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Barriers prevent professionals performing laparoscopic surgeries from reporting near misses and adverse events: A mixed methodology approach

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Corresponding Author:	Latif Al-Hakim University of Southern Queensland AUSTRALIA
Corresponding Author Secondary Information:	
Corresponding Author's Institution:	University of Southern Queensland
Corresponding Author's Secondary Institution:	
First Author:	Min Yan, MD
First Author Secondary Information:	
Order of Authors:	Min Yan, MD Ming Wang, MD Latif Al-Hakim
Order of Authors Secondary Information:	
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Abstract:	<p>Background</p> <p>Literature identified factors preventing surgical professionals from reporting adverse events, but with much less emphasis on near misses. No attempt was made to categorise near misses by type and reportability. This paper attempts to fill these two gaps in literature.</p> <p>Methods</p> <p>A mixed methodology approach was adopted. A sample of 16 laparoscopic surgeries were observed followed by a questionnaire distributed among professionals dealing with laparoscopies. Non-parametric tests were used to compare responses. Factors moderating and mediating management-workload relationship were identified.</p> <p>Results</p> <p>A total of 469 non-consequential events were observed. Near misses were classified into two categories: reportable events and common events. Among 23 observed reportable events, only 9 events were reported. Out of 350 distributed questionnaires, we received 168 valid responses (response rate 48%). The professionals strongly disagreed that reporting near misses (Mean 4.09, STD 0.95) and adverse events (4.17, 1.02) makes little contribution to the quality of surgery. Heavy workload, and fear from disciplinary actions negatively affected professionals' willingness to report near misses. The Wilcoxon test illustrates that 76% of respondents gave higher ratings to reporting adverse events relative to near misses. Results show that professional's attitude mediates the management-workload relationship, while knowledge moderate the</p>

relationship.

Discussion

Error reporting should aim to promote safety, knowledge sharing and education. It is important to differentiate near misses that should be reported from voluntary reported events. Hospital's management might award professionals who frequently report errors and provide solutions, Quality rather than quantity of reports should be emphasised with flexibility in the way near misses are reported.

Conclusion

The outcome of this study has benefits of understanding the attitudes of surgical professionals towards error reporting. It provides healthcare management with tool for enhancing safety and providing suitable training for their professionals.

Title: Barriers prevent professionals performing laparoscopic surgeries from reporting near misses and adverse events: A mixed methodology approach

Running head: Error reporting during laparoscopies

Authors: Min Yan MD¹, Ming Wang MD², Latif Al-Hakim PhD³

Affiliations:

¹ Department of Anesthesiology, The Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, China.

² Department of Urology, The Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, China.

³ School of Management and Enterprise, University of Southern Queensland, Queensland, Australia.

Correspondence to:

Latif Al-Hakim

Email: latif.Al-hakim@usq.edu.au

Mobile: +61479091246

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Abstract

Background. Literature identified factors preventing surgical professionals from reporting adverse events, but with much less emphasis on near misses. No attempt was made to categorise near misses by type and reportability. This paper attempts to fill these two gaps in literature.

Methods. A mixed methodology approach was adopted. A sample of 16 laparoscopic surgeries were observed followed by a questionnaire distributed among professionals dealing

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with laparoscopies. Non-parametric tests were used to compare responses. Factors moderating and mediating management-workload relationship were identified.

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Discussion. Error reporting should aim to promote safety, knowledge sharing and education. It is important to differentiate near misses that should be reported from voluntary reported events. Hospital's management might award professionals who frequently report errors and provide solutions, Quality rather than quantity of reports should be emphasised with flexibility in the way near misses are reported.

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Keywords. Adverse event, disruptive event, error reporting, factor, laparoscopy, near miss.

Introduction

1 The report of American Institute of Medicine “To err is human“ [1] identified medical
2 errors as a significant contributor to patient morbidity and mortality in hospitals. The report
3 stressed that errors during procedures form a leading cause of death in United States. The
4 report emphasised that most errors were the consequences of system and human errors and
5 can be prevented. An error is the failure of a planned action to be completed as intended
6 (error of execution) or the use of a wrong plan to achieve an aim (error of planning) [1].
7 Francis et al. [2] classified error into consequential and non-consequential errors depends on
8 effect of the error on the postoperative outcome. We use Francis et al. classification with
9 some adaptation. We refer to non-consequential errors as ‘near misses’ (NMs), otherwise,
10 they are ‘adverse events’ (AEs) [3]. NMs may or may not need corrective action during
11 surgery but with no change or obvious change in the postoperative care. Not all the errors are
12 the consequences of medical interventions, that is, they are the consequences of patient
13 health. An error, NM or AE, occurs as consequence of a system and human error is known as
14 preventable error [1, 4-7]. Kable et al. [8] investigated the adverse events occurs in
15 Australian hospitals and found that 48% of adverse events were highly preventable. Nilsson
16 et al. [9] studied the adverse events in Sweden hospitals and stressed that total of 62.5% of
17 the adverse events were considered probably preventable. In addition, near misses by far
18 outnumbered the adverse events. Francis et al. [2], for instance, investigated intraoperative
19 errors in laparoscopic surgery and find only 2.1 of the errors required major corrective action,
20 while 60.1% of the incidences observed were minor errors with no damage or corrective
21 actions required, and 37.1 minor errors required corrective action but no change in
22 postoperative care. Bosma [6] applied the common cause hypothesis and submits that the
23 near misses have similar pathways as adverse events. de Level et al. [10] asserted that even
24 minor intraoperative events can lead to higher rate of patient morbidity and mortality.
25 Bonrath et al. [11] agreed and affirmed that near misses in surgery environment were neither
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1 widely acknowledged nor investigated. The study of Howell et al. [12] used Delphi approach
2 to establish international expert consensus on error reporting. The majority (96.2%) of the
3 expert panel recommended that near misses should also be reported.
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7 Literature stresses that errors in healthcare are underreported [4, 13]. Much research works
8 investigate barrier preventing physicians and nurses from reporting errors [4, 14]. Little is
9 known about barriers preventing reporting during surgeries [1, 15-17]. In addition, research
10 works examining barriers preventing surgical professionals (surgeons, anaesthetists, and
11 nurses) from reporting NMs and AEs during minimally invasive or laparoscopic surgeries is
12 limited [2, 18-21]. Observational studies revealed that majority of non-consequential or NMs
13 errors are repetitive, non-consequential, require minor or no corrective action during surgery,
14 and with no change (or obvious change) in postoperative care [2, 22], and the question arise
15 as whether there is need to report all NMs and if not, which NMS should be reported. This
16 issue has not been investigated in previous research works. This study considers error
17 reporting with a dual aim. First, to differentiate the type of NMs that should be reported from
18 other common repetitive errors and second, to explore barriers preventing surgical
19 professionals dealing with laparoscopic surgeries from reporting errors.
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40 Review of literature shows that more papers reported medical errors carried out in USA
41 and Western countries [23-27]. Giving the high population of China relative to other
42 countries, it is very surprising to note that there are very limited research works on medical
43 errors conducted in China mainland. In an attempt to fill this gap in the literature, this study
44 used a large Chinese hospital as a case.
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52 As our study conducted in Chinas, it has benefits to briefly elaborate into continuing
53 organisational transition in China. During the last three decays, China has faced
54 organisational transition as a result of international business and globalisation [28, 29]. Such
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1 transition has impacted the way Chinese managers are managing the healthcare hospitals.
2 Ralston et al. [30] suggested that the new generation managers in China are “more
3 individualistic and more likely to act independently, while taking risks in the pursuit of
4 profits”. This conclusion has been supported by other researchers [31, 32]. Though, the
5 Chinese healthcare reforms launched in and after 2009, were target profit-making in public
6 hospital, the status of profit-orientation of public institutions remains unknown [33]. This
7 suggests that the healthcare managers in China may attempt to modernise or craft their
8 traditional Chinese organisational cultures with the Western style of organisational culture,
9 with more emphasis on profit [34, 35]. Such modernisation may create a gap between ‘as
10 is’ organisational support and that ‘should be’. Such gap could be reflected on the way the
11 managers deals with surgical professionals and their workload. It may also make
12 professionals to belief that organisational support does not match their effort and workload.
13 Beside fearing from disciplinary actions and litigations, the heavy workload affects the
14 willingness of medical professionals to spare extra time to report errors. From this
15 perspective, it is of some benefits to identify factors affecting the causal relationships
16 between management and professionals’ workload. Two types of factors affecting causal
17 relationships; mediators and moderators. A mediator is a variable that alter the strength of
18 the relationship between an independent variable and dependent variable, while a moderator
19 is a variable that specifies conditions under which a given independent variable is related to
20 dependent variable [36]. According to our best knowledge, this study is the first of its kind
21 that considers causal relationships in dealing with error reporting.
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51 **The case hospital**

52 The case hospital is a large public teaching hospital located in Zhejiang Province, China.
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54 The hospital was founded in 1869 by a British Church Missionary Society. In 1885, the
55 hospital established a medical school, which was one of the earliest medical educational
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1 institutions in China. The hospital core value is “the needs of patients and customers come
2 first”, and its vision is to be “an internationally recognized and branded hospital with
3 distinguished clinical specialties”.
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8 The hospital has two campuses with 58 clinical departments and a total capacity of 3200
9 beds. In 2017, the hospital has over 5000 employees, including 1569 professional doctors,
10 2280 nurses, and 595 medical staff. It had served around 154,000 inpatients and conducted
11 130,000 surgeries. Nationally, the hospital ranks top 20 and is one of the largest hospitals in
12 the Zhejiang province. It affiliates with 9 hospitals and collaborates with over 200 hospitals
13 and 31 community clinics across the country. In 2013, the case hospital succeeded in Joint
14 Commission International (JCI)- Academic Medical Centre Hospital and passed the JCI
15 accreditation in 2016. As part of the accreditation process, the hospital established error
16 reporting system and encouraged its medical staff to attend related training courses and
17 seminars.
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31 **Materials and methods**

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36 Initially, ethical approval was obtained from R&D office at the case hospital and the
37 study had been conducted during March, April, and November 2018 at the time where the
38 third author (LH) available in the China. We adopted mixed methodology in which an
39 observational study, a pilot study and self-administrative questionnaire were formulated and
40 distributed among professionals who were dealing with laparoscopies.
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49 A total of 16 endoscopic surgeries were observed with the purpose of recording errors.
50 Observations were conducted mainly by human factor expert (LH). In some cases, the main
51 observer was accompanied by a senior surgeon (MW). The video record of the surgical field
52 was subsequently reviewed, and the data collected during the observation was cross-checked
53 against that recorded in the video. After each observation, the observers met the surgeons and
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1 discusses various observed errors. Emphasis was placed on the opinion of the surgeon on the
2 classification of observed events, whether events were reported, and reasons for reporting or
3 not reporting events. As a result of information gained from the observational study, we
4 formulate the second phase of the methodology, which comprises three stages: preparation,
5 stage data collection stage, and data analysis stage.
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12 The first stage consists three phases. In the first phase, a list of factors affecting error
13 reporting was extracted from literature using ‘Google Scholar’, Baidu Scholar’ and PubMed
14 databases. The search allowed us to formulate an initial questionnaire with factors and
15 strategies stated in literature [4-6, 11, 16-18, 37]. A focus group of five senior surgeons, an
16 anaesthetist and two senior nurses from the case hospital together with a human engineering
17 expert was formed. The focus group revised and modified the initial questionnaire. In the
18 third phase, a pilot study was conducted in which the questionnaire was then distributed
19 among 32 surgical professionals. Initially, the questionnaire constituted 31 items and
20 measured using 7-point Likert scale. Based of the comments and suggestions received from
21 the participants, items were reduced from 31 items to 27 items. As suggested, the scale for
22 items was changed to 5-point Likert scale because of difficulties to differentiate between 1
23 and 2, and 6 and 7 within 7-point Likert scale. In the second stage, the questionnaire was
24 randomly distributed among members of surgical teams in the hospital. Telephone calls and
25 emails were used to follow the questionnaire’s recipients. The third stage deals with data
26 analysis and comprises two phases: determining differences in assessments, and finding
27 factors affecting management-workload relationship.
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52 Considering the sample size with no prior assumption of normality of data distribution,
53 non-parametric tests were used to measure differences in assessments between groups [38].
54 Wilcoxon signed-rank test was used to determine differences between the respondents’
55 evaluation of near misses and adverse events [39]. SPSS version 25 with an add-on model of
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1 SPSS referred to as PROCESS v.3.3 model in a bootstrap approach [40, 41] were used to
2 analyse data.
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5 **The questionnaire**

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8 A covering letter attached with the questionnaire illustrating the survey's purpose with
9 indication that responding the questionnaire is voluntary and implies the consent of the
10 respondent. Benefiting from the outcome of observational study, the covering letter explains,
11 with examples, two type of NMs; NM events that should be reported, (reportable NM
12 events), and common events that often occurs during surgeries, (refer also to Results –
13 Observational study).
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24 The questionnaire consists four sections. The first section deals with the demographic
25 data of the respondents. The second section focuses on factors affecting error reporting. It
26 comprises 27 items in a form of question arranged into eight groups; Attitude, (4 items),
27 workload (3 item), privacy (3 items), system, (3 items), Society and law (3 items), knowledge
28 (4 items), management (4 items), staff (3 items). Each item requires two input concerning the
29 evaluation of the respondents in case of reportable near misses events and in case of adverse
30 events. A 5-point Likert scale is used to evaluate the factors with '1' represents 'strongly
31 agree', and '5' indicates 'strongly disagree'. The third section deals with common events
32 (other than reportable NMs). It includes 8 statements and the respondents asked either agree
33 or disagree, or have no view with each statement. The last section comprises an open
34 question for the respondent's opinions and suggestions.
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54 **Results**

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56 **Observational study**

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1 A total of 469 non-consequential errors, ie., NMs, were observed, but no consequential,
2 ie., AE, was observed or recorded (Table 1). The table shows that NMs are classified into two
3 categories: Reportable events 'RE' and common events 'CEs'. The latter was further
4 classified into marginal events and soft events. Discovering faulty surgical instrument and
5 excessive bleeding due to vessel injury are two examples of RE, while minor bleeding due to
6 failure to coagulate before dissection and correcting the direction of inserted instrument are
7 two examples of CE near misses errors.
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17 Our observations show that only 9 out of 23 REs were reported (Table 1). Heavy
18 workload, details required, and fear from disciplinary actions were the main reasons for non-
19 reporting. The surgeons argued that CEs are often occur during surgeries, difficult to
20 determine their number of occurrences, and inappropriate for reporting them as reportable
21 events. However, they indirectly contributed to errors and they most discussed thoroughly to
22 enhance surgery performance, and for training purposes.
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33 **Table 1.** Observed non-consequential (near misses) events.
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39 **Quantitative study**

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42 The questionnaires were distributed among 350 surgical members randomly selected from
43 surgical professionals dealing with the laparoscopic surgeries. We received 221 responses,
44 among them only 178 responses were considered valid, (valid response rate 48%). A total of
45 81 responses (45.51%) were received from surgeons and assistant surgeons (Table 2). The
46 number of responses from anaesthetists and their assistants was 40 responses forming 22.47%
47 of the total participants, while the number of valid responses from scrub and circulation
48 nurses was 57 responses forming 32.02% of the total valid responses. Table 2 shows that a
49 total of 103 participants were female (57.87%), and 75 were male (42.13%). Largest number
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1 the respondents (78, 43.82%) had experience more up to 5 years, 55 respondents (30.90%)
2 had experience between 5 and 10 years, and only 45 (25.28%) respondents had experience
3 more than 10 years, among them 13 (07.30%) respondents had experience more than 20 years
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7 (Table 2).
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10 To explore the willingness of professionals to report both REs and AEs, we need first to
11 investigate the knowledge and attitude of professionals towards reporting errors, and the
12 willingness of reporting errors as a results of heavy workload, that is, to investigate the
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10 Table 3 shows descriptive statistics and the outcome of Wilcoxon signed-rank test.
11 Starting with the first item of Knowledge, that is, KNO1, the surgical professionals strongly
12 disagreed with statement of the item that error reporting makes little contribution to the
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10 The professionals rejected the statements of the first three items of Attitude, but with more
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1 (4.168,0.860). The Wilcoxon test, however, reveals that there is statistically difference in
2 rating RE and AEs for covering errors with higher weights was given to AEs ($\rho < 0.001$, 25,
3 78, 75). Alike conclusion can be depicted from ATT2 and ATT2 items of Attitude variables.
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5 Regarding ATT4, the professionals accepted the statement that they report REs if the others
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7 do (2.360, 0.960), but rejected the statement for reporting AEs (3,169, 0.905). The Wilcoxon
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9 test shows significant differences in rating item ATT4 with 75 participants gave higher rating
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11 to AEs relative to only 4 participants gave higher rating to REs ($\rho = 0.000$, 4, 75, 99).
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17 However, this is not the case with items associated with Workload variable, where most of
18 the respondents agreed with statements of Workload variables for REs but disagreed for AEs.
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20 The results regarding item WOR3, for instance, shows that heavy workload affected
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22 negatively the professionals' willingness to report REs (2.669, 0.888) in comparison to
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24 reporting AEs (3.826, 0.829). The Wilcoxon test illustrates that most of the respondents (136
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26 respondents) gave higher ratings to AEs ($\rho = 0.000$, 3, 136, 39). Similar results can be
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28 detected from results related to WOR1 and WOR2.
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35 The outcome of Wilcoxon test associated with Workload reflects stronger willingness to
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37 report AEs relative to REs. No doubt, such outcome was not the outcome wanted by the
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39 hospital's management. This was evidenced from the results associated with three items of
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41 Management variables for both REs and AEs. The professionals disagree with statement
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43 associated with items MAN1, MAN2 and MAN3 for both REs and AEs that management did
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45 not support error reporting, did not encourage reporting unless they asked for, and did not
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47 provide feedback. However, the professional agreed with the statement of MAN2 for both
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49 REs and AEs that they were worried from disciplinary actions. The Wilcoxon test shows
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51 there is no significant differences in ratings REs and AEs for item MAN2 ($\rho = 0.656$, 44, 31,
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To further explore reasons for having stronger willingness for reporting AEs than REs, we need also to investigate outcome associated with items of other variables; System, Privacy, and Staff. Results of item 'SYS2: 'There is no clear guideline about the errors' show that the surgical professionals agreed with the statement in regard to RE (Mean = 2.472, STD = 1.032) but disagree in regard to AEs (3.770, 0.822). The Wilcoxon test shows that most of participants (129 participants) gave AEs higher weights than REs against only 2 participants gave lower weight to AE ($\rho < 0.001$). This is the case also with item 'SYS1: 'The form takes too long to fill in' (NM = 2.90, 1.16; AE = 3.39, 1.10). Results for item 'SYS3' that the system could be used as trap to track down the reporter reflect the surgical professionals agreed with the statement of the item for both REs and AEs (RE = 2.65, 1.11; AE = 2.61, 1.07).

The surgical professionals agreed with 'PRIV1' that their errors should not be discussed openly (2.584, 1.25; 2.54, 1.21) and with 'PRIV2' that they were not sure who will have full access to the information (2.702, 1.08; 2.88, 1.13). However, they disagree with 'PRIV3' that they were worried that the privacy could be breached (3.48, 1.20; 3.10, 1.20). The results of Wilcoxon test indicate that participants gave more weights to REs than AEs ($\rho = 0.000$, 61, 27, 90).

Results from item SOC1 'I am worried about litigation' reveals that the surgical professionals disagreed with the statement for REs (3.30, 1.24) but agreed with the statement for AEs (2.75, 1.06). The Wilcoxon test shows that 85 participants gave higher weights to REs opposite to only 1 participant gave a higher weight to AE ($\rho = 0.000$, 85, 1, 82). The results revealed that participants were agreed with SOC2 'I am worried from media involvement' for both REs (2.90, 1.10) and AEs (2.78, 1.03). For the three items associated with STAFF, the professional agreed with the statements with no significant differences between REs and AEs.

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Regarding the general events, the professionals rejected statements that is waste time to report general events because they are known to them, to consider them as errors because they do not harm patient, or to report them because they do not affect the surgery outcome. The majority of professionals stressed that reporting general events should be voluntary, should be used for training and learning, awards should be provided for professionals providing effective solutions, and professionals should have flexibility to report general events as they see it fit,

Table 2. Demographic data of the participants.

<Insert Table 2 around here>

Table 3. Descriptive statistics and the outcome of Wilcoxon signed-rank test.

<Insert Table 3 around here>

Outcome regarding CEs

Statements in the third section of the questionnaire deal with the professional's opinion regarding the reporting of CEs. Table 4 illustrates the professionals' responses. It shows that 88% of the professionals disagree with the statement that there is no need to report CEs. The majority of professionals (94%) recommend reporting CEs should be voluntary with flexibility in the way they report CEs. 91% of the surveyed professionals recommend establishing awards to those regularly report CEs and provide solutions (Table 4).

Table 4. Professionals' suggestions on encouraging CEs reporting

<Insert Table 4 around here>

Testing the mediation and moderation effects for REs.

1 The management-workload relationship gives some explanation about surgical
2 professional attitude towards error reporting. Our results show that Workload does not
3 correlate significantly with Society & Law ($\rho = 0.715$) and Staff ($\rho = 0.584$). Also, the
4 Management variable does not correlate significantly with Knowledge ($\rho = 0.111$).
5 Accordingly, the variables Knowledge, Society & law, and Staff have no potential to
6 mediate the Management-Workload relationship. Table 4 summarises the outcome of
7 implementing PROCESS model 4 for variables that may have the role of mediator. This
8 outcome signifies that where Attitude proposed to mediate the Management-Workload
9 relationship, the value of total effect for Management on Workload becomes significant ($\rho =$
10 0.0345), direct effect is insignificant ($\rho = 0.3101$), and indirect effect is significant with
11 confidence bands (LLCI, ULCI) do not contain zero (0.0101, 0.1530). Accordingly, Attitude
12 mediates the Management-Workload relationship. Similarly, Privacy mediates the
13 relationship. Table 4 shows that the confidence interval (LLCI, ULCI) associated with
14 indirect effect for the System include zero (-0.0088, 0.0760) and accordingly, System has no
15 role for mediating the Management-Workload relationship.
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37 Table 5 depicts the outcome of using PROCESS model code 1 for testing the moderation
38 effects. It shows that Society & Law, Knowledge and Staff moderate the Management-
39 Workload relationship. The negative value of the effect (β) associated with the three variables
40 reflect that the variables form 'buffering' variables. That is, increasing the scale of the
41 moderator would decrease the effect of Management on Workload as shown in Figure 1(A,
42 B, C).
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52 Testing the mediation and moderation effects for AEs

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55 Table 4 shows the outcome of using PROCESS model 4 for testing the mediation. The
56 results show that variable Attitude mediates that Management-Knowledge relationship, with
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1 significant total effect ($p = 0.0041$), insignificant direct effect ($p = 0.1764$), and indirect effect
2 with confidence interval does not include zero (0.0283, 0.1932). Similarly, System,
3 Knowledge, and Staff variables mediate the Management-Workload relationship.
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7 From Table 6 we can conclude that Privacy is the only variable that moderate the
8 Management-Workload relationship with $\beta = -0.1283$ and the confidence interval for indirect
9 effect does not include zero (-0.2546, -0.0020). Figure 2 illustrates the effect of Privacy on
10 Management-Workload relationship.
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18 **Table 5.** The mediation effect of variables on the relationship between Management and
19 Workload.
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27 **Table 6.** The moderation effect of variables on the relationship between Management
28 and Workload using PROCESS toll model code 1.
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38 **Figure 1.** The moderating effects of (a) society & Law, (b) knowledge, and (c) Staff on
39 professionals' willingness to report near misses -moderating effect on management-workload
40 relationship.
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45 *<Insert Figure 2 around here>*
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50 **Figure 2.** The moderating effect of privacy on professionals' willingness to report adverse
51 events.
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58 **Discussion**
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1 Our study reveals key conclusions regarding error reporting. Of primary importance are
2 the positive attitude of surgical professionals toward error reporting, the belief that reporting
3 of errors significantly contribute to the quality of care, and the consensus that hospital's
4 management encouraging the disclosure and reporting errors, even if they did not ask for. In
5 addition, the results indicate that professionals had knowledge about which errors should be
6 reported, how to report, and to whom they need to report. However, the observational study
7 reveals that only 9 out of 23 reportable near misses (REs) were reported. The qualitative
8 study exhibits that the surgical professionals were more likely willing to disclose adverse
9 events (AEs) than REs, despite their fear from litigation. Three main reasons behind the
10 willingness of the professionals to disclose AEs. First, unlike REs, AEs are likely to be
11 recognisable and accordingly, patients and their families want to know what wrong happened
12 and why [42]. In addition, professionals have ethical obligations to disclose errors. The way
13 of disclosing AE to patient and family may be critical in the decision whether to lay a formal
14 complaint. In some situations, disclosure errors with careful selecting of words and apology
15 may lead to resolve the issue in amical way [43].

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37 Second, the heavy workload the professionals have faced reduces their willingness to
38 report REs. Except for instrument malfunction or missing test reports, the other REs are not
39 well stated or defined. Management attitude towards errors, privacy and complexity of error
40 system are additional factors affecting professional from reporting REs. In general, the
41 professionals have obligation to report AEs but voluntary for reporting NMs [44, 45]. It
42 should be noticed that World Health Organisation established in 2005 a guidelines for
43 reporting AEs [46]. However, no clear guidelines were established regarding NMs, including
44 REs. We hope WHO will attempt to fill this gap in error reporting literature.

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57 The third reason is that the case hospital has been accredited by the Joint Commission
58 International (JCI). JCI demands, as a condition of accreditation, that the hospital establishes
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1 system for reporting error, trains professionals on error reporting, and informs patients of
2 unanticipated outcome [47]. The positive attitude of professionals toward reporting and
3 disclosing AEs, had made the hospital lined up with the requirements of the JCI.
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8 Our results show that factors associated with the system form the main barrier from
9 reporting REs. Apparently, same form was used to report REs and AEs. The professionals
10 perceived the form as unsuitable and too long for reporting REs. To maximise REs reporting,
11 the system should give opportunity to the professionals to report REs with flexibility in the
12 way as they report them.
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21 Privacy, management support, and heavy workload comprised factors affecting the
22 disclosure of REs. In addition, there was no clear guidance in reporting REs. Professionals
23 believed that reporting REs may be used as trap to track the reporter down. In addition,
24 professionals had no clear idea who had access to information, and they were worried from
25 disciplinary actions because of reporting REs. Our results associated with workload indicate
26 that large number of professionals believed that heavy workload affected their willingness to
27 report NMs, or to spare extra time for reporting REs. In addition, professional believed that
28 reporting NMs is not recognised as part of their workload. Literature emphasises that
29 workload creates mental and physical stress to professionals and may creates environmental
30 factors for errors [48-50]. While the management encouragement is very important to
31 promote reporting, the management should comprehend that rreporting system, and
32 specifically the reporting of REs, should not be used for issues other than promoting solutions
33 for patient safety, learning and training. The hospital professionals perceived reporting errors
34 makes considerable contribution to the quality of care and safety performance but this,
35 however, was not borne out in practice [51]. Professional afraid from disciplinary actions and
36 from using reporting against them [52]. To promote error reporting management should shift
37 attention of professionals away from perceived disciplinary actions and alleged discreditable
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1 associated with errors, and view errors instead as a critical step in a journey of learning and patient
2 safety [53]. The quality, rather the quantity of reports should be also emphasised [54, 55]. It
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4 may have advantage to create incentive system for awarding professionals contributing for
5 reporting and developing solutions to reduce NMs and associated disruptive events.
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10 We learn from the observational study, as well as from other studies [2, 3, 21, 22], there
11 are large list of common events (CEs) that have no effect on postoperative care but disturb
12 the surgical flow and often occur during surgery. CEs may be considered minor (see Table 1),
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14 the accumulation of these events, however, can create stress and fatigue and may predispose the
15 surgical team to AEs [56, 57]. Here, we are facing a dilemma. From one hand there are some
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17 difficulty for having professionals reporting REs. On the other hand, there is obvious need to report
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19 and understand the cause roots of CEs. Outcome from observational study provides some good
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21 suggestions. Though reporting CEs is voluntary, the management should encourage professionals
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23 reporting CEs. It may have advantage to encouraging reporting CEs by giving flexibility in the way
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25 the professionals report CEs, and awarding professionals who regularly report CEs and suggest
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27 effective solutions. Summary of CEs report should be discussed in department meetings or by
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29 professionals committee with the aim to establish recommendations for safer environment
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31 and the need for training.
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41 The relationship between management and professional workload plays considerable role
42 in reporting NMs and AEs. From one hand, management try to increase professional
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44 workload as much as they could. In other hand, increasing workload limits the willingness of
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46 professionals to report errors. The roles of factors affecting management-workload
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48 relationship reveal reasons and conditions for willingness to report errors.
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54 Our results show that, for reporting REs, the attitude and privacy mediate the
55 management-workload relationship. Accordingly, the willingness of professional to report
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57 REs despite lack of management support and high workload can be explained from the
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1 professional attitude, and degree of privacy. The willingness of professional to report AEs
2 can be explained via four variables; professional attitude, professional knowledge, effect of
3 other staff, and error system. It should be noticed that Attitude mediates the Management-
4 Workload relationship for willingness to report both REs and AEs, while Society & Law has
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10 Moderators are variables have ability to change the direction and strength of the
11 management-workload relationship. Our results show that Knowledge and Staff are two
12 internal variables that moderates the Management-Workload relationship, and hence the
13 professional's willingness to report REs. The external variable, Society & Law also
14 moderation the relationship. The three variables could change the direction of reporting REs
15 as depicted in Figure 1(A, B, and C). Regarding AEs, Privacy is the only variable that
16 moderates the Management-Workload relationship, and hence the willingness to reporting
17 AEs. Figure 2, illustrates the effect of Privacy in changing the direction of reporting AE.
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33 **Research Limitations**

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37 There are limitations in our research. First, one may argue that the context of other
38 hospitals may differ and, accordingly, the results cannot be generalised. However, our
39 research aims to identifies factors affecting error reporting in a select hospital. Having
40 generalised outcome, without considering the hospital specific environment may not provide
41 adequate picture of affecting factors. The second limitation is that we did not consider the
42 opinions of hospital's managers and other non-surgical professionals. We plan to expand our
43 study to tackle these limitations in our future research.
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55 Given the choice of answering the questionnaire, not all professionals were willing to respond
56 our questionnaire. Non-responders may affect the randomised selection of the sample. Having a
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2 larger sample size may considered as a solution. A greater sample, however, could have been chosen
3 if time had not been a limiting factor.
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2 **Figure Legends**
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4 **Figure 1.** The moderating effects of (a) society & Law, (b) knowledge, and (c) Staff on
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6 professionals' willingness to report near misses -moderating effect on management-workload
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11 **Figure 2.** The moderating effect of privacy on professionals' willingness to report adverse
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Tables

Table 1. Observed non-consequential (near misses) events.

Category	Sub-category	Events	Comments
Reportable Events	Reported	Complication during Anaesthesia injection. Procedure stopped and patient returned to pre-operative area.	One event. Failure of patient to follow roles before the surgery.
		Malfunction of anaesthesia equipment	One. The equipment should be maintained and checked earlier. Failure of communication
		Receiving malfunctioned endoscopic instrument	One event. Failure to check the instrument earlier.
		Missing test report	One event. Retrieved – Failure of communication
		Incomplete requested materials	Two events. Managed to be received before procedure.
		Massive bleeding during surgery	One event. Only one was reported. As explained by surgeon the patient continued to take tablets before surgery.
		Incomplete patient record	Two events. Test report / X-ray
	Unreported - External	Oxygen cannula was dislodged during patient's transfer to operating table	One event
		Assistant's feet tangled with tubes and wires scattered in the ground of OR	Two times. Failure to protect tubes and wires with special cover.
		Bleeding from hand resulted from separation of I.V. catheter during surgery	One event. Discovered and repaired
		Left hand of the patient slipped under the patient body during patient's transfer to operating table	One event
Incorrectly positioning patient		One event. The positioning was repeated.	

	Unreported - Internal	Noticeable bleeding due to organ injury	Three events. Actions were taken to repair the error and stop bleeding.
		Noticeable bleeding due to failure to coagulate or clip before dissection	Three events
		Incorrect suturing	One event. Suturing was removed and Repeated
		Noticeable bleeding resulted from searching for slipped clip	One event.
			23 observed reportable events
Common Events	Marginal errors - Internal	Minor bleeding due to vessel injury	Repeatedly happen during surgeries. They are minor events but potentially disposes surgeons to errors. These events should be discussed in meetings for purpose of enhance surgeon performance and reduce errors.
		Minor bleeding due to organ injury	
		Failure to inspect before dissection	
		Failure to coagulate before dissection	
		Failure to clip before dissection	
		Using incorrect clip size	
		Instrument interactions	
		Inserting wrong instrument	
		Difficulty in piercing tissues with the suture needle	
		Difficulty to passing the needle in the correct direction	
		Difficulty in tying suture	
		Dissection with wrong instrument	
		Difficulty in manoeuvring retrieval bag	
		Difficulty in putting specimen in the retrieval bag	
		Difficulty in tying retrieval bag	
		Searching for foreign materials	
		Difficulty in retention foreign materials	
		Failure in managing blood suction	
	Dissection with blunt end instrument		
	Marginal errors - External	Hand crossing	These events have high potential to dispose surgeons to errors. They should be carefully discussed and managed. Also they suitable for training.
Incorrect Position of the display			
Incorrect height of the display			
Incorrect number of the display			
Display with low resolution			

		Inadequate ergonomic posture	Repeatedly happen during surgeries. These events disturb surgical flow. The accumulative of them may lead to potential errors. These events are for discussion in meetings for the purpose of training the surgeon's assistants.
		Failure to inspect after patient positioning	
		Unsuitable team location	
	Soft events	Delay in inserting instrument	
		Delay in receiving instrument	
		Receiving wrong instrument	
		Delay in cleaning endoscope	
		Delay in inserting endoscope	
		Inserting instrument in wrong direction	
		Delay or failure to switch on / off the endoscope	
		Difficulty with equipment connection	
		Difficulty in pressing / locating Pedal's button	
		Difficulty in orienting endoscope	
		Failure / delay in cleaning lens of the endoscope	
		Failure / delay in changing the endoscope	
		Delay in managing suction	
		Difficulty in retracting	
		Inserting incorrect clip	
		Inserting clip in wrong direction	
	446 observed common events		
	469 total events		

Table 2. Demographic data of the participants.

Category	Item	Number	Percentage
Gender	Male	75	42.13
	Female	103	57.87
Experience	Up to 5 years	78	43.82
	5 to 10 years	55	30.90
	10 to 20 years	32	17.98

	More than 20 years	13	07.30
Surgery	General surgeons	23	12.91 (28.40)
	Urologists	21	11.80 (25.92)
	Other surgeons	17	09.55 (20.99)
	Assistant surgeons	20	11.24 (24.69)
	Total surgeons	81	45.51 (100)
Anaesthesiology	Anaesthetists	29	16.29 (72.50)
	Assistant anaesthetists	11	06.18 (27.50)
	Total anaesthetists	40	22.47 (100)
Nursing	Scrub nurses	40	22.47 (70.18)
	Circulator nurses	17	09.96 (29.82)
	Total nurses	57	32.02 (100)
Participation	Total participants	178	100

Table 3. Descriptive statistics and the outcome of Wilcoxon signed-rank test.

Category	Code: Item Statement	RE/ AE	Descriptive Statistics				Wilcoxon Signed-Rank Test		
			Mean	STD	Median	IQR	PAE ? RE#	Z	p ^{&}
Attitude	ATT1: I would cover an error I had made if I could	RE	3.590	1.251	4	2	25, 78, 75	-6.073b	0.000
		AE	4.169	0.860	4	1			
	ATT2: Reporting errors affects my identity as a medical professional	RE	3.562	1.130	4	1	0, 13, 165	-3.606b	0.000
		AE	3.635	1.138	4	2			
	ATT3: There is no need to report errors if the surgery outcome appears to be acceptable	RE	3.360	1.087	3	2	8, 23, 147	-2.922b	0.003
		AE	3.489	1.026	4	1			
	ATT4: When others report errors, I will also do	RE	2.360	0.960	2	1	4, 75, 99	-7.512b	0.000
		AE	3.169	0.905	3	1			
Workload	WOR1: I have a heavy workload and no time I spare to fill the error reporting forms	RE	2.843	0.967	3	2	17,99, 62	-7.223b	0.000
		AE	3.612	1.126	4	1			
	WOR2: Error reporting is not recognized as part of my workload, so there is no obligation to report.	RE	2.848	0.911	3	1	21,93, 64	-7.051b	0.000
		AE	3.624	1.083	4	2			

	WOR3: My heavy workload affects my willingness to report errors.	RE	2.669	0.888	3	1	3, 136, 39	-10.270b	0.000
		AE	3.826	0.829	4	1			
Privacy	PRIV1: I do not want my errors to be discussed openly.	RE	2.584	1.252	2	2	28, 22, 128	-0.424c	0.671
		AE	2.539	1.213	2	2			
	PRIV2: I am not sure who will have full access to my information.	RE	2.702	1.077	3	2	22, 39, 117	-1.752b	0.080
		AE	2.876	1.128	3	2			
	PRIV3: I am worried that the privacy could be breached.	RE	3.483	1.199	4	1	61, 27, 90	-4.433 ^b	0.000
		AE	3.096	1.201	3	2			
System	SYS1: The form takes too long to fill in.	RE	2.904	1.163	3	2	22, 67, 89	-4.736b	0.000
		AE	3.393	1.101	3	1			
	SYS2: There is no clear guideline about errors.	RE	2.472	1.032	3	1	2, 129, 47	-10.041b	0.000
		AE	3.770	0.822	4	1			
	SYS2: Reporting system operates with ID and I am worried from using it as trap to track me down.	RE	2.652	1.111	3	1	4, 0, 174	-1.890c	0.059
		AE	2.612	1.074	3	1			
Society & Law	SOC1: I am worried about litigation.	RE	3.298	1.238	3	2	58, 1, 119	-6.713b	0.000
		AE	2.742	1.058	3	1			
	SOC2: I am worried about media involvement.	RE	2.899	1.100	3	2	17, 3, 158	-2.926b	0.003
		AE	2.781	1.026	3	2			
	SOC3: Our society will not tolerate errors – I may loss social credibility.	RE	3.174	1.088	3	2	11, 6, 161	-0.667b	0.505
		AE	3.146	0.998	3	2			
Knowledge	KNO1: Error reporting makes little contribution to the quality of surgery	RE	4.090	0.952	4	2	37, 52, 89	-1.066b	0.287
		AE	4.169	1.017	4	1			
	KNO2: Error reporting will not change the outcome of the surgery.	RE	3.410	0.983	3	1	54, 78, 46	-1.627b	0.104
		AE	3.624	1.094	4	1			
	KNO3: I do not know which errors that should be reported.	RE	3.551	1.047	4	1	38, 53, 87	-1.992b	0.046
		AE	3.708	1.044	4	1			
	KNO4: I do not know to whom I need to report.	RE	3.736	1.126	4	2	44, 37, 97	-0.265c	0.791
		AE	3.713	1.121	4	2			
Management	MAN1: I will not receive support from our management if I report an error.	RE	3.236	1.298	3	2	41, 40, 97	-0.441b	0.659
		AE	3.208	1.385	3	3			
	MAN2: I am worried about management disciplinary action.	RE	2.472	0.884	2	1	44, 31, 103	-0.446b	0.656
		AE	2.427	1.088	2	1			

	MAN3: Our management do not encourage disclosure unless they asked for.	RE	3.871	1.089	4	2	25, 38, 115	-2.441c	0.015
		AE	4.039	0.971	4	1.75			
	MAN4: I do not get feedback from management after reporting an error.	RE	3.758	1.086	4	2	9, 7, 162	-0.645b	0.519
		AE	3.730	1.033	4	2			
Staff	STA1: I will not receive support from my colleagues if I disclose an error.	RE	2.742	1.042	3	1	26, 102, 50	-6.673b	0.000
		AE	3.556	1.244	4	2			
	STA2: I may be blamed unfairly by my colleagues for reporting the error.	RE	2.697	1.013	3	1.75	21, 109, 48	-7.167b	0.000
		AE	3.472	1.227	4	1.75			
	STA3: I do not get feedback from my colleagues after I report an error	RE	2.831	1.055	3	2	11, 123, 44	-8.937b	0.000
		AE	3.944	1.051	4	2			

#: The three values in this column represent the number where AE < RE. AE > RE and AE = RE (ties).

&: p represents asymptotic significance value (2-tailed).

b: based on negative ranks; c: based on positive ranks.

Table 4. Professional's responses regarding common events

No.	Statement	Answers in percentages (%)		
		Agree	Disagree	No view
1	Common events have no effect on surgical outcome and there is no need to report them.	-	157 (88%)	21 (12%)
2	A separate local system should be designed to report common events	85 (48%)	40 (22%)	53 (30%)
3	Professionals should have flexibility in the way they report common events	167 (94%)	-	11 (6%)
4	Common events should regularly be discussed during departmental meetings for recommendation to hospital's management.	102 (57%)	40 (23%)	36 (20%)
5	Reporting of common events should be used for training and learning staff.	167 (94%)	-	11 (6%)

6	Awards should be offered to professional who regularly report common events and provide solutions	162 (91%)	-	16 (9%)
7	Reporting common events should be voluntary	167 (94%)	-	11 (6%)
8	Reporting common events should be recognized as part of professional workload.	76 (43%)	55 (31%)	47 (26%)

Table 5. The mediation effect of variables on the relationship between Management and Workload.

Variable	RE/AE	Effect Type	β	SE	t	ρ	LLCI	ULCI	Mediator
Attitude	RE	Total Effect	.1589	.0746	2.1309	.0345	.0117	.3061	Yes
		Direct Effect	.0819	.0805	1.0179	.3101	-.0769	.2408	
		Indirect Effect	.0770	.0374			.0101	.1580	
Attitude	AE	Total Effect	.2105	.0724	2.9053	.0041	.0675	.3535	Yes
		Direct Effect	.1065	.0785	1.3574	.1764	-.0484	.2614	
		Indirect Effect	.1040	.0417			.0283	.1932	
Privacy	RE	Total Effect	.1589	.0746	2.1309	.0345	.0117	.3061	Yes
		Direct Effect	.0731	.0730	1.0012	.3181	-.0710	.2171	
		Indirect Effect	.0858	.0405			.0192	.1761	
Privacy	AE	Total Effect	.2105	.0724	2.9053	.0041	.0675	.3535	No
		Direct Effect	.1517	.0712	2.1310	.0345	.0112	.2921	
		Indirect Effect	.0588	.0310			-.0043	.1200	
System	RE	Total Effect	.1589	.0746	2.1309	.0345	.0117	.3061	No
		Direct Effect	.1338	.0758	1.7656	.0792	-.0158	.2834	
		Indirect Effect	.0251	.0219			-.0088	.0760	
System	AE	Total Effect	.2105	.0724	2.9053	.0041	.0675	.3535	Yes
		Direct Effect	.1276	.0717	1.7801	.0768	-.0139	.2692	
		Indirect Effect	.0828	.0323			.0274	.1516	
Society & Law	RE	Total Effect	.1589	.0746	2.1309	.0345	.0117	.3061	No
		Direct Effect	.2028	.0813	2.4955	.0135	.0424	.3631	
		Indirect Effect	-.0439	.0396			-.1253	.0292	
Society & Law	AE	Total Effect	.2105	.0724	2.9053	.0041	.0675	.3535	No

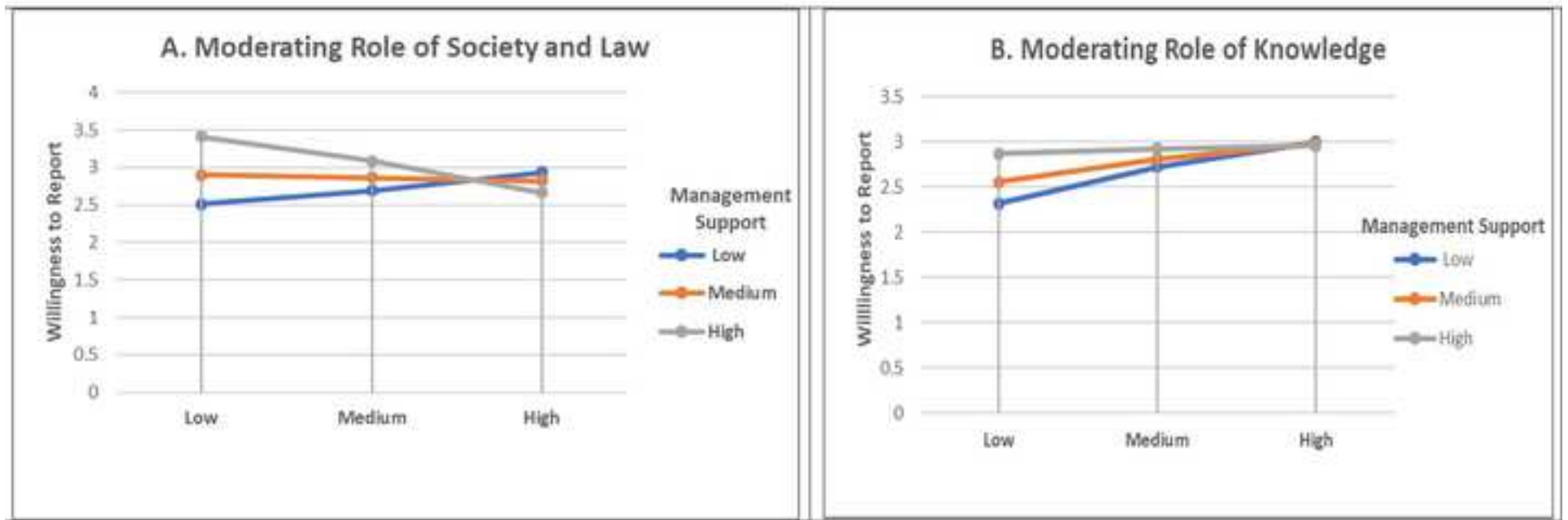
		Direct Effect	.1521	.0784	1.9406	.0539	-.0026	.3067	
		Indirect Effect	.0584	.0352			-.0077	.1312	
Knowledge	RE	Total Effect	.1589	.0746	2.1309	.0345	.0117	.3061	No
		Direct Effect	.1275	.0727	1.7540	.0812	-.0160	.2709	
		Indirect Effect	.0314	.0242			-.0069	.0871	
Knowledge	AE	Total Effect	.2105	.0724	2.9053	.0041	.0675	.3535	Yes
		Direct Effect	.1054	.0670	1.5734	.1174	-.0268	.2377	
		Indirect Effect	.1050	.0445			.0292	.2051	
Staff	RE	Total Effect	.1589	.0746	2.1309	.0345	.0117	.3061	No
		Direct Effect	.1927	.0787	2.4490	.0153	.0374	.3480	
		Indirect Effect	-.0338	.0295			-.0938	.0216	
Staff	AE	Total Effect	.2105	.0724	2.9053	.0041	.0675	.3535	Yes
		Direct Effect	.0253	.0950	.2662	.7904	-.1623	.2129	
		Indirect Effect	.1852	.0664			.0552	.3196	

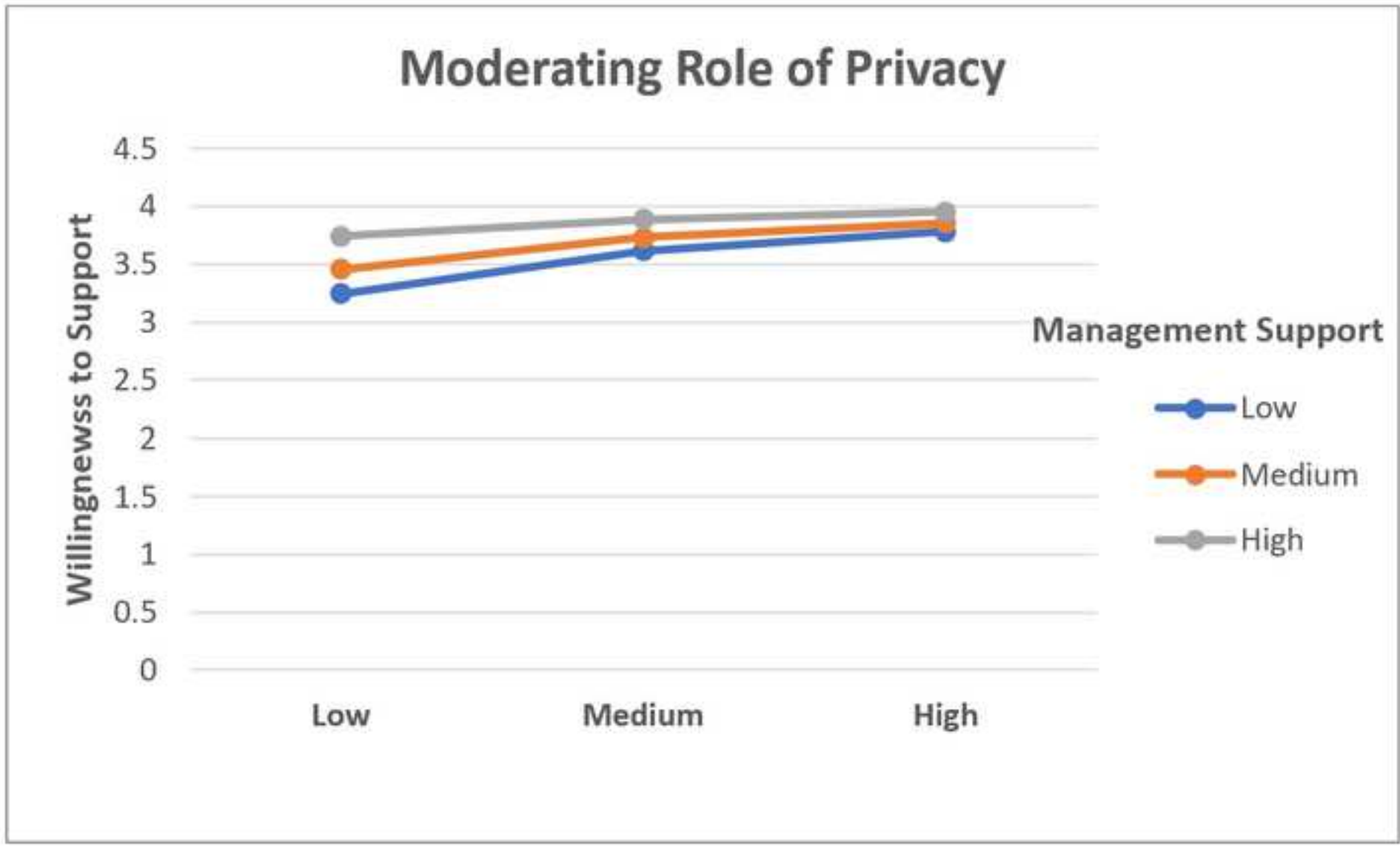
Table 6. The moderation effect of variables on the relationship between Management and Workload using PROCESS toll model code 1.

Moderator	RE / AE	Effect type	β	SE	t	ρ	LLCI	ULCI	Moderator
Attitude	RE	Model Summary				.0068			No
		Management	.0805	.0802	1.0031	.3172	-.0779	.2388	
		Attitude	.1888	.0960	1.9677	.0507	-.0006	.3782	
		Int-1 (MAN_X_ATT)	-.1445	.0962	-1.5021	.1349	-.3344	.0454	
Attitude	AE	Model Summary				.0004			No
		Management	.1055	.0785	1.3433	.1809	-.0495	.2605	
		Attitude	.2670	.0896	2.9794	.0033	.0901	.4439	
		Int-1 (MAN_X_ATT)	-.0864	.1005	-.8599	.3910	-.2847	.1119	
Privacy	RE	Model Summary				.0000			No
		Management	.0731	.0731	1.0001	.3186	-.0712	.2175	
		Privacy	.3500	.0794	4.4063	.0000	.1932	.5068	
		Int-1 (MAN_X_PRIV)	-.0393	.0741	-.5302	.5967	-.1854	.1069	
Privacy	AE	Model Summary				.0000			Yes
		Management	.1770	.0717	2.4694	.0145	.0355	.3185	

		Privacy	.2625	.0712	3.6871	.0003	.1220	.4031	
		Int-1 (MAN_X_PRIV)	-.1283	.0640	-2.0050	.0465	-.2546	-.0020	
System	RE	Model Summary				.0370			No
		Management	.1298	.0758	1.7126	.0886	-.0198	.2794	
		System	.1210	.0769	1.5742	.1172	-.0307	.2728	
		Int-1 (MAN_X_SYS)	-.0882	.0748	-1.1796	.2398	-.2358	.0594	
System	AE	Model Summary				.0000			No
		Management	.1244	.0720	1.7281	.0857	-.0177	.2665	
		System	.3652	.0859	4.2492	.0000	.1955	.5348	
		Int-1 (MAN_X_SYS)	-.0665	.1020	-.6515	.5156	-.2679	.1349	
Society & Law	RE	Model Summary				.0001			Yes
		Management	.1908	.0781	2.4447	.0155	.0368	.3449	
		Society	-.0579	.0670	-.8649	.3883	-.1901	.0742	
		Int-1 (MAN_X_SOC)	-.2846	.0714	-3.9875	.0001	-.4254	-.1437	
Society & Law	AE	Model Summary				.0047			No
		Management	.1675	.0795	2.1088	.0364	.0107	.3244	
		Society	.1137	.0750	1.5167	.1311	-.0343	.2617	
		Int-1 (MAN_X_SOC)	.0926	.0809	1.1443	.2541	-.0671	.2522	
Knowledge	RE	Model Summary				.0000			Yes
		Management	.1265	.0715	1.7688	.0787	-.0147	.2676	
		Knowledge	.3171	.0887	3.5744	.0005	.1420	.4922	
		Int-1 (MAN_X_KNO)	-.2714	.1041	-2.6062	.0099	-.4770	-.0659	
Knowledge	AE	Model Summary				.0000			No
		Management	.1430	.0695	2.0568	.0412	.0058	.2803	
		Knowledge	.3852	.0739	5.2114	.0000	.2393	.5311	
		Int-1 (MAN_X_KNO)	-.1547	.0831	-1.8618	.0643	-.3187	.0093	
Staff	RE	Model Summary				.0137			Yes
		Management	.1508	.0804	1.8762	.0623	-.0078	.3094	
		Staff	-.0513	.0711	-.7210	.4719	-.1917	.0891	
		Int-1 (MAN_X_STA)	-.1836	.0863	-2.1272	.0348	-.3540	-.0133	
Staff	AE	Model Summary				.0006			No

		Management	.0124	.0960	.1296	.8970	-.1770	.2019	
		Staff	.2675	.0877	3.0488	.0027	.0943	.4407	
		Int-1 (MAN_X_STA)	-.0909	.0950	-.9576	.3396	-.2784	.0965	





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