CRITICAL INCIDENTS IN GYNAECOLOGY: AUDIT AT CHARLOTTE MAXEKE . JOHANNESBURG ACADEMIC HOSPITAL

Christopher Chikwiri

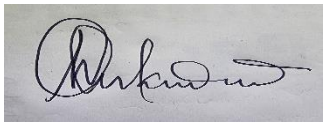
A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand,

in partial fulfilment of the requirements for the degree of Master of Medicine

July, 2023

DECLARATION

I, Christopher Chikwiri, declare that this Research Report is my own, unaided work. It is being submitting for the degree Master of Medicine, Obstetrics and Gynaecology, at the University of the Witwatersrand, Johannesburg.it has not been submitted before for any degree or examination at any other university.



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21st day of July 2023

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To my wife, Mafhungo Musefuwa, and my three children, Nokutenda, Tinotenda and Tinashe a huge thank you for the love and support.

ABSTRACT

Background

Critical incidents are among the ten leading causes of death and disability worldwide. Improving patient safety has become a global priority and one way to reach this goal is to report and analyse critical incidents.

Objectives

To describe the epidemiology, patient outcomes and avoidable factors associated with critical incidents in gynaecology department at Charlotte Maxeke Johannesburg Academic Hospital (CJMAH)

Methods

This research was a retrospective descriptive analysis of critical incidents in patients admitted to gynaecology wards at CMJAH from 1st January 2019 to 31st December 2019. All medical records of patients identified to have experienced critical incidents were reviewed and demographic information, timing of admission, critical incident markers and avoidable factors were extracted for analysis.

Results

In total there were 257 critical incidents (CI) in 2082 gynaecology admissions during the one-year study period, which gives a critical incidence of 12.3%. A total of 158 patients experienced at least one or more critical incidents. The mean age (SD) of patients was 41.1 (14.8) years. The median (IQR) duration of admission was 6 days (3-10). Reasons for admission were emergencies 60 (38.0%), elective 54 (34.2%), oncology 44 (27.8%).

Majority of the critical incident events were omission of procedures (n=45, 17.5%), deaths (n=34, 13.2%), massive transfusion (n=30, 11.7%), repeat laparotomies (n=29,11.3%) and fistula/organ damage (n=19, 7.4%). Avoidable critical incidents were (n=87, 55.1%). Most critical incidents were associated with no harmful outcomes to the patients (50, 31.5%), death (34, 22.8%) (mainly as a result on oncology admissions), moderate disability (29, 17.9%), minimal disability (26, 16,1%), permanent/severe disability (14, 8.6%) and in (5, 3.1%) harm could not be specified. Critical incidents forms were only filled out in 39 patients, that is a reporting rate of 24.7%.

Conclusions

Critical incidents are a major cause of unnecessary harm in gynaecology at CMJAH. Half of these critical incidents are avoidable and therefore corrective measures can be undertaken to eliminate them in order to improve patient safety. Underreporting of critical incidents is still a major problem. There is need for precise definitions of critical incidents terms and modification of critical incident reporting system (including electronic) to promote patient safety culture in gynaecology.

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ABBREVIATIONS

ASO: Acute salpingo-ophorectomy

CMJAH: Charlotte Maxeke Johannesburg Academic Hospital

HIV: Human immunodeficiency virus

ICU: Intensive care unit

IQR: Interquartile range

LAVH: Laparoscopic assisted vaginal hysterectomy

PID: Pelvic inflammatory disease

PRC: Packed red cells

RVF: Recto-vaginal fistula

SD: Standard deviation

VTE: Venous thromboembolism

VVF: Vesico-vaginal fistula

WHO: World health organisation

CHAPTER 1; SUBMISIBLE PAPER

TITLE: CRITICAL INCIDENTS IN GYNAECOLOGY; AUDIT AT CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Authors:

Christopher Chikwiri[1]

Lawrence Chauke[1,2]

Affiliations:

1. Department of Obstetrics and Gynaecology, University of the Witwatersrand & Charlotte Maxeke Johannesburg Academic Hospital, Johannesburg, South Africa
2. Head of Department, Obstetrics and Gynaecology, University of the Witwatersrand, Charlotte Maxeke Johannesburg Academic Hospital, Johannesburg, South Africa

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Corresponding Author: Dr Christopher Chikwiri:

Email: cchikwiri@yahoo.com, +27735468398

Address: Charlotte Maxeke Johannesburg Academic Hospital

7 York Road, Parktown, Johannesburg 2193, South Africa

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INTRODUCTION

Patient safety is defined as the absence of avoidable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum [1]. Every stage during the provision of health care has a risk of certain degree of inherent unsafety [1,2]. Critical incidents are increasing recognised as a source of harm to patients. Improving patient safety is a global priority and another way to reach this goal is to report and analyse critical incidents systemically.

According to the World Health Organisation (WHO), critical incidents are likely to be one of the 10 leading causes of death and disability worldwide [3]. Hospitals in Low- and middle-income countries (LMICs) experience about 134 million critical incidents each year, resulting in 2.6 million deaths annually. High-income countries (HICs) estimate shows that as many as 1 in 10 patients are affected by critical incidents with approximately 50% of them preventable [3]. Critical incidents exert a high toll in financial loss as a consequent of additional hospital stay, medical expenses and litigation [2]. A South African study showed that litigation because of medical malpractice has remarkably increased in the last decade, negatively impacting financing of public healthcare, for example, the huge legal bills could have been used to finance hiring of more staff, professional development, build hospitals and procure equipment [4].

Literature on patient safety is associated with semantic relationship on the meaning of critical incidents. Other terms commonly used to describe critical incidents are ‘adverse clinical event’, ‘clinical incident’, ’iatrogenic events’ and ‘patient safety incident’, which is currently the preferred terminology. To this end, the WHO’s World Alliance for Patient Safety developed an International Classification for Patient Safety to devise classification of patient safety information. It defines a patient safety incident as an event or circumstance that could have resulted or did result in unnecessary harm to a patient. Incidents may arise from either intended or unintended acts and comprise of reportable circumstances, near miss incidents, no harm, or harmful incidents (adverse events) [5-10].

The critical incident reporting system was firstly published as an outgrowth of studies among military pilots, in early 1940s, by Flanagan [11-13]. In the medical field it started to be considered in the 90’s with the issuing of the much-cited Harvard Medical Practice Study [14,15]. The study found that about 4% of patients sustained a certain degree of harm in hospitals, and 70% of adverse events resulted in disability and 14% resulting in mortality. Various studies in developed countries, thereafter, investigated the extent of critical

incidents and have shown that approximately 2.9%-16.6% of patients experience incidents and in 4.5%--20.8% of the adverse events, the patient dies. Most of these studies show that 50% of adverse events are judged to be preventable [2,16,17].

There is lack of data and awareness about critical incidents in developing countries. A large-scale patient safety study in developing countries (including South Africa) showed that 8.2% of patients suffered at least one adverse event, with an average of 2.5% to18.4% per country and, 83% of these events being judged to be preventable [9,18]. There is currently no national data on the occurrence of critical incidents in South Africa

Specialty based critical incident reporting system gives a clear picture into unit-specific safety issues, which might not be necessarily exposed by hospital or national data [19]. Tanaka et al did a meta-analysis of studies which researched on gynaecological critical incidence (including one South African study) and their results showed that the incidence of adverse events in gynaecological hospital admissions was 10.8% (95%CI 9.4%-12%). Preventability of these events in their review was 52.5% (95%CI 47.3%-57.7%) and mortality 1.2% (95%.CL 0.25%) [17]. Literature search revealed two retrospective studies previously done in gynaecology units in South Africa. Lombaard et al found that the critical incidents rate at Kalafong Hospital was 7.9% over a six-month period with 2.1% deaths in all gynaecology admissions [20]. Another study at King Edward VIII Hospital showed that adverse events were observed in 11.7% of admissions, with 52% of them being avoidable [21].

We therefore aimed to describe the epidemiology, patient outcomes and avoidable factors associated with critical incidents in gynaecology department at CJMAH.

MATERIALS AND METHODS

Study population and data collection

This research was a retrospective descriptive analysis of critical incidents in gynaecology at CMJAH from 1st January 2019 to 31st December 2019.This study site was in the department of Obstetrics and Gynaecology at the above-named hospital, a tertiary referral hospital and the main teaching hospital for the University of the Witwatersrand. All patients admitted in year 2019, in the gynaecology department formed part of the study. It is estimated that approximately 2000 patients are admitted per annum and approximately 100 critical incidents are recorded. Clinical records of patients identified to have had a critical incident during their care were assessed and analysed.

The department of Obstetrics and Gynaecology at CMJAH keeps a record of patient critical incidents using a specially designed patient critical incident form. This data is then captured on RedCap. The incidents are discussed during the daily audit meetings as part of service improvement strategies. In every patient, any critical incident is reported to the hospital management using a specially designed patient safety form.

Critical incidents were sought using the following methods: -

i. Completed gynaecology critical incident forms.
ii. Analysing Redcap daily surveys for the year 2019
iii. Analysing the monthly gynaecology morbidity and mortality meeting presentations.
iv. Review of theatre and ward records
v. Review nursing patient safety reports

All medical records of patients identified to have experienced critical incidents during the study period were retrieved from the hospital filling system and demographic information, timing of admission, critical incidence marker, avoidable factors and patient outcomes were extracted using a specially designed critical incident form (Appendix A) and later transferred into Microsoft Excel spreadsheet to prepare for analysis.

Ethics

Permission to access patient files was granted from the Chief Executive Officer (CEO) of CMJAH and ethics approval was obtained from the Human Research and Ethics Committee of the University of Witwatersrand (Medical clearance certificate number M201083). Since this study was a retrospective audit of medical records, there was no requirement for individual patient consent. Identifying patient information was removed prior to analysis thereby always maintaining anonymity. All data was handled with strictest confidentiality.

Data analysis

Study data was imported from Microsoft Excel to Stata statistical software version 16 (Stata Corp, Texas USA) for analysis. Categorical data was described using frequencies and percentages. Continuous data was assessed for normality using Shapiro Wilk test, quantile distribution plots and histograms. Normally distributed continuous data was described as means and standard deviations, whilst non-normal data was described using median and interquartile ranges. Significance level (P-value) was set at 0.05.

RESULTS

There was a total of 2082 gynecology admissions during the one-year study period. A total of 176 (8.6%) patients were found to have suffered critical incidents; however, 18 patients' medical records were not complete or entirely not found from the hospital filing system, therefore were excluded from the study. Therefore, of the medical records analyzed, 158 patients experienced at least one or more critical incidents. Variation in the number of events per patient is shown in table 1. In total, 257 critical incidents were found, equating to an incidence of 12.3%

Table 1: Variation in the number of events per patient (N=158)

Number of events	N (%)
1 event	106 (67.1%)
2 events	30 (19)
3 events	9 (5.7)
4 events	8 (5.1)
5 events	2 (1.3)
6 events	2 (1.3)
10 events	1 (0.6)

The mean age (SD) of patients was 41.1 (14.8) years. The median (IQR) duration of admission was 6 (3-10) days, with the longest hospital stay of 48 days. The median (IQR) parity and gravity were the same; 2 (1 -3). Reasons for admission were emergencies 60 (38%), elective 54 (34.2%) and oncology 44 (27.8%). The initial intention of treatment on admission was surgical 112 (70.9%), medical 14 (8.8%) and palliative 32 (20.3%). The most common comorbid condition was Human Immunodeficiency Virus (HIV), with 65 (41.1%) of the patients HIV positive. The demographic characteristics of patients are shown in table 2 below.

Table 2: Basic demographic characteristics of patients (N=158)

Description	

	Mean (SD) or median (IQR) or n (%)
Mean age (SD) years	41.1 (14.8)
Nationality	
RSA	117 (74.1)
Other	41 (25.9)
Duration of admission (days)	6 (3-10)
Reason for admission	
Elective	54 (34.2)
Emergency	60 (38.0)
Oncology	44 (27.8)
Type of admission	
Surgical	112 (70.9)
Medical	14 (8.8)
Palliative	32 (20.3)
Parity	2 (1-3)
Gravidity	2 (1-3)
HIV positive	65 (41.1)

The most common cause of critical incidents was omission of procedures 45 (17.5%), 26 (57.8%) being operation cancelled due to lack of theater time. There were 34 deaths, which was 1.63% of total admissions, contributing 13.2% of the critical incidents. The most deaths, 30 (88.2%), were in the oncology population, whilst three were emergency admissions (unsafe abortion, puerperal sepsis, pelvic inflammatory disease grade 4, one each) and one was elective admission (hysterectomy done for multi-fibroid uterus). A total of 30 (11.7%) patients were transfused at least four units of packed red cells. These were mostly early

pregnancy complications (miscarriages and ectopic pregnancies). There were 29 (11.3%) repeat laparotomies for several reasons, mainly postoperative sepsis and hemorrhage. Fistula and organ damages were found in 19 (7.4%), comprising of six ureteric injuries, five bowel injuries, four fistulae (two vesicovaginal fistulae, one rectovaginal fistula, one enterocutaneous fistula), three uterine perforations and one bladder injury. There were no anesthetic complications reported or found in the records. The rest of the critical events are shown in Table 3

Table 3: Frequency of critical events (N=257)

Type of critical event	n (%)
Death	34 (13.2)
ICU admission	15 (5.8)
VTE	8 (3.1)
Repeat laparotomy	29 (11.3)
Laparotomy for ASO	15 (5.8)
Unplanned surgery	13 (5.1)
Transfusion > 4.0 PRC	30 (11.7)
Organ dysfunction post-surgery	9 (3.5)
Fistula and organ damages	19(7.4)
Delayed diagnosis	8 (3.1)
Omission of procedure	45 (17.5)
Emergency hysterectomy	12 (4.7)
Post op complications requiring surgery	3 (1.2)
Wound sepsis	17 (6.6)

Patient outcomes were assessed on a six-point scale of disability as outlined in the National Policy for Patient Safety Incident Reporting and Learning in South Africa (PSIRL) [9]. No harm category was defined as patient outcomes with no symptoms and where no treatment

was required. Minimal disability was an outcome with mild symptoms and no or minimal interventions (e.g. extra observation). Moderate disability was patient outcome associated with increased hospital stay requiring intervention (e.g. additional operative procedure/ therapeutic treatment). Permanent and severe disability is an outcome which required lifesaving intervention or major surgical/medical intervention, shortening life expectancy or causing long term/permanent harm. Death category is outcome associated with death, or death caused or brought forward in the short term by the incident. Most critical incidents were associated with no harmful outcomes to the patient 31.5%, death 22.8%, minimal disability 16%, moderate disability 12.9%, permanent/severe disability 8.6% and in 3.1% harm could not be specified. Figure 1 below show the patient outcomes.

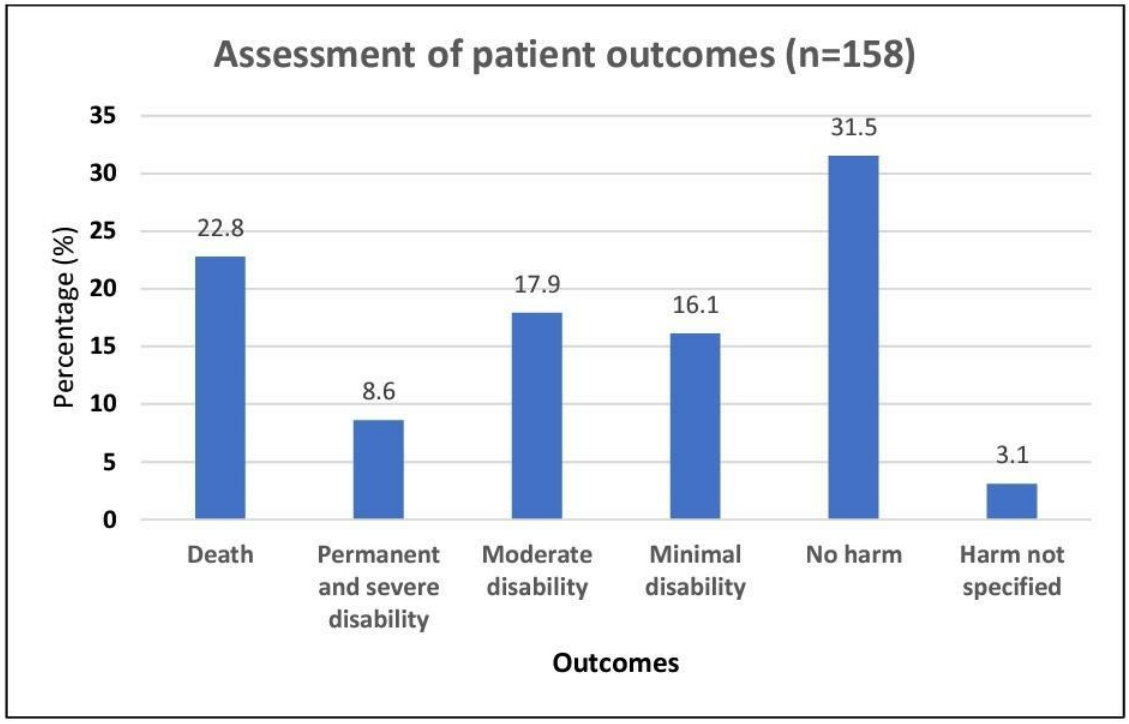

Figure 1: patient outcomes

In 87 (55.1%) of the 158 patients who suffered critical incidents, there were avoidable factors. Grouping the avoidable factors into three main groups, health-care worker related factors were 53, (47.8%), administrative factors were 33, (29.7%) and patient related factors were 25, (22.5%). The main cause of avoidable factors during medical care were surgical complications, 36, (32.4%), mostly post operative hemorrhage, nine patients. Main contributor in the administrative related factors were operations cancelled due to lack of theater time, 26 (23.4%) cases. Delay in seeking medical care 16 (14.4%) patients, was the

most common avoidable factor in the patient orientated problems. Table 4 shows the breakdown of the available factors found.

Table: 4: Avoidable factors

Description	n (%)
Avoidable factors	111
Patient factors (22.5%)	
No antenatal care	1 (0.9)
Delay in seeking medical care	16 (14.4)
Unsafe abortion	6 (5.4)
Other	2 (1.8)
Administrative factors (29.7%)	
Lack of health care facilities: ICU	3(2.7)
Lack of healthcare facilities: equipment and drugs	29 (26.1)
Lack of personnel	1 (0.9)
Transport problems - none	
Resuscitation - none	
Medical care factors (47.8%)	
Initial assessment	2 (1.8)
Diagnosis	5 (4.5)
Delay in referral	4 (3.6)
Incorrect management	3 (2.7)
Sub-standard management (correct diagnosis but wrong treatment)	2 (1.8)

Monitoring problem	1 (0.9)
Surgical complications	36 (32.4)

There was under-reporting of the critical incidents, with a reporting rate of only 24.7%. Only 39 critical incidents forms were filled in for the 1-year study period. The commonly reported critical incident event were operations not done due to lack of theater time 23 (59%) of the 39 forms. Most of the critical incidents were identified in the nursing theater records and ward admission books.

DISCUSSION

The incidence of critical incidents was 12.3% of gynaecological hospital admission over a one-year period that was assessed. This figure translates into 8.6% if missing files were included. Our results were similar to WHO estimates which shows that as many as 1 in 10 patients are affected by critical incidents [3]. Our results are also comparable to gynaecology specific studies. In a meta-analysis by Tanaka et al, the critical incident rate was 10.8% [17]. Two similar studies were done in South Africa. Lombaard et al found that critical incidents rate at Kalafong hospital over a 6-month period was 7.9%, and Matsaseng et al showed that adverse events were observed in 11.7% of admissions [20,21].

The mean age (SD) of patients who had critical incidents was 41.1 (14.8) years. From literature reviewed increasing age is a well-established risk factor for critical incidents [17,20]. Wilson et al showed an increasing rate of critical incidents with age in hospital patients in developing countries. Their study results also showed that critical incident rate increased with length of hospital stay and, their median length of hospital stay ranged from 2 to 7 days which was comparable with our results [18]. Our study could not draw an inference on the association between demographic characteristics of patients and critical incidents rate because we did not analyse data of all the admitted patients. What was evident though was that critical incidents resulted in increased hospital stay. The longest hospital stay was 48 days, for a patient who was electively admitted for a diagnostic laparoscopy for Mullerian agenesis which was complicated by abdominal sepsis, leading to three relook laparotomies. Another example is a patient who was admitted three times with a multifibroid uterus for an elective hysterectomy. The procedure was cancelled three times due to a lack of theatre time, despite spending a total of 17 days in hospital. Above examples illustrate

how critical incidents negatively affect public healthcare financing through extra cost of prolonged hospital stay [4]. Patients are also affected through loss of income, disability, medical expenses not forgetting the psychological and social impact.

The most common type of critical incidents was omission of procedure (n=45, 17.5%), which was mainly cancellation of surgical operations for various reasons. A total 26 (57.8%) operations were cancelled due to lack of theatre time, while other reasons for cancellation were lack of intensive care unit beds, staff and linen shortages, and poor patient pre-operation preparation. Although this type of critical incident event was associated with no harm to minimal disability, it exerted a high toll in financial losses because of additional hospital stay, medical expenses and a loss of income. It may also result in the loss of confidence and dissatisfaction of patients with the public health sector.

A meta-analysis on deaths associated with gynaecological hospital admissions showed a low mortality rate of 1.2% (95% CI 0 -2.5%) [17]. The two South African studies into gynaecological critical incidents showed a mortality of 2.1% of all admissions (Matsaseng et al), and 2.1% of all admissions (Lombaard et al) [20,21]. These findings were similar to our results of a total of 34 deaths, which was 1.6% of total admissions and contributed 13.2% critical incidents. Thirty (88.2) deaths were in the oncology/palliative admissions group in which patients had advanced disease and death was mostly unavoidable. Only four deaths were outside the oncology population (one each; unsafe abortion, puerperal sepsis, PID grade 4 and post hysterectomy for multifibroid uterus). These four deaths were avoidable, and emphasis should be put in auditing deaths outside the oncology population, as the ultimate goal of studying critical incidents is to reduce avoidable critical incidents [15,17]. Whilst all deaths are reportable events, there is need to refine our definition of deaths as a critical incident marker. Only deaths which were directly caused or brought forward in the short term during the process of health care should be recorded as critical incidents, and therefore the aim is to reduce such deaths.

The critical incident event which resulted in most moderate to severe disability in patients were fistula and organ damages at surgery (n=19, 74%). There were six cases of ureteric injuries, five cases of bowel injuries, four fistulae formation, three uterine perforations and one bladder injury. There were six laparoscopic surgery complications resulting in unplanned laparotomy. Of the six, two were as a result of abdominal wall haematoma, two post operation haemorrhage following a laparoscopic assisted vaginal hysterectomy, one uterine perforation by a uterine manipulator and one for lost instrument. Our research did

not look at complication rates of different gynaecological operations to compare with local and international literature, we therefore recommend that future studies look at this aspect.

Comparing crude numbers of ureteric injuries with two other South African studies showed some differences. No ureteric injuries were reported by Matsaseng et al (1866 admissions, 9-month study period), and only one ureteric injury reported by Lombaard et al (1165 admissions, 6-month study period) [20,21]. There were six ureteric injuries reported in our study. Two injuries were during radical hysterectomy in patients with cervical cancer, one during a hysterectomy for a multifibroid uterus and unexpectedly three ureteric injuries from oophorectomy for ovarian masses. These numbers show that surgeons are more cautious about ureteric injuries during hysterectomy and less so when operating on the adnexa. We therefore highlight this so that the same vigilance is taken during oophorectomy to reduce these types of injuries.

Assessment of outcomes of patients who experienced gynaecological related critical incidence was particularly challenging. The major challenge is the lack of a universally accepted criteria to assess patient harm. This lack of uniformity in data made it impossible to compare our critical incident patient outcomes with other studies. We used the classification as described in the National Policy for Patient Safety Incident Reporting and Learning in the Public Health Sector of South Africa, July 2016 [9]. The other challenge was that there was no long-term follow-up of patients to determine duration of harm, additional intervention needed or pick up harm which was not apparent on the initial assessment. Other files were incomplete hence harm could not be specified.

Brennan et al stated that critical incidents will not always point to substandard care nor do their absence point to good quality care [15]. Occurrence of unavoidable critical incidents are inherent risks in medical care. However, the goal of studying critical incidents is to lower the incidence of avoidable factors causing them, thereby improving patient safety [17]. There were avoidable factors in 55.1% of the patients who suffered critical incidents in our study. WHO estimates that 50% of critical incidents are avoidable which is a similar result to our study and most of the studies reviewed [2,3,16,17]. Health-care worker related avoidable factors were the majority, 47.8%, mainly surgical complications. We therefore recommend more effort to be put to improve surgical skills among registrars. Administrative avoidable factors were 29.7%, mostly due to operations being cancelled for lack of theatre time. Improving patient safety at a gynaecology department administrative level can be challenging as it involves complex issues which can be resolved at a national level. Challenges like increasing population size without corresponding increase in hospital beds

or staff, and limited health care budgets will need political will to see an improvement in patient safety.

We still saw a worrying number of unsafe abortions, (n=6, 5.4%), contributing to avoidable critical incidents events. This is despite the provisions of the Choice on Termination of Pregnancy Act which strive to provide for safe abortions. An equally worrying result is the number of patients, n=16 (14.4% of avoidable factors), who delay seeking medical care. This is more so especially in the oncology group in which patients normally present with advanced stage of disease. More community health education is needed to improve early health seeking behaviour and awareness on the availability of safe abortion services.

We audited the critical incident reporting system in our clinical department. Of the 158 patients who suffered critical incidents, only 39 patients (24.7%), had critical incident forms filled in. Despite the advantages of critical incident reporting, it is known that it is an underutilised tool in health care because of widespread underreporting found in different studies [12,14]. Mahajan R P et al noted that underreporting especially by doctors remains a significant problem [12]. This observation was similar to our study as most of the critical incidents were not reported by doctors but were found in nursing records (theatre and ward admission books).

The commonly reported critical incident event were operations not done due to lack of theatre time, 23 of the 39 forms (59%). These critical incidents were associated with no harm to the patients. This is in keeping with the observation that routine incident reporting systems are poor at identifying patient safety incidents that result in patient harm [11]. For example, all the 6 cases of ureteric injuries found in our study were not reported by doctors but were found in nursing theatre records. Factors responsible for poor reporting include fear of punitive actions, discrimination at workplace and litigation [12]. Other factors for underreporting are incidents not recognized and no clarity on what should be reported. No anaesthetic complications were reported in our research. It is however more likely to be part of the underreporting than a real absence of anaesthetic critical incident events.

Our electronic critical incident reporting system, done on RedCap daily surveys, also recorded some critical incidents. However, the data is of limited value, as the system doesn't specify the type of critical incident event, nor does it capture any details of the patients involved. We therefore recommend modification of the electronic system so that it can capture data which is useful to analyse critical incidents.

Limitations

This was a retrospective descriptive study and we faced limitations inherent to such studies such as missing patient files and data variables incompletely filled in. Our study may also have been affected by observer bias when it comes to analyzing patient outcomes. We relied only on critical incidents which were reported in various records, and we did not go through all the medical records of patients admitted during the study period to find unreported events.

CONCLUSION

Critical incidents are a major cause of unnecessary harm in gynaecology at CMJAH. Half of these critical incidents are avoidable and therefore corrective measures can be undertaken to eliminate them in order to improve patient safety. Underreporting of critical incidents is still a major problem. There is need for precise definitions of critical incidents terms and modification of critical incident reporting system (including electronic) to promote patient safety culture in gynaecology.

What is already known on this topic?

. Critical incidents are likely to be one of the 10 leading causes of deaths and disability worldwide.

. There is a lack of data and research on patient safety, despite critical incidents causing more death than AIDS, motor vehicle accidents or breast cancer.

. Critical incidents reporting system is an underutilized tool in improving patient safety.

What this study adds.

. Our research adds data about incidence of specialty-based critical incidents especially in low-income settings.

. Suggestions on how to improve patient safety.

. Highlight need for precise definitions of critical incidents terms and modifications of critical incidents reporting systems.

ACKNOWLEDGEMENTS

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AUTHORS' CONTRIBUTIONS

CC : conception and design, literature review, funding, data collection, statistical analysis, writing and editing article

LC : conception, methodology, reviewing article and overall supervision of project.

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CHAPTER 2: INSTRUCTIONS TO AUTHOR- PAN AFRICAN MEDICAL JOURNAL

Maximum length: 4000 words in main text (i.e., excluding abstract, references, legends, tables and figures), 4 tables/figures maximum, and a structured abstract of 250 words plus up to 50 references.

Title page - This page should states: a) The title of the paper (include the study design if appropriate; for example: A versus B in the treatment of C: a randomized controlled trial; X is a risk factor for Y: a case control study), b) Authors names (full name - no qualification, no abbreviations). **Strictly follow this order: First Name, Middle name (if ever), Last Name. E.g.: Paul Kevin Akuna**), c) institution(s) of origin, d) Corresponding author plus his/her address, telephone and fax number, e-mail address, e) Word count (for both abstract and the main text)

Abstract - The abstract of the manuscript should not exceed 250 words and must be structured into separate sections: **Background:** the context and purpose of the study; **Methods:** how the study was performed and statistical tests used; **Results:** the main findings; **Conclusion:** brief summary and potential implications. Please minimize the use of abbreviations and do not cite references in the abstract.

Keywords. Up to ten keywords should be provided at the end of the Abstract. The keywords should be Medical Subject Headings (MeSH®) Terms. Use the MeSH on Deman Tool to help suggest keywords.

Abbreviations a list of abbreviations is not accepted. Define abbreviations the first time they are used in the text and use them thereafter. No abbreviations in the abstract except for vary know ones.

Background The background section should be written from the standpoint of researchers without specialist knowledge in that area and must clearly state - and, if helpful, illustrate - the background to the research and its aims. Reports of clinical research should, where appropriate, include a summary of a search of the literature to indicate why this study was necessary and what it aimed to contribute to the field. The section should end with a very brief statement of what is being reported in the article.

Methods Sufficient information should be given to permit repetition of the experimental work. This should include the design of the study, the setting, the type of participants or

materials involved, a clear description of all interventions and comparisons, and the type of analysis used, including a power calculation if appropriate.

Results - The Results should be stated concisely without discussion and should not normally contain any references. The same data should not be presented in figures and tables. Do not repeat all the data that is set out in the tables or figures in the text; emphasize or summarize only important observations.

Discussion - The Discussion should deal with the interpretation of the results and not recapitulate them. We encourage authors to write their Discussion in a structured way, as follows:a) statement of principal findings; b) strengths and weaknesses of the study; c) strengths and weaknesses in relation to other studies; d) discussion of important differences in results; e) meaning of the study; f) unanswered questions and future research.

Limitations - Always aknowledge the potential the limitations of your study that and how they impact or influence the interpretation of the findings from your research, the generalizability, applications to practice, and/or utility of findings.

Conclusion - The conclusion should provide a brief summarize of the key findings, potential implications and the way forward.

***What is already known on this topic*:** include a maximum of 03 bullet points on what is already known on this topic.

***What this study adds*:** include a maximum of 03 bullet points on what your study adds.

Acknowledgements - Please acknowledge anyone who contributed towards the study by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include their source(s) of funding. Please also acknowledge anyone who contributed materials essential for the study. The role of a medical writer must be included in the acknowledgements section, including their source(s) of funding. Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements. Please list the source(s) of funding for the study, for each author, and for the manuscript preparation in the acknowledgements section. Authors must describe the role of the funding body, if

any, in study design; in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

Competing interest - Authors are responsible for recognizing and disclosing conflicts of interest that might bias their work. They should acknowledge in the manuscript all financial support for the work and other personal connections. Authors are required to complete a declaration of competing interests. All competing interests that are declared will be listed at the end of published articles. Where an author gives no competing interests, the listing will read 'The author(s) declare that they have no competing interests'. When completing your declaration, please consider the following questions:

Financial competing interests

- In the past five years have you received reimbursements, fees, funding, or salary from an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? Is such an organization financing this manuscript (including the article-processing charge)? If so, please specify.
- Do you hold any stocks or shares in an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? If so, please specify
- Do you hold or are you currently applying for any patents relating to the content of the manuscript? Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript? If so, please specify.
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- Are there any non-financial competing interests (political, personal, religious, ideological, academic, intellectual, commercial or any other) to declare in relation to this manuscript? If so, please specify.
- If you are unsure as to whether you, or one your co-authors, has a competing interest please discuss it with the editorial office.

Authors' contributions - In order to give appropriate credit to each author of a paper, the individual contributions of authors to the manuscript should be specified in this section.

The Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URM) of the International Committee of Medical Journal Editors (ICJME) recommends the following criteria for authorship (Learn more about the URM on Authorship and Contributorship):

- Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript (3). These individuals should fully meet the criteria for authorship/contributorship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms. When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group in the Acknowledgments. The NLM indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript; it also lists the names of collaborators if they are listed in Acknowledgments.
- Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

References - References must be numbered consecutively, in square brackets (like this [1], or this [2,3] or even this [4-7]), in the order in which they are cited in the text, followed by any in tables or legends. Reference citations should not appear in titles or headings. Each reference must have an individual reference number. Preferably, limit the number of references to 50. If automatic numbering systems are used, the reference numbers must be finalized and the bibliography must be fully formatted before submission. We encourage authors to use a recent version of EndNote (version 5 and above) or Reference Manager when formatting their reference list, as this allows references to be automatically extracted. Examples of the PAMJ reference style are shown below. Please take care to

follow the reference style precisely; references not in the correct style may be retyped, necessitating tedious proofreading.

We strongly advocate the use of **Zotero**, a free and open source reference management software which is a very good alternative to expensive ones.

- Download output style (PAMJ.os) for **Reference Manager**.
- Download output style (PAMJ.ens) for **EndNote**.
- Download output style (PAMJ.csl)) for **Zotero**.

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2. Kirikou Thomas, Doe JA, Shaba Kevin, Kashawa TB. Another sample of the PAMJ reference style: as shown on the journal website. J Hist Fant. 2006; 76(12):212-228
3. Kirikou TA, Doe John, Shaba KV, Kashawa TB. Another sample of the PAMJ reference style: as shown on the journal website. J Hist Fant. 2006; 76:212-228

Formatting book references: Use the format below to reference a book
Author of the book. Title of the book. Year of publication. Publisher Location. Publisher name
Example: Fleiss JL. Statistical methods for rates and proportions - 3rd edition. 2003. Hoboken. J Wiley
NB: Note the use of dots to separate the sections of the book reference.

Formatting web references: Use the format below to reference a web page or a web site
Author of the page. Name of the source (if any). Year of data. url. Date link accessed
Example: SAS Institute. SAS 9. http://support.sas.com/software/index.htm. Accessed 10 April 2005
NB: Note the use of dots to separate the sections of the web reference.

Supplementary material/Appendices (if any) - Submit any supplementary material to the editorial office bye email. The editorial office can also decide which material will be published as supplemental material.

Tables (if any) - General instructions for tables.

- Append tables at the end of your manuscript, after the reference section
- Maximum 3 tables per articles. If more tables are required, it will have to be justified
- Each table should fit on one page. No table overlapping over several pages. So no matter the size of the table, make sure it can comfortably fit on a single page (portrait or landscape)
- Elements inside the table should be contained within cells.

Download samples of correctly formatted tables (Microsoft Word 2002-2003, *.DOC): **Table 1**, **Table 2**.

Figures (if any) - General instructions for figures.

- Include a legend for your images inside the main text, after the reference section
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- Major image formats are accepted excluding BMP. (JPEG, PNG, TIFF)
- Provide high resolution images, not tiny thumbnails. Image of poor quality will be rejected.
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Files must be named with the three letter file extension appropriate to the file type (eg: .jpeg, .png). You will be asked to provide figure labels during the submission process. (The label is the small comment that usually goes with the figure. Example: **Figure 1:** Prevalence of diabetes in the study population aged 18 years and above. Findings of the TRICARE Diabetes Study, Uganda, 2006.)

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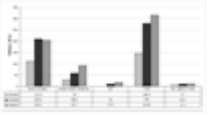
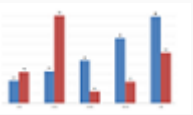

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Consult the PAMJ submission checklist to ensure that your submission complies with our basic requirements.

When finalizing your research manuscript, ask yourself the following questions:

1. Are your study aims clearly stated and logical?
2. Is the rationale/justification for conducting the study clear?
3. Are the methods described in sufficient detail so that the experiment could be reproduced?
4. Is the study design robust and appropriate to the stated aim(s)?
5. Are the conclusions drawn supported by the data?
6. Is the discussion section critical and comprehensive?
7. Are the references appropriate in number and up-to-date?
8. Are statements supported appropriately by parenthetical citations?

The STROBE Checklists provide good guidance on how to report observational research well. We strongly advise that you use them.
Unofficial French versions of some STROBE checklists are available here: STROBE Case-Control Studies | STROBE Cross Sectional Studies

Download the MS Word version of the STROBE checklists. Include the completed form as an annex to your submission.

STROBE cross-sectional studies (English)

STROBE case-control studies (English)

STROBE cohort studies (English)

STROBE études transversales (Francais)

STROBE étude cas-témoins (Francais)

For **qualitative Studies**, we recommend the use of the Consolidated criteria for reporting qualitative research (COREQ), available at the Equator Network.

CHAPTER 3: PROTOCOL

1 INTRODUCTION

Patient safety is defined as the absence of avoidable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum[1].Every stage during the provision of health care has a risk of certain degree of inherent unsafety[1,2].

Patient safety is a cause for distress in health-care system all over the world. Although there is an increasing focus in the study of patient safety, there is a general lack of understanding of the magnitude of the problem. Critical incidents are increasing recognised as a source of harm to patients. Improving patient safety has become a global priority and another way to reach this goal is to report and analyse critical incidents systemically.

According to the World Health Organisation (WHO), critical incidents are likely to be one of the 10 leading causes of death and disability worldwide[3]. Low- and middle-income countries hospitals experience about 134 million critical incidents each year, resulting in 2.6 million deaths annually. High-income countries estimate shows that as many as 1 in 10 patients are affected by critical incidents with approximately 50% of them preventable [3]. Hospital infections affect 7% of hospitalized patients in high-income countries whilst 10% are affected in low- and middle-income countries. Furthermore, WHO estimate that of the 7 million surgical complications which are recorded annually, 1 million will die intra-operatively or during immediate recovery period.

Critical incidents exert a high toll in financial loss as a consequent of additional hospital stay, medical expenses and litigation[2]. A South African study showed that litigation because of medical malpractice has remarkably increased in the last decade, negatively impacting financing of public healthcare, for example, the huge legal bills could have been used to finance hiring of more staff, professional development, build hospitals and procure equipment[4]. Critical incidents affect patients negatively through loss of income, disability, medical expenses not forgetting the psychological and social impact. In addition to the above costs, there is erosion of trust, loss of confidence and dissatisfaction among the public and health-care providers.

Global advances in patient safety field research are retarded by lack of consistency in the language and definitions of the central concepts[5]. Despite many proposed concepts for the classification of patient safety terms and central concepts, none is widely implemented,

which in turn has restricted the ability to consolidate and compare information across individual fields. A precise definition is required of which incidents are classified as critical incidents. Literature review on patient safety is associated with semantic relationship on the meaning of critical incidents. Other terms commonly used to describe critical incidents are ‘adverse clinical event’, ‘clinical incident’, ’iatrogenic events’ and ‘patient safety incident’, which is currently the preferred terminology.

To this end, the World Health Organization’s World Alliance for Patient Safety developed an International Classification for Patient Safety to devise classification of patient safety information. It defines a patient safety incident as an event or circumstance that could have resulted or did result in unnecessary harm to a patient. Incidents may arise from either intended or unintended acts and comprise of reportable circumstances, near miss incidents, no harm, or harmful incidents (adverse events) [5,6,7,8,9,10]

In the context of our research, we will use the term critical incident as it is the one currently in use at our hospital and was the one commonly used by most authors in literature reviewed. The critical incident reporting system was firstly published as an outgrowth of studies among military pilots, in early 1940s, by Flanagan[11,12,13]. In the medical field it started to be considered in the 90’s with the issuing of the much-cited Harvard Medical Practice Study[14]. The study found that about 4% of patients sustained a certain degree of harm in hospitals, and 70% of adverse events resulted in disability and 14% resulting in mortality. Various studies in developed countries, thereafter, investigated the extent of critical incidents and have shown that approximately 2.9%-16.6% of patients experience incidents and in 4.5%--20.8% of the adverse events, the patient dies. Most of these studies show that 50% of adverse events are judged to be preventable[2,16,17].

There is lack of data and awareness about critical incidents in developing countries. A large-scale patient safety study in developing countries (including South Africa) showed that 8.2% of patients suffered at least one adverse event, with average of 2.5%-18.4%per country, 83% of these events being judged to be preventable[9,18]. The study also concluded that 30% of patients who sustained an adverse event died, 14% suffered permanent disability, 16% suffered moderate disability, 30% suffered minimal disability and in 8% harm was not specified. The research also showed that 34% of the encountered incidents was a result of therapeutic errors, diagnostic errors contributed 19%, surgical errors lead 18%, 9% resulted from obstetrical procedures, 8% from neonatal procedures, 5% non- surgical procedures, 4% from drug related incidents, 2% fractures, 0.5% anaesthesia 0.5% and 0.5% from falls[9]. There is currently no national data on the occurrence of critical incidents in South Africa.

Specialty based critical incident reporting system gives a clear picture into unit-specific safety issues, which might not be necessarily exposed by hospital or national data. Cardula Wagner et al concluded that although there were comparable incidents and cause in different hospital specialties, there were differences between units[19].They noted that speciality based critical incident reporting is specific, making improvement easier, thereby giving an advantage over hospital or national –wide reporting systems. The above logic is one of the factors our study is going to focus on critical incidents in gynaecology speciality at our hospitals.

There is however a scarcity of data about incidence of specialty-based critical incidents in general and in gynaecology. Tanaka et al did a meta-analysis of studies which researched on gynaecological critical incidence (including one South African study) and their results showed that the incidence of adverse events in gynaecological hospital admissions was 10.8%. (95%CL 9.4%-12%). Preventability of these events in their review was 52.5% (95%CL 47.3%-57.7%) and mortality was 1.2% (95%.CL 0.25%) [17]. Literature search revealed two retrospective studies previously done in gynaecology units in South Africa. Lombaard et al found that the critical incidents rate at Kalafong Hospital was 7.98% over a six-month period with 2.15% deaths in all gynaecology admissions[20]. Another study at King Edward VIII Hospital showed that adverse events were observed in 11.7% of admissions, with 52% of them being avoidable[21].

To further strengthen the argument about lack of enough research being done on patient safety, hence the need for our research, Norton looked at patient safety citations in PubMed[14]. He noted that of all the listings in 1998, patient safety research contributed 0.3%, in 2006 it contributed 0.7% and projected that PubMed will have about 2% of patient safety papers in 2035. However, critical incidents cause more death than AIDS, motor vehicle accidents or breast cancer. 1.58% of the PubMed listings in 2006 comprised of breast cancer papers whilst cardiovascular disease contributed 9.66%. Patient safety research is therefore lagging, if you compare with the burden on population, showing that more intellectual effort need be directed into this field.

WHO's World Alliance for Patient Safety noted that patient safety can be enhanced by three complimentary actions: preventing critical incidents, reporting them and minimise their effects when they occur[2]. Similarly, Petschnig et al concluded that there is an intimate correlation between the initiation of critical incidents reporting systems in health care organisation and patient safety[22]. There is a positive change on safety culture,

notwithstanding a quantitative correlation between reporting systems and safety is still to be established[22].

Pattinson et al, argued that basic statistics are needed in the effective management of health as it allows identification of problem areas[23]. They further stated that to design local solutions, local data is required. According to their paper it is generally accepted that by reporting the areas of poor-quality care, clinicians will automatically adjust and prevent the same mistakes again. However, change in some organisational factors (such as shortage of staff or equipment) might take time.

This study also analysed avoidability of critical incidents identified during the period of assessment. Brennan et al stated that critical incidents will not always point to substandard care nor do their absence point to good quality care[17]. Occurrence of unavoidable critical incidents (e.g., drug reaction or complications in complex oncology surgery) are inherent risks in medical care and cannot be viewed as poor care. However, the goal of studying critical incidents is to lower the incidence of avoidable factors and the amendments that need to take place to improve patient safety. This analysis, however is challenging as avoidability can only be determined from available documentation, subjective and depends on the study personnel experience and knowledge[17,23].

We are also going to audit the critical incident reporting system in our clinical department. Despite the advantages of critical incidents reporting, it is an underutilized tool in health care. There is widespread underreporting which reduces the reliability of data to moderate[12,14]. Factors responsible for poor reporting include incidents not recognized, no clarity on what should be reported, fear of punitive actions, uncertainty regarding how the reported incidents will improve patient safety and administrative issues which make reporting difficult (insufficient time, long forms and lack of feedback). As there is no gold standard estimating the incidence of critical incidents[14], our study will include both records review and reporting systems thereby picking up cases which might have been missed by the later systems.

In July 2016, the Department of Health produced National Policy for Patient Safety Incident Reporting and Learning in the Public Health Sector of South Africa[9]. One of the policy recommendations is to make it mandatory for public health institutions to have a critical incident reporting and learning system. It points out that emphasis should not only be on reporting but also on learning quoting WHO envoy, Sir Liam Donaldson stated that “To err is human, to cover up is unforgivable but to fail to learn is inexcusable”. We, therefore,

envisage that our research will highlight and encourage health care managers to improve on the exposed deficiencies.

This study aims to enlighten clinicians, patients, the community and health care managers about the incidence, types of avoidable factors and impact of critical incidents in gynaecology department at CMJAH.

2: **AIMS AND OBJECTIVES**

The aim of this study is to describe and analyse critical incidents in the gynaecology in the department of Obstetrics and Gynaecology at CMJAH.

Objectives of the study are:

i. To establish the incidence and the type of critical incidents in gynaecology
ii. To assess outcome of patients who experienced gynaecological related critical incidence.
iii. To identify avoidable factors associated with the critical incidents.
iv. To audit the critical incidents reporting systems in gynaecology department

3: METHODS

3.1 STUDY DESIGN AND SETTING

This research was a retrospective descriptive analysis of critical incidents in gynaecology at CMJAH from 1st January 2019 to 31st December 2019.

The study site was in the department of Obstetrics and Gynaecology at the above-named hospital, a tertiary referral hospital and also the main teaching hospital for the University of the Witwatersrand.

3.2 STUDY POPULATION

All patients admitted in year 2019, in the gynaecology department were part of the study. It is estimated that approximately 2000 patients are admitted per annum and approximately 100 critical incidents are recorded. Clinical records of patients identified to have had a critical incident during their care were assessed and analysed.

3.3 DATA COLLECTION

The department of Obstetrics and Gynaecology at CMJAH keeps a record of patient critical incidents using a specially designed patient critical incident form. This data is then captured on RedCap. The incidents are discussed during the daily audit meetings as part of service improvement strategies. In every patient critical incident is reported to the hospital management using a specially designed patient safety form.

Critical incidents will be sought using the following methods: -

I. Completed gynaecology critical incident forms.
II. Analysing Redcap daily surveys for the year 2019
III. Analysing the monthly gynaecology morbidity and mortality meeting presentations.
IV. Review of theatre and ward records
V. Review nursing patient safety reports

All medical records of patients identified to have experienced critical incidents during the study period were retrieved from the hospital filling system and demographic information, timing of admission, critical incidence marker and avoidable factor were extracted using a specially designed critical incident form (Appendix A) and later transferred into Microsoft Excel spreadsheet to prepare for analysis.

4.DATA ANALYSIS

Study data was imported from Microsoft Excel to Stata statistical software version 16 (Stata Corp, Texas USA) for analysis. Categorical data was described using frequencies and percentages. Continuous data was assessed for normality using quantile distribution plots and histograms. Normally distributed continuous data was described as means and standard deviations, whilst non-normal data was described using median and interquartile ranges. Significance level (P-value) was set at 0.05.

5.ETHICS

Permission to access patient files was granted from the Chief Executive Officer (CEO) of CMJAH and ethics approval was obtained from the Human Research and Ethics Committee of the University of Witwatersrand. Since this study was a retrospective audit of medical records, there was no requirement for individual patient consent. Identifying patient information was removed prior to analysis thereby maintaining anonymity at all times. All data was handled with strictest confidentiality.

6. TIMING

ACTIVITTY	MAY 2020	JUNE 2020	JULY 2020	AUG 2020	OCT 2020	NOV 2020	DEC 2020	JAN 2020	FEB 2021	MAR 2021
Protocol preparation and Literature Review	X	X	X							
Protocol Submission				X						
Ethics Application					X					
Data Collection						X	X			
Data Analysis							X	X		
Write-up								X	X	
Research report and submission										X

7. POTENTIAL CHALLENGES

- Since it is a retrospective study some patient files may be missing, and some data maybe incompletely filled in.
- We are currently in the midst of uncertain times, due to the COVID 19 Pandemic, unforeseeable circumstances may delay/hinder the research e.g., protocol submission meetings were already postponed.

8. FUNDING

All the necessary expenses like stationery, printing and transport were met by the researcher. An estimated cost of R 3000 was budgeted for this research.

9. DISSEMINATION OF RESEARCH FINDINGS

The findings of this research project will be written up in the form of a publishable research paper format. It will be submitted for the degree of Masters in Medicine, in the department of Obstetrics and Gynaecology, University of Witwatersrand. Research findings will also be presented to colleagues at CMJAH and Department of Health, South Africa. The researcher also aims to publish the findings of the study in a peer-reviewed Journal.

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APPENDIX A: DATA COLLECTION SHEET

GYNAE CRITICAL INCIDENT FORM

GYNAE CRITICAL INCIDENT FORM

Study number_____Age_____
Date of Incident_____ Firm_____HIV Status + / -
Parity_____Gray_____ **Admission:**
Elective/Emergency/Oncology
CD4:_____ VL :_____ Date:_____ Discharge:_____ Days Spent in Hospital:_____

Intention of treatment on admission: Surgical/Medical/Palliative

Primary gynecological problems	Oncology: Diagnosis and stage

Associated Medical Problems	

Surgical Procedures and dates done	

CRITICAL INCIDENT

Event	Tick Block	Specify Details
Death		
ICU Admission		
Pulmonary Embolism / DVT		
Repeat Laparotomies (specify reasons)		
Laparotomy for ASO		
Unplanned surgery		
Blood transfusion > 4 units		
Organ dysfunction post-surgery		

Fistula and other organ damages		
Delayed diagnosis		
Omission of Procedure		
Emergency hysterectomy		
Post-op complications requiring surgery		
Wound sepsis post-op requiring surgery		
Anaesthetic complications		
Others (specify)		

Avoidable factors (tick type and level where problem occurred)

Patient Orientated Problems

	Lack of Information
	No Avoidable factor
If either of the above options has been selected, do not complete below	
	No antenatal care
	Infrequent antenatal care
	Delay in seeking medical help
	Unsafe abortion
	Family problem
	Communication problem
	Other (specify)

Emergency Care Problems: (tick type and level where problem occurred)	
Patient Age Group	
	Pregnancy related
	Reproductive Years
	Peri-menopausal
	Post-menopausal

Administrative Problems

Lack of Information			
No Avoidable factors			
If either of the above options has been selected, do not complete below			
	Primary	Secondary	Tertiary
Transport problems: home-institute			
Transport problems: institute-institute			
Barriers to entry			
Lack of accessibility			
Lack of Health care facilities: ICU beds			
Lack of health care facilities: equipment, drugs, blood			
Lack of Personnel			
Lack of appropriately trained staff			
Communication problems			
Other administrative problems			
Specify:			

Resuscitation	
	Lack of Information
	No avoidable factor

Medical Care			
Lack of Information			
No avoidable factor			

	If either of the above options has been selected, do not complete below.
	Airway problem
	Breathing problem
	Circulation problem
	Drug problem
	Investigating problem
	Monitoring problem
	Oncology Related

If either of the above options has been selected, do not complete below.			
	Primary	Secondary	Tertiary
Initial Assessment			
Problem Recognition/dx			
Delay in referring pt			
Mx at inappropriate level			
Incorrect mx (wrond dx)			
Sub-Standard mx (correct dx)			
Monitoring problem: Not/infrequently done			
Monitoring problem: Prolonged abn obs with No action			
Surgical Complications			
Anaesthetic Problem (pre-op evaluation not sufficient)			
Treatment/medication not given			

Oncology Related	
a.	Delay in Diagnosis
	Patient Related
	Screening / Diagnostic test not performed
	Delay in referral to tertiary institute

b.	Inappropriate Facility
	Palliative care in 2 / 3° Hosp

	Level of Surgery Performed
	Registrar
	Consultant
	Intern
	Midwife (mva)

1) Assessment of Patient Outcome_____

_____

_____

_____

_____

_____

_____

_____

2 i) Was the Gynae Critical Incident form filled in (Y/N)

ii) If initially filled in was it completely/correctly done? (Y/N)

iii) Details)_____

_____

_____

_____

iv) If not initially filled in, where was the critical incidence identified?_____

3) Summary _____

Name of Registrar (Print):_____

APPENDIX B: HOSPITAL APPROVAL

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL (CMJAH)
Office of the Clinical Director

Enquiries: Ms. TT Mahlangu
Tel: (011) 488-3365
Email: Thandi.Mahlangu4@gauteng.gov

Physical Address: Room 262A,17 Jubilee, Parktown 2193 Postal Address: Private Bag x39, Johannesburg 2000

17 August 2020

Dear Dr Christopher, Chikwiri

STUDY TITTLE: Critical incidents in Gynaecology: Audit at Charlotte Maxeke Johannesburg Academic Hospital

Permission to conduct the above-mentioned study is provisionally approved. Your study can only commence once Ethics approval is obtained. Please forward a copy of your Ethics Clearance Certificate as soon as the study is approved by the Ethics Committee. This will enable the CEO's office to grant you the final approval to conduct the study.

Supported/Not Supported

Dr PN Africa
Acting Clinical Director
Date: 18/08/2020

Approved/Not Approved

Ms. G Bogoshi
Chief Executive Officer
Date: 19.08.2020

APPENDIX C: ETHICAL APPROVAL

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr C Chikwiri

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M201083

NAME: **(Principal Investigator)**	Dr C Chikwiri
DEPARTMENT:	School of Clinical Medicine Department of Obstetrics and Gynaecology Medical School University
PROJECT TITLE:	Critical incidents in gynaecology; audit at Charlotte Maxeke Johannesburg Academic Hospital
DATE CONSIDERED:	30 October 2020
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Professor L Chauke
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	27 November 2020

This clearance certificate is valid for 5 years from the date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **October** and will therefore reports and re-certification will be due early in the month of **October** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

APPENDIX D: TURNITIN REPORT

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