong patient India” and “wrong procedure India” for original articles, case reports, abstracts and citations in all languages published between Jan 1, 1975, and Dec 31, 2018, describing any WSS. All original articles were included, case reports, letter to the editor and commentaries were also included. We excluded articles on WSS in neurosurgical and dental procedures. Reference lists of key articles were also systematically checked. The final search was performed in December 2018. Data regarding a brief description of the wrong site, side, procedure or patient was identified and analyzed.

*Results*

After extensively searching the online databases only one case report related to WSS in India could be found [8]. Dheeraj et al.[8] have described two cases where the wrong side was avoided due to surgical safety check-list. This result puts the incidence of WSS in general surgical procedures in India to be zero since 1975. This did not appear to be true. Hence we expanded our search to include news reports as well. We found all types of WSS only within the past four years of search [9,10,11,12]. Hence this apparent incidence of zero based on published literature cannot be true.

*Discussion*

This survey result suggested a major lacuna in the Indian health care system which is non-reporting of WSS. Zero incidence of WSS can never be true although it should be the goal. Reporting is fundamental to detecting patient safety issues. Non-reporting is like not acknowledging the issue. A Harvard study by Jha et al. [13] shows that there are approximately 16.8 million injuries annually due to adverse events among hospitalized patients in high-income countries. LMICs, which have five times the population of HICs, experienced approximately 50% more adverse events (25.9 million). Based on these findings, they estimated that there were 22.6 million disability-adjusted life years (DALYs) lost due to these adverse events in 2009. The number of DALYs lost were more than twice as high in LMICs (15.5 million) as they were in HICs (7.2 million). There is a lack of any such comprehensive report on WSS from India due to non-reporting. The cause of non-reporting is multiple; like fear of social punishment, such as being judged by the administration or coworkers and peer envy. Studies have shown that the first step towards increasing the reporting of adverse incidents requires creation of a safe and positive environment. Emphasizing on an organizational approach instead of an individual one, can increase the sense of security and reduce the denial of one’s errors [14,15].

Registries that collect information on specific WSS detection, processing, and reporting lead to a better understanding of surgical loophole and lead to the implementation of checks to prevent these adverse events. In fall 1999, the Institute of Medicine (IOM) released its groundbreaking report, To Err Is Human, which estimated that the annual number of deaths in the United States due to medical errors is between 44,000 and 98,000[16]. A standardized medication error reporting system, MEDMARX, an Internet-based commercial reporting application was selected by the US Department of Defense leadership as the standard tool for medication event reporting. MEDMARX was implemented initially at five military hospitals in fall 2000 as part of a patient safety pilot project and was later made available to all 143 military treatment facilities worldwide [17]. Other organizations such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the ISMP have identified numerous medication error patterns and corresponding strategies for reducing errors that could benefit all clinical facilities [18]. India and other LMICs have a long way to go to reach this level but implementing and maintaining a national registry should be the first step towards this goal.

*Conclusion*

Zero incidences of WSS in general surgery from India seems to be fallacious and is due to non-reporting of such events. Government of India should implement a national registry to maintain data on WSS which can lead to improved surgical care.

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