

**Audit of orthopaedic surgery operation notes at Chris Hani Baragwanath
Academic Hospital**

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**A research report submitted to the Faculty of Health Sciences, University of
the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for
the degree of Master of Medicine in the branch of Orthopaedic surgery**

Declaration

I, Nyiko Zakaria Chauke, hereby declare that this research report is my own unaided work. It is being submitted for the degree of Master of Medicine in Orthopaedic surgery at the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other university.

Signature: N.Z. Chauke

Date

Dedication

This work is dedicated to my mother Grace Manganyi, my late father Elias Chauke, Tshianeo my dear wife and my two lovely children.

Thank you very much for your support

Publications and Presentations

The results of this study have not been published or presented in any peer reviewed journals or academic meetings or conferences.

Abstract:**Introduction:**

The medical record is critical for the documentation of the patient's current and possible future health status, as well as for communication between the healthcare professional and other service providers, statutory and regulatory bodies. Statutory and /or regulatory bodies and medical councils around the world emphasises the importance of accurate, adequate and comprehensive medical records. The operative notes are the official documentation of a surgical operation or procedure and serves as a key form of surgical communication between healthcare professionals and other healthcare service providers. Surgical operative notes also serve other important functions related to medical cost billing, quality assurance, medical education, research purposes and medico-legal issues. There is no consensus among surgical disciplines on the required standard operative notes or acceptable operative notes documentation. The royal college of surgeons of England (RCSE) has published guidelines on the operative notes documentation that are widely accepted in the United Kingdom and supported by the British Orthopaedic Association.

Aim:

The aim of the study was to assess the completeness of the clinical records for the Orthopaedic surgery operative notes to:

- Evaluate the completeness of operative notes with respect to the RCSE 2008 guidelines
- Determine the essential information that was omitted from operative notes

Methodology:

The study was a retrospective, descriptive single centre study conducted at Chris Hani Baragwanath Academic Hospital between 01 August 2013 and 30 November 2013. Clinical records were evaluated specifically for the orthopaedic surgery operative notes details and compared to the guidelines based on the RCSE 2008. The data were collected from 25 % of all orthopaedic surgical procedures performed in the year 2013.

Results:

A total of 400 clinical records were available for the review of orthopaedic surgery operative notes. All operative notes were hand-written and no separate operative notes proforma or template was used for operative notes documentation; all operative notes were written in the daily ward round progress sheet. No aide-memoire was available or used to assist the surgeon and or assistant with writing of the operative notes. The study revealed poor documentation of essential information in the operative notes with only 0.25 % meeting all the parameters as per RCSE guidelines. Up to 93.3 % of the operative notes were written by the medical officers and registrars, whereas 4.3 % of the operative notes were written by the consultants. In addition, 56.8 % were missing 5 – 9 parameters, and of the additional parameters included in the study 50.6 % were missing 5 – 9 parameters and 48.5 % missing 10 or more parameters. Poor documentation was found with regards to details of prophylactic antibiotics missing in 90.8 % of all operative notes, tourniquet usage missing in 58.4 %, operative findings not mentioned in 55.8 %, identification of prosthetic material or implants missing in 77.0 % and use of blood and or blood products missing in 95.5 %.

Discussion:

The study represents 25 % of all orthopaedic surgery operations performed in the year 2013. The findings of the study are consistent with the previous published studies reporting poor operative notes documentation without the use of aide-memoire, proformas, computerised or paper based templates and procedure specific proforma following acceptable guidelines.

Conclusions:

The findings of this study confirm poor documentation and significant deficiency of essential parameters in the operative notes that is required for the patient safety and highlight lack of consensus on the essential parameters required for a complete operative notes details. Future research using the orthopaedic operative notes template and/or proformas is recommended to assess completeness of the operative notes documentation.

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Nomenclature

BOA – British Orthopaedic Association

CMS – Centres for Medicare and Medicaid Services

CPT – Current Procedural Terminology

GMC – General Medical Council

HPCSA – Healthcare Professional Council of South Africa

ICD – International Classification of Diseases

JCAHO – Joint Commission on Accreditation and Healthcare Organisations

MPS – Medical Protection Society

NHS – National Health Service

NHSLA – National Health Service Litigation Authority

POPI – Protection of Personal Information

RCSE – Royal College of Surgeons of England

WHO – World Health Organisation

d – precision

n – sample size

P – expected prevalence proportion

Z – statistics for chosen level of confidence

Chapter 1: Introduction

The Health Professional Council of South Africa (HPCSA) adopted a definition of a health record from an article published by A. de Klerk in a Medical Law journal (Volume 12, 1993 , pages 77 – 83) as any relevant record made by a health care practitioner at the time of or subsequent to a consultation and / or examination or the application of health management.¹ A health record contains all essential information about the health of an identifiable individual recorded by a health care professional, either personally or at his or her instruction.^{1,2,4,5}

Medical authorities around the world use the words such as the medical record, medical report or clinical report/record interchangeably to refer to a health record.² In this report, the health record will be used to refer to the medical record as preferred by the HPCSA.

The National Health Act ³ of South Africa Number 61 of 2003 under section 14 states that all information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment is confidential, so it is mandatory that health care practitioners oblige and / or comply with all the statutory obligations to avoid a fine or imprisonment for a period not exceeding one year or both, and a possible future medical negligence lawsuit.³

The World Health Organisation (WHO) ⁶ in 2009 published guidelines for safe surgery in which they stated that an accurate, complete, signed and timed surgical record, whether hand-written or typed/electronic should be maintained at all times. ^{1,2,4,5,7} Furthermore , they also suggested that all patient's health records should comprise of the following attributes: ^{2,4,5,7}

- Clear – both legible and understandable whether hand- written or type or electronic, and patient identified by his or her name on each page, dated, timed and signed or official stamp
- Objective – health records should be factual and free from subjective comments about the patient and / or relatives
- Contemporaneous – health records should be written up at the time of contact/consultation to ensure accuracy

- Tamper-proof – attempts to amend health records should be immediately apparent; if electronic health records system is used, they should record the date and author of any notes and track any amendments
- Original – health records should not be altered or amended once an entry is complete. If mistake is noticed, amendments or corrections may be added and clearly identified as such. If a change is made to the health record, it should be signed and dated, and a note should explain why the change was made

The WHO ² in their 'Guide for Developing Countries' manual states that a comprehensive health record should consist of the four major sections which include the following: ^{1,2,4,5,8}

- Administrative data which includes demographic and socioeconomic details
- Legal data including a signed informed consent and authorisation details
- Financial data relating to the cost of services and payment of fees
- Clinical data of the patient whether admitted or treated as an outpatient or emergency treatment

The main purpose of any health record is to provide a continuity of care, but are also used for other purposes such as: ^{1,2,4,5}

- Administrative purposes
- Further diagnosis or ongoing clinical management of the patient
- Conducting a clinical audit
- Promote teaching and research
- Evidence in litigation or compensation purposes
- Financial reimbursement
- Serve as a basis for accreditation
- Communication with health care providers, and statutory and regulatory bodies to facilitate patient safety improvements

Similarly, McIntyre ⁸ from the Westchester Orthopaedic Associates assessed the future impact of an electronic health records in an Orthopaedic surgery department and argued that the health record serves mainly three purposes, with which the surgeons should comply, even with the use of electronic health records:

- Stores information used by the health care providers and coordinates medical care.
- Provides legal documentation of the health care provider/physician – patient interaction for the purposes of litigation and or compensation.
- Medicare or Medical aid schemes and insurance companies uses the health record to determine the appropriate level of health care provider/physician reimbursement. Furthermore, health record has become exceptionally important source of health cost, legal claims and health economic data.

Medical or Health care professionals and statutory bodies around the world emphasises the importance of an accurate, legible, and comprehensive health records and furthermore, states that the essential component of the health record, depending on the nature of the individual case, must include the following: ^{1-5,7}

- Hand – written or typed contemporaneous clinical notes
- Computerised/electronic clinical records, emails, photos
- Referral letters to and from other health care providers, including discharge summaries
- Laboratory reports and or automated analysers
- Radiological investigation studies such as radiology report and films
- Audio-visual records
- Clinical research forms and clinical trial data
- Death certificates and autopsy reports
- Other forms completed during the health care practitioner interaction such as insurance forms, informed consent form, disability assessments and injury on duty compensation forms

The health records are also used in court for the following medico-legal purposes: ^{2,5} insurance cases, worker's compensation, malpractice claims and criminal cases.

Gidwani *et al.* (2009) ⁹ reviewed 130 medical negligence orthopaedic reported and they classified them into one of the following categories: substandard quality of surgery, extreme delay in diagnosis or treatment, substandard perioperative care, surgical operation not indicated, adequate informed consent not obtained and patient not warned of specific risks and or complications, and use of defective prosthetic implants or products. Of these cases, 55 % were abandoned by the claimants' legal representatives and 45 % were settled out of court with the highest paid amount of 2.7 million pounds.

Furthermore, the abovementioned authors noticed that most cases were brought in for two or more specific reasons. These included an alleged and or demonstrated failure of duty of care for the patient such as inappropriate timing of the surgical procedures, substandard quality of fracture reduction, substandard care related to the use of prosthetic implants, prophylactic antibiotic not use despite overwhelming evidence-based medicine studies, inadequate operative notes documentation of the surgical approach and intraoperative difficulty or complications encountered.⁹

Therefore, the authors concluded that the aspects of patient management that contributed to medico-legal cases being lost and resulting in some huge financial settlements in an elective surgical procedure include the following:⁹

- Inadequate informed consent and poor health records and explanation for performing surgical procedure
- Inadequate surgical approach description such as no record of identification and protection of nerves in the operative notes
- Poor documentation of intraoperative surgical complications and poor communication with the patient and relatives
- Poor surgical techniques such as malposition of prosthetic components
- Surgical procedure performed by inexperienced surgeon or unsupervised, leading to substandard outcomes
- Surgical procedure performed by a surgeon who does not belong to the intuition or the local team

However, they further claim that the following features can help the surgeon in defending a case against the medico-legal claims: ⁷

- A clear health record in the preoperative planning phase outlining the decision-making process with special references to potential risk and complications
- Good health record keeping
- Health record management changes, decision process and any handover care
- Early senior health care practitioner input and recruitment of the other teams
- Clear operative notes with special reference to the major soft tissue structures

East and Synckers (2011) ¹⁰ retrospectively reviewed all the orthopaedic surgery medico-legal cases reported the Medical Protection Society (MPS) in South Africa. They found that there was a 20 % increase in the number of medico-legal cases involving orthopaedic surgeons belonging to the MPS in the past five years. Furthermore, they argue that communicating openly and attending 'Mastering your risk' workshops can reduce the possibility of litigation and helps ensure that a good health records/notes are produced in every case. ¹⁰

Similarly, Briggs (2015) ¹¹ in a recent United Kingdom(UK) review of adult elective orthopaedic surgery services found that the total cost of orthopaedic claims has risen by 60 % over the last three years compared to a 12 % rise in an overall the National Health Service (NHS) litigation claims. In addition, to account for this huge and rapid increase, the author claim that a change in society reflected in a less trusting public and more active promotion of legal services as the reason. Furthermore, he cited a key ruling from the House of Lords (Chester versus Afshar (2004)) that raised some concerns about the acceptable standards of care and emphasises that the responsibilities of the surgeon to provide informed consent. However, the top cases highlighting the rapid rise in NHS potential liability for medical negligence claims release from the NHSLA includes the following: poor judgement, improper surgical procedure, soft tissue damage, and poor clinical outcomes which are all potentially preventable. Of note, he further found that most the cases were related to the surgical training, errors due to high volume work and high demands of service delivery.

A clinical audit retrospective observation study was conducted to review the operative notes to assess the completeness based on the RCSE 2008 guidelines to see if the operative notes in our institution would be defensible in a medico-legal lawsuit, and whether they could be used for research purposes and assist in reimbursement claims.

26,28,30,35,37,70

A universally accepted definition by the National Institute for Health and Clinical Excellence(NICE) in their 'Principles for Best Practice in Clinical Audit' states that a clinical audit it is a quality improvement process that seeks to improve the patient care and the outcomes through a systemic review of care against explicit criteria and the implementation of change.^{12,13}

The following checklist must be applied and maintained always when conducting a clinical audit: ¹³

Stage 1: Plan for an audit

- Involve all stakeholders
- Determine the audit topic
- Plan the delivery of the audit fieldwork

Stage 2: Select a standard or criteria

- Identify standards or evidence based
- Identify the audit criteria – measurable statements
- Set targets or expected performance levels
- Agree acceptable exceptions

Stage 3: Measure the performance

- Collect the data
- Analyse the data
- Draw the conclusions
- Presents the results

Stage 4: Make improvements

- Share the audit report
- Review the areas for improvements and agree on the priorities for the action
- Identify appropriate interventions
- Develop a quality improvement plan
- Identify:
 - ✓ Personnel responsible for each task or action
 - ✓ Reasonable time scale for completion
 - ✓ How and when progress will be measured
- Ensure that a change is supported by those with the necessary authority to affect such change

Stage 5: Sustain improvements

- Monitor implementation of the changes
- Report on progress of implementation as required
- Re-audit to ensure that changes have improve the practice and decide if further audit procedures are required

There are many reasons to undertake a clinical audit which includes the following: ¹³

- Assess and improve patient care, uphold the professional standards and do the right thing
- Identify and measure the areas of risk within the service
- Creates a culture of quality improvement in the clinical setting
- Educational purposes for the participants
- Offers an opportunity for increased job satisfaction
- Essential component of professional practice
- Improve the quality and effectiveness of the healthcare system

Despite the set minimum standards required by the Guidelines for Clinicians on Medical Records and Notes (RCSE March 1990), deficiency in the operative notes was noticed in the Report of the National Confidential Enquiry into Perioperative Deaths ¹⁴ in 1989/1990 in the United Kingdom. This report, which reviews the quality delivery of anaesthesia and surgery and perioperative care, found that surgical operation notes were generally poor in all the surgical specialities except for the paediatric surgery and neurosurgery. Furthermore, they noticed that the common deficiencies in the operative notes details, indication for operation or surgery, sutures used and closure techniques and lastly the details of prosthetic material used. Additionally, the worst deficiency in the operative notes were written by unsupervised registrar with the details of the surgical procedure abbreviated as 'L.I.H.' for an abdominal surgery.

To improve the documentation of the operative notes, the RCSE published guidelines in the early 1990 which were reviewed and modified in 1994, 2008, and recently in 2014. ^{7,15} the guidelines recommend that the surgeon must ensure that all health records are clear, legible, complete, and contemporaneous. Furthermore, they advise that operative notes should preferably be typed and written immediately or within 24 hours and provide sufficient to enable continuity of care for every patient who has undergone an operative procedure.^{4,6,7,15}

Most studies have been published in general surgery specialities around the world assessing the operative notes documentation in comparison and based on the RCSE guidelines with and without the use of aide-memoire, templates and procedure specific proforma.^{17,26,27-34}

Similarly, the Joint Commission on Accreditation and Healthcare Organisation ¹⁶ (JCAHO)/ Medicare in the United States have set the minimum required standards for the operative notes, but they claim that for the most part, the content documented is not regulated.

1.1. Problem Statement

Despite advance made in orthopaedic surgery, there are currently no local studies that have examined the adequate documentation of orthopaedic operative notes against the RCSE guidelines or any other guidelines available. Several published studies have reported on the importance of adequate documentation operative notes, and its use and value with regards to medical cost billing, assisting in a medico-legal lawsuit and insurance pay-out, assist in research purposes and continuity of care.^{19,20,26} Therefore, there is a need to conduct an audit of orthopaedic surgery operative notes to assess whether the operative notes in our institution are adequately documented and comply the set standards by the RCSE 2008 guidelines.

With the ever-spiralling cost of health care services and medico-legal lawsuits, adequate documentation of the operative notes will help reduce the risk of medicolegal-lawsuits, assist in research, improve correct medical billing claims and ensure fair reimbursement without delay or avoid rejection and further provide support for continuity of care. The main focus of this research is to audit Chris Hani Baragwanath Academic hospital orthopaedic surgery operative notes against the RCSE 2008 operative notes guidelines.

The results obtained from this study will provide an insight into the adequacy of the operative notes documentation in Orthopaedic surgery as well as provide awareness of the RCSE operative note guidelines. It will also encourage the medical practitioners to comply with the requirements set out by various statutory bodies in South Africa with regards to the health record keeping.

Chapter 2: Literature review

2.1. Introduction

In this chapter the literature that is relevant to this study will be presented in different categories. These categories include a literature search strategy, the definition of operative notes/reports, uses of operative notes, the adequacy of operative notes based on the RCSE guidelines and ways to improve the documentation.

2.2. Literature Search

A search term using the Boolean operators was constructed to perform a review of the published data.

Search engines used include the following:

- a. PubMed (<http://www.ncbi.nlm.gov/PubMed>) offered by the National Library of Medicine on the internet
- b. Google Scholar (<http://scholar.google.com>) Google search engine
- c. Science Direct (<http://www.sciencedirect.com>) provided by the Elsevier publication

In terms of the duration, the search included all articles published between 01 January 2000 and 31 July 2016. The list of references retrieved from the publications were manually checked for additional studies potentially fulfilling the inclusion criteria that were not found using the search engine.

Full articles were searched for in the individual journals and different medical health care council and /or health authorities or association bodies. Abstract only articles and papers not accessible were excluded. Only studies published in the English language were reviewed.

Mesh (Medical Subject Heading) and the text words used included:

- a. Operative notes
- b. Operative report
- c. Surgical operative notes/reports
- d. Orthopaedic operative notes/reports
- e. RCSE operative notes/ reports

An operative note or report is defined as a document produced by a surgeon or surgeon assistant who has participated in a surgical procedure, which contains a detailed account of the operative findings, surgical approach/procedure used, the specimen removed, the preoperative and postoperative diagnoses, and names of the primary surgeon and any assistants involved. ¹⁶

Good surgical practice guidelines published by the RCSE ¹⁵, emphasises that the surgeon must ensure that all health records are accurate, clear, legible, comprehensive and contemporaneous, and should have the patients' identification details and preferably typed for every surgical procedure.^{4,6,7} In addition, they also suggested that health care practitioners should be familiar and fully compliant with the guidelines of the Data Protection Act 1998 around the use and storage of all patient identifiable information. ^{5,7,15}

Deficient operative notes have been raised in some several general surgery specialities. Mathew *et al.* (2003) ¹⁶ assessed the quality of the operative notes in a district hospital to evaluate the extent of adherence to the RCSE 2002 operative notes guidelines. They found that the surgical operation time recorded in 6 % of the operative notes, intraoperative complications encountered mentioned in 16 % of the operative notes written by the consultants and 0 % of the operative notes written by the registrars.

Baigrie *et al.* (1994) ¹⁸ audited the quality of 264 general surgery operation notes written by consultants and surgical trainees in two district general hospital. They found that the post-operative instructions were absent in two-thirds of the operative notes and the prosthetic material or implants serial numbers were non-existent. Furthermore, 70 % of the operative notes written by the consultants were illegible.

Flynn and Allen (2004) ¹⁹ from the University of Louisville School of Medicine in Kentucky evaluated a total of 550 elective orthopaedic surgery operative notes written by 39 surgeons. Their aim was to evaluate the operative notes as a billing document, based on the ten most often missed criteria, as well as incomplete information required for the reimbursement as identified by the certified professional coders. They found that 76 % of the operative notes were missing one or more criteria, of which the most commonly missed criteria included an incomplete description of the operative procedure in 56 % of the cases, 49 % had inadequate description of the indication for surgical procedure, and only 45 % of the operative were written within 24 hours, with subsequent delay in reimbursement or rejection of the medical billing claims.

In addition, Novitsky *et al.* (2005) ²⁰ did a prospective double blind study of the operative notes written by senior registrars and attending surgeons in the Surgery Department, Carolinas Medical Centre, to review the accuracy and specific descriptions of the primary and additional procedures and /or justifications of modifiers, and furthermore review the completeness of operative notes to justify the current procedural terminology (CPT) on a billing sheet submitted the department for reimbursement. Their study revealed that the operative notes written by registrars or residents had 28 % incorrect CPT coding and poor documentation of the modifiers, with subsequent financial analysis showed reimbursement loss of 9.7 %, 29.5 % would have resulted in the denial or delay reimbursement. Of note, 67.0 % of the incomplete operative documentation were written more than 24 hours after the surgical procedure.

An incomplete and inaccurate operative note often results in a reduced or delayed reimbursement. It was also found that operative notes written by the registrars or residents had a high percentage of deficiencies despite surgical education and training. ^{19,20,22,25}

Novitsky *et al.* (2005) ²⁰ findings led to others raising concerns about whether the coding should be done by the administrators and / or certified professional coders or by surgeon/assistants. ²²⁻²⁵

Clinical coding is the process by which the details on the patient's medical conditions, consultations, surgical procedures, and complications during the treatment are extracted and translated from the clinical terminology to an internationally recognised coding language. ²¹

In the United States, the largest health care payer, the Centres for Medicare and Medicaid Services (CMS), imposes a financial penalty to the professional coders and the health care practitioners for a coding fraud under the Health Insurance Privacy and Accountability Act of 1996.⁶⁴ Similarly, in terms of the regulation 5(f), Chapter 2 Administrative requirements of the Medical Schemes Act 131 of 1998, the National Department of Health of South Africa and the Council of Medical Schemes, requires that all registered health care providers include a diagnostic code on accounts or statements that may be used to claim benefits from the medical schemes and administrators.⁹⁹

The International Classification of Diseases (ICD)²⁰ is the international standard diagnostic classification that provide data codes sets to define disease, signs, symptoms, abnormal findings, complaints, social circumstances and the external causes of injury or disease. It was developed in 1992 and designed to promote the international comparability in the collection, processing, classification and presentation of morbidity and mortality statistics, reimbursement systems and automated decision support in medicine.

The Council for Medical Schemes and the National Department of Health of South Africa⁹⁹ adopted the ICD-10 IN 1996 as the national standard diagnostic coding in both the public and private health sector and has been implemented in phases since January 2005 under the auspice of the National ICD-10 Implementation Task Team, which is a joint task between the National Department of Health and Council for Medical Schemes. Therefore, since July 2005, it is compulsory that the ICD-10 codes appear on all claims provided by the health care providers, meaning that if a medical scheme receive a claim without an ICD-10 code or incorrect code, they are going to reject that claim.⁹⁹

Despite the critical importance of coding and billing to maintain practice solvency, surgeons spend less time teaching or learning about medical billing and coding either during their training or in their practices.²²

Naran *et al.* (2014)¹⁰⁰ did an audit to assess the accuracy of the clinical coding for primary and secondary diagnosis and for surgical procedures performed, furthermore they also review coding done the certified professional coders group. They found that at least 41% of the secondary procedures were missed or incorrect, 19 % of the

primary diagnosis were changed, and 35 % of the primary procedures were also changes when compared to the initial coding done, while the coding done by the professional codes changed in 54 % of the patients. Financial analysis of poor and /or incorrect coding found loss of revenue of 114 pounds per patient.

Arthur and Nair (2004) ²³ in their study to determine the effects of hand-written and typed operative notes on coding accuracy, as well as determine the relative coding accuracy between the surgeon and coding clerks, found that the coding clerks were better coder in 97 % of the typed operative notes and 85 % in hand-written operative notes, while the surgeon with coding accuracy of 48 % and 38 % respectively.

However, Britton *et al.* (2008) ²⁴ carried out a retrospective review of a random elective operative procedures of ten consultants at the Avon Orthopaedic Centre, Bristol. They found that the certified professional coders only used one code for each procedure, whereas 35 % of the operative procedure coded by the surgeon were assigned multiple codes, with subsequent financial loss if certified professional coders were used. Similarly, Lifchez *et al.* (2014) ²⁵ in their study to assess the coding knowledge of the surgeon and professional coder using hypothetical cases, they observed a marked disparity in the codes chosen.

The RCSE recommends that operative notes be typed after concerns were raised regarding the accuracy and legibility and the quality of operative notes produced to defend a medico-legal lawsuit .^{23,33-37,39-41,52,55}

Lefter *et al.* (2008) ²⁶ audited handwritten operative notes at the Royal Hobart Hospital, Australia, jointly with a medico-legal lawyer and the medical expert on medico-legal law to establish the level of legibility and importance of the operative notes in a virtual court case. They found that, almost 45 % of the operative notes were non-defensible in a potential complaint in court, and none of the operative notes review met all the investigated parameters.

Dukica *et al.* (2010) ²⁷ did a comparison of the handwritten and computerised version operative notes using the RCSE 2008 guidelines, they found that computer assisted operative notes documentation had a recording of all parameter in 95 % of the cases. Deficiencies in the hand written operative notes has also been in the other studies

where they omission of vital or crucial operative notes details, with up to 20 % illegibility in some studies. ²⁷⁻³¹

In a retrospective study ³¹ conducted in Nigeria at the University of Abuja Teaching Hospital Gwagwalada, to assess the orthopaedic operative notes based on the RCSE 2008 guidelines, they found that patient names were missing in 21.7 %, furthermore, none had the time of surgery recorded, 57.5 % were missing operative findings, 65 % had no post-operative instruction written and only 2.5 % of all operative had reported on intraoperative complications.

Khan *et al.* (2010) ³³ assessed the quality of operative notes in a general surgery department at the Civil Hospital Karachi, Pakistan, and compared them to the RCSE 2008 guidelines, found that the time of surgery was missing in all operation notes, 55 % were missing operative findings details and details of intra-operative complications were missing in 79 % of the operative notes.

Coughlan *et al.* (2015) ²⁸ did a retrospective audit of the hand written orthopaedic operative notes as per the RCSE 2008 guidelines against the St. James Hospital standard operation sheets. They found that none of the operative notes had tourniquet time, 30 % documentation of the prosthetic material use, and 0 % or none indicated the type of surgery as elective or emergency surgery. A similar study by Sweed *et al.* (2014) ³⁰ using the proforma found that 20 % of the operative notes were illegible and 32 % poor documentation of the tourniquet time. In addition, Ali *et al.* (2015) ²⁹ did an observational prospective study to assess the quality of operative notes against the RCSE guidelines, they found none of the operative notes mentioned the surgical time and the type of surgery, and only 66.7 % mentioned the operative findings.

The use of typed surgical operative notes and use of either aide-memoire, templates, and proformas have been shown to improve the quality of operative notes, documentation of coding, recording of intraoperative data and legibility. ^{23,25,34-36}

Bateman *et al.* (1999) ³⁷ audited operation notes carried out in the Otolaryngology department and they found that using an aide-memoire improved the quality of operative notes, with an improvement from 74 % to 93 %, and avoided the use of abbreviations from 53 % to 84 % after the introduction of aide-memoire. Similar

findings were demonstrated by Singh *et al.* (2012) ³⁸ reporting compliance of up to almost 100 %.

Rigby *et al.* (1999) ³⁹ did a prospective study on colorectal cancer patients at the Northern General Hospital to assess the completeness of operative notes documentation using the proformas, they demonstrated improvement from 85 % inadequate operative notes to merely 18 % deficiency. Furthermore, they noticed that the improved operative notes documentation led to better communication between the surgeon and the pathologist.

Payne *et al.* (2011) ³⁴ conducted a study to assess compliance regarding the RCSE 2008 guidelines using the proforma, they reported improvement of operative notes documentation from 76.1 % to 98.3 %, with the degree of legibility improving from 45 % to 63 %. Al Hussainya *et al.* (2004) ³⁵ and Barritt *et al.* (2010) ⁴⁰ found that the electronic templates and or proformas significantly improved the accuracy of operative notes from 35 % to 92 % and in addition they showed reduced interpersonal variation on documentation of the specific RCSE parameters and hand written notes improved from 58.7 % to 93 % following the introduction of the detailed computerised proformas.

Computerised operative notes have also been demonstrated to improve the quality of operative notes details as shown by Edhemovic *et al.* (2004). ⁴² They designed and piloted a computerised synoptic operative report template (WebSMR) to replace the standard narrative operative record. Using the WebSMR, they reported improvement from about 46 % to 99 %, and only took six minutes to compile the operative notes. O'Bichere and Sellu (1997) ⁴³ in their study to compare the proforma against the word processor and predesigned templates, found that the computer generated operative notes were legible, quick to compile, and easier to be analysed for audit purposes and research.

However, others have questioned the use of aide memoire, computerised proforma are adequate to allow complete documentation of all operative notes details, with some studies preferring the use of procedure specific operative notes proformas allow for comprehensive operative notes. ^{40,44,45}

Goyal *et al.* (2012) ⁴⁴ conducted a cohort study in a joint arthroplasty databases for patients who underwent revision hip arthroplasty by a single surgeon, to determine if

previous operative notes provides the critical information necessary for the revision total hip arthroplasty. They found that 58 % of the previous operative notes documented all essential acetabular cup information, furthermore they noticed that 60 % did not indicate the manufacturer of the acetabular liner, 70 % did not document the product name, bearing surfaces was not indicated in 67 %. They claimed that the implementation of a standardised procedure specific operative notes would minimise incomplete documentation. Abbas *et al.* (2016) ⁴⁵ found that the introduction of the procedure specific proforma in laparoscopic operation increased compliance from 66 % to 94 %.

Due to poor documentation of operative notes, the question of the standard of surgeon training was raised. However, there is conflicting evidence in the literature about the role of senior staff in teaching operative notes guidelines and coding, despite evidence that poor operative lead to financial loss.^{23,24,25,47,48} Zwintscher *et al.* (2012) ⁴⁶ conducted a retrospective study of 999 operative notes from the multidisciplinary surgical specialities, they revealed poor documentation with only 0.2 % operative notes meeting the required criteria, post-operative plan was documented in 16 % of the cases, and only 21 % documented a preoperative physical examination findings.

Gillman *et al.* (2010) ⁴⁷ did a nationwide survey in Canada to assess the status of the registrar operative notes writing training, they found significant deficiency, with 73 % of the registrar reporting the need for improvement in operative note documentation. Furthermore, they found that 80 % of the registrars learned operative notes writing by reading old operative notes, 75 % reported they receive no formal training from the registrar's program and 70 % requested training. Of note, even the registrar program directors felt that there is a need for formal training, but could not identify the method to use.

Melton *et al.* (2014) ⁴⁸ found that only 13 % of the registrar training program directors reported the formal training or teaching operative notes writing, and up to 44 % believed poor operative notes lead to financial loss. Eichholz *et al.* (2004) ⁴⁹ found that only 23 % of the training programs offers training in the operative notes writing, with about 83 % of the program directors preferring the use of templates with formal instruction. Gillman *et al.* (2010) ⁵⁰ demonstrated improvement in the operative notes documentation after the introduction of formal training using the template. However,

Johari *et al.* (2013) ⁵¹ question the effective of surgical operative notes training, when he demonstrated marginal improvement in the previously poor documentation with about 29 % mentioning the time of the operation and almost 5 % mentioning the type of surgery whether performed as elective or emergency procedure.

Dumitra *et al.* (2015) ⁵² conducted a systemic literature review of 13 studies to assess the teaching and the quality of operative notes documentation in all surgical specialities, they found that 60 % to 90 % of the registrar supported the implementation of formal training.

Surgeons are not aware of any orthopaedic surgery operative notes guidelines in South Africa. There is no consensus on the acceptable or standardised operative notes parameters as shown in Table 2.1., with the capital letter Y, indicating four or more of the most included parameters. Most of the studies published in the literature have been conducted using the RCSE operative notes guidelines.

Table 2.1: Comparison of the different operative notes guidelines

Criteria	RCSE 2014	BOA THR	BOA TKR	JCAHO	DSS	AU/NSW
Patient identification		Y			Y	
Date	Y	Y	Y	Y	Y	Y
Time	Y			Y		
Elective/emergency	Y					
Procedure safety checklist					Y	
Anaesthetist	Y	Y			Y	Y
Anaesthesia	Y	Y			Y	
Scrub nurse					Y	Y
Consultant in charge		Y	Y			
Surgeon	Y	Y	Y	Y	Y	Y
Assistants	Y	Y	Y	Y	Y	Y
Operative procedures/description	Y	Y	Y	Y		Y
Incision/approach	Y	Y	Y		Y	
Position/laterality		Y			Y	
Preparations/precautions		Y				
Post-operative diagnosis				Y	Y	Y
Operative diagnosis/indications	Y	Y	Y	Y	Y	Y
Operative findings	Y	Y	Y	Y		Y
Problems/complications/difficulty	Y	Y	Y		Y	Y
Extra procedures performed and reasons	Y					
Details of soft tissue release			Y			
Details of soft tissue altered/Histology specimen	Y	Y		Y	Y	Y
Remove gallbladder					Y	
Haemostasis					Y	
Identification of the prosthetic material used	Y	Y	Y			Y
Significant tissue excision/transposition/augmentation			Y			
Component alignment and rotation			Y			
Post-surgery flexion range			Y			
Tourniquet time			Y			
Bone cement use/and technique		Y				
Bone graft		Y	Y			

Drains or infiltration catheters		Y			Y	
Closure techniques/sutures	Y	Y	Y		Y	
Bandage					Y	
Blood loss	Y			Y	Y	
Antibiotic prophylaxis/specific medications	Y	Y			Y	
VTE prophylaxis		Y				
Stability of the joint		Y				
Details of the hospital HSSD		Y				
Post-operative instructions/summary	Y	Y			Y	Y
Signature	Y	Y	Y			

RCSE – Royal College of Surgeons of England, **BOA** – British Orthopaedic Association, **THR** – Total Hip Replacement, **TKR** – Total Knee Replacement, **DSS** – Dutch Surgical Society Laparoscopic cholecystectomy operative notes guidelines, **JCAHO** – Joint Commission on Accreditation of Healthcare Organisation, **AU/NWU** – Australia, North South Wales government policy and guidelines, **VTE** – venous thromboprophylaxis, **HSSD** – hospital sterile services department

Rodgers *et al.* (2008) ⁵³ assessed the compliance and reliability of the RCSE 1994 operative notes guidelines in the department of plastic surgery, they found that using aide-memoire showed a marked improvement and applicability of the RCSE operative notes guidelines. However, they noticed that failure to complete aide -memoire in 47 % of the operative notes by consultants, 41 % by the registrars. In addition, Shayah *et al.* (2007) ³⁴ in the ENT department at Hull Royal Infirmary, they demonstrated improvement from 46 % to 100 % operative notes completeness, with the exception for the time of surgery and the type of surgery.

The Severn Audit and Research Collaborative in Orthopaedics (SARCO) ⁵⁴ compared the quality of the operative notes against the RCSE and BOA, in order to improve patient safety in the orthopaedic department of the nine hospitals in the South West of England. They found that only 0.2 % of all operative notes met all the standards set by the RCSE and BOA. In addition, a high number of the operative notes revealed poor documentation of the diagnosis, operative findings, and use of antibiotics and

thromboprophylaxis. However, they noticed that the typed operative notes significantly improved the recording of the operative notes details. Wauben *et al.* (2010) ⁵⁵ demonstrated 52 % to 69 % compliance with the Dutch guidelines in the laparoscopic cholecystectomy. They argue that procedure specific guideline and proformas should be established to improve the quality of operative notes and improve patient safety.

Morgan *et al.* (2009) ⁵⁶ conducted a prospective review of the operative notes of patients undergoing the total knee replacement and compared to the BOA guidelines. They noticed marked improvement in the operative notes details when using the BOA guidelines, except for the poor documentation of the operative findings. In addition, Parth *et al.* (2016) ⁵⁷ review the operative notes against standards set by the RCSE and BOA guidelines, they noticed improvement from about 69 % to 93 % in patient undergoing joint arthroplasty procedure after introduction of procedure-specific proforma, however, there was minimal improvement in orthopaedic trauma.

There is no consensus among the medical council and health authority on the basic standard requirements of the operative notes documentation in different specialities. There are several operative notes guidelines published in the literature, but the most widely used are the RCSE guidelines.

In this study, the RCSE 2008 operative notes guidelines as shown in Table 2.2 will be used to conduct an audit of the orthopaedic surgery operative notes. Additional parameter, as shown in Table 2.3, will be included in the audit.

Table 2.2: The operation notes standard criteria set by the RCSE 2008

RCSE 2008
Patient name
Date of birth
Hospital number
Date of operation
Time of operation
Elective/emergency procedure
Name of the operating surgeon
Name of the operating assistant
Name of the operation
The incision/approach
Operative findings/diagnosis
Intraoperative complications
Any extra procedures performed and the reason why it was performed
Details of the tissue removed, added or altered
Identification of any prosthesis used, including serial numbers and other implanted materials
Details of closure technique
Post-operative care instructions
Signature of surgeon

Table 2.3: Additional parameters that are not included in the RCSE 2008 guidelines

Age and gender
ICD -10 coding
Indication for operation
Prophylactic antibiotics
Preparation: position, skin cleansing solution
Type of irrigation
Tourniquet time
Estimated blood loss
Legibility
Informed consent obtained and signed by:

2.3. Conclusion:

Health authorities and or statutory and legal bodies around the encourages health care practitioners to maintain a clear, objective, contemporaneous, tamper-proof and original health records. Operative notes have been found to be essential in the management of patients and /or continuity of care, medical billing, research and education, and medicolegal claims.

Despite multiples studies published in the literature with regards to the operative notes, there is still no acceptable standard and / or consensus on the adequate and or complete surgical operative notes. There are several operative notes guidelines published in the literature, but the most widely used are the RCSE guidelines.

Incomplete surgery operative notes have been found to be associated with delay in reimbursement and / or rejection of the medical claims billing, leading to poor financial outcomes.

The use of electronic typed surgery operative notes has been shown to improve accuracy and legibility of the operation notes compared to the hand-written operation notes. Therefore, the use of a proformas or template either electronic or hard copy, compliance audit and training in previously published studies have been shown, to decrease inaccuracies, provide clear, legible and comprehensive operative notes and improve communication among healthcare providers and other services providers.

However, controversy still exists whether health care professionals training or education improves documentation of the surgical operation notes. Recently, the use of procedure specific procedures proformas or template have been shown to improve operation notes documentation.

Chapter 3: Research Aim and Methodology

3.1. Introduction

This chapter will provide a brief overview of Chris Hani Baragwanath Academic Hospital and the Orthopaedic surgery department. In addition, the methodological approach used to carry out the current study will be presented.

3.2. Background

Chris Hani Baragwanath Academic Hospital is the third largest hospital in the world, with at least 3200 beds. The hospital is located in Soweto, Johannesburg, South Africa. It is one of the 40 Gauteng provincial hospitals, and financed and run by the Gauteng Provincial Health Authorities. It is a teaching/academic hospital for the University of the Witwatersrand's Medical School, along with Charlotte Maxeke Johannesburg Academic Hospital, Helen Joseph Hospital and Rahima Moosa Mother and Child Hospital. It serves the community of Soweto and is a referral hospital for other areas of South Africa and Southern Africa.⁵⁸

The Department of Orthopaedic Surgery at Chris Hani Baragwanath Academic Hospital comprises an adults' unit with different subspecialties and a paediatric unit. The hospital provides a 24-hour theatre services for orthopaedic surgery trauma injuries and acute musculoskeletal infections with the full support of an anaesthetic department, intensive care unit and general trauma surgery.

Orthopaedic elective surgeries are mainly conducted by the consultants and registrars under the supervision of the consultants during normal working hours (7 am to 4 pm), whereas emergency surgeries are usually performed by the registrars with the supervision of a consultant at any time during the day.

3.3 Research Aim and Objectives

The aim of the study was to assess the completeness of operation notes with regards to the guidelines of the RCSE 2008 in patients who have undergone orthopaedic surgery at Chris Hani Baragwanath Academic Hospital. The research objectives were as follows:

- Evaluate the completeness of operative notes with respect to the RCSE 2008 guidelines
- Determine the essential information that was omitted from operation notes

3.4. Study design

The study was a retrospective, descriptive observational audit conducted by reviewing clinical/health records/patient information of Orthopaedic surgery operation notes with respect to the RCSE 2008 guidelines, and additional features that are not included in the RCSE 2008 guidelines. Each patient health record was given a unique study number, and patient confidentiality was maintained at all times. The extracted information was recorded on a data collection sheet (see appendix B, D, and E). Informed consent was not needed from the patient, the study was a retrospective review of already collected data, and no patient consultation or contact was required.

3.5. Study population

The study was conducted at Chris Hani Baragwanath Academic Hospital located in, Johannesburg, Gauteng province, South Africa, over a period of four months (01 August 2013 to 30 November 2013). The study population included adult and paediatric patients who were admitted to the hospital's orthopaedic unit and had orthopaedic surgery.

3.6. Sample size

Since the aim of this study was to report descriptive percentages, a sample size estimation calculation was used to determine the sample size required for the study. The calculation was based on the reporting of a 50 % proportion (worst -case) with 5 % precision, at the 95 % confidence level. This study required a sample size of 384 patient files. A sample size of 400 patient files was chosen for the study.

Sample size for proportions was determined using the following formula.⁵⁹

$$n = \frac{Z^2 P(1 - P)}{d^2}$$

where n = sample size,

Z = Z-statistic for the chosen level of confidence,

P = expected prevalence or proportion

d = precision

3.7. Inclusion criteria

The inclusion criteria for this study:

- orthopaedic patients requiring surgery (elective and emergency surgery)

3.8. Exclusion criteria

The exclusion criteria for this study:

- patients who sustained polytrauma/multiple trauma injuries and were not fit for surgical procedures or needed intensive care services before surgery
- patients who required manipulation under anaesthesia without hardware insertion
- repeat surgical procedure during the same hospitalisation period
- intra-articular /intra-tendinous injections, and /or caudal or epidural injections
- procedures without implant fixation
- patients operated on by the primary investigator
- health records of patients participating in clinical trials
- pending medico-legal review health records were also excluded

3.9. Data collection

The demographic details of the patient who had an Orthopaedic surgery procedure done between 01 August 2013 and 30 November 2013 were extracted from the theatre registry. Every hospital number from the theatre registry was considered, and the corresponding name and surname were retrieved from the hospital records department.

Health records of the selected patients were requested from the hospital storage department. The information extracted were recorded in the data collection sheet as per the RCSE 2008 guidelines and the information deemed necessary was included (see appendix B and C). The information collected was divided into the following categories: demographic characteristic, preoperative assessment, operative procedure and post-operative details (see appendix D). All the operation notes were reviewed by a single reviewer. The presence or absence of each feature was entered into a Microsoft Excel 2010 spreadsheet in preparation for further analysis.

Opinions about the legibility of the operative notes were sought from the orthopaedic nursing staff and ward clerk. A legibility assessment was done using the Likert scale similar to previous studies done by Payne *et al.* (2011)³⁶ and Albaraak *et al.* (2014)⁶⁰. The degree of legibility was categorised as follows: easily readable, partially illegible, and totally illegible.

3.10. Ethical considerations

The study was approved unconditionally by the Human Research Ethics Committee(Medical), Faculty of Health Services, University of the Witwatersrand, Clearance certificate no. M 140135. (see appendix A)

No informed consent was required from the patient. All the data collected were stored in a pass-word protected computer.

3.11. Data analysis

To analyse the completeness of the Orthopaedic surgery operative notes compared to the RCSE 2008 operative notes guidelines, a database was created using the Microsoft Excel 2010. The information contained in the RCSE operative notes guidelines was coded in binary fashion: 1 (present), 0 (absent), or non-applicable (N/A). the percentage of present codes for each variable and the mean value of percentages from the reports were calculated. The data was analysed descriptively by frequency and percentage tabulation, and is illustrated using bar charts. Data analysis were carried out using STATISTICA version 12

The outcomes measures were assessed by reviewing the number of criteria matching the RCSE 2008 operative notes guidelines. The number of parameters missing from the 18 set standards guidelines were recorded as follows: 1 – 4 items, 5 – 9 items, and 10 or more items.

Chapter 4. Results

4.1. Introduction

In this chapter the results obtained for each objective are presented as shown on the flow diagram showing selection of patients files for the study (see Figure 4.1). The results are based on general observation, followed by the specific findings in the different categories.

According to the data compiled monthly from the hospital theatre registry and the data presented daily during a morbidity and mortality meetings in the Orthopaedic surgery department, a total of 4329 patients (average of 366.3 per month) had an orthopaedic surgical procedure done (see Table 4.1). The procedures done were both elective and emergency orthopaedic surgery at Chris Hani Baragwanath Academic Hospital during the year 2013. Elective surgeries were done between mid-January and mid-December, whereas emergency surgeries were done on a 24-hour basis from January to December. The data for this study was extracted from a total of 1086 patients (see Table 4.2) i.e. an average of 90.5 patients per month had orthopaedic surgery during the study period, (25 % of all procedures done).

Table 4.1: Orthopaedic theatre cases done per speciality January to December 2013
(n= 4396)

Discipline	Total
Orthopaedic trauma – upper and lower limb units	974
Paediatrics includes trauma	1012
Arthroplasty/Tumour and Sepsis	339
Hands	1696
Spine – paediatric and adults	188
Sports and General	187
	4396

Table 4.2: Total operations done during the study period (n=1086)

Discipline	Total
Orthopaedic trauma – upper and lower limb units	154
Paediatrics includes trauma	140
Arthroplasty/Tumour and Sepsis	112
Hands	576
Spine – paediatric and adults	46
Sports and General	58
	1086

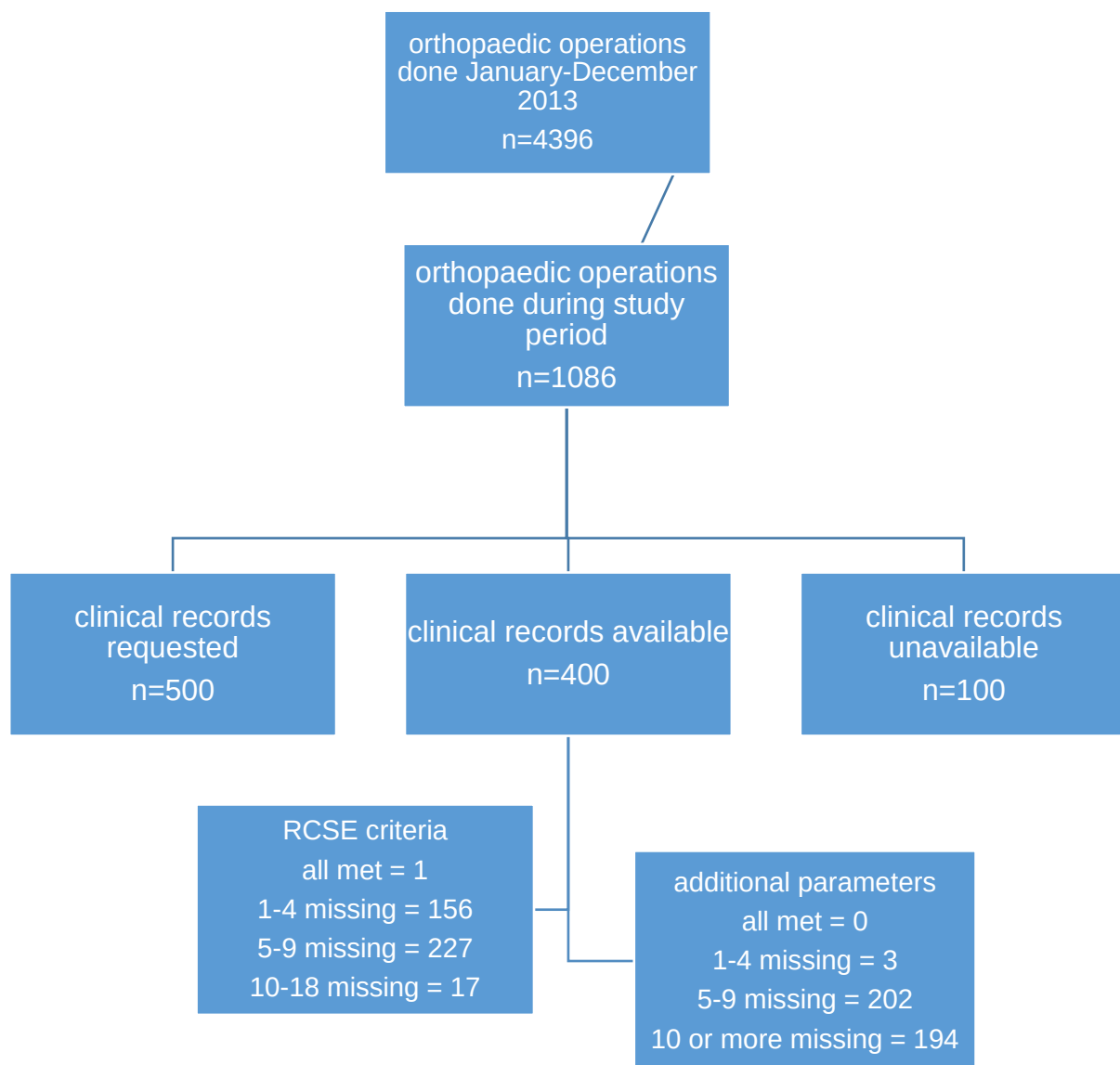


Figure 4.1: Flow diagram showing selection of patients' files for the study

The study revealed that 100 % of the Orthopaedic surgery operative notes at the study institution are written in the daily progress notes documentation sheet, there is no separate operative notes document. Demographic details documentation was collected from the theatre registry and compared to the health records.

All the operative notes in the study were hand written. There was no documentation of chronic illness or comorbid disease documented and the body mass index was not recorded. None of the operative notes documented the use of intraoperative fluoroscopy and radiation dosage time used during the surgery.

None met all the set criteria of the additional parameters included for this study. Out of 400 health records, only 0.25 % of the operative notes reviewed included the data that met all the set RCSE 2008 guidelines, 25 % ($n=156$) of the operation notes were missing between 1 – 4 parameters, 56.8 % ($n=227$) were missing between 5 – 9 parameters, and 4.3 % ($n=17$) were missing between 10 – 18 parameters. The majority of the operative notes missing 1 – 4 parameters were written by the surgeon from the arthroplasty and sports and general unit.

Seventeen ($n=17$, 4.3 %) of the operative notes were written by the consultants. Most of them were from the Sports and General Orthopaedic unit. Furthermore, 93.3 % ($n=373$) of the operative notes were written by the registrar and medical officers. Thirty-three ($n=33$, 8.3 %) illegible operative notes were written by the same group of four surgeons. The signature was missing in 2 % ($n=8$) of the informed consent forms, and operative notes were completely missing in 1.8 % ($n=7$) of the health records.

With regards to the additional parameters, 0.8 % ($n=3$) were missing 1 -4 parameters, 51 % ($n= 202$) were missing 5 – 9 parameters and 49 % ($n= 194$) missing 10 or more parameters.

4.2. Demographic details

It was found that 45.5 % of the patients were adult females, 34.0 % were adult males and 20.5 % were children which included both trauma-related injuries and non-traumatic conditions as shown in Figure 4.2. The mean age of the patients reviewed was 39.25 years, standard deviation of 20.93 years shown in Figure 4.3.

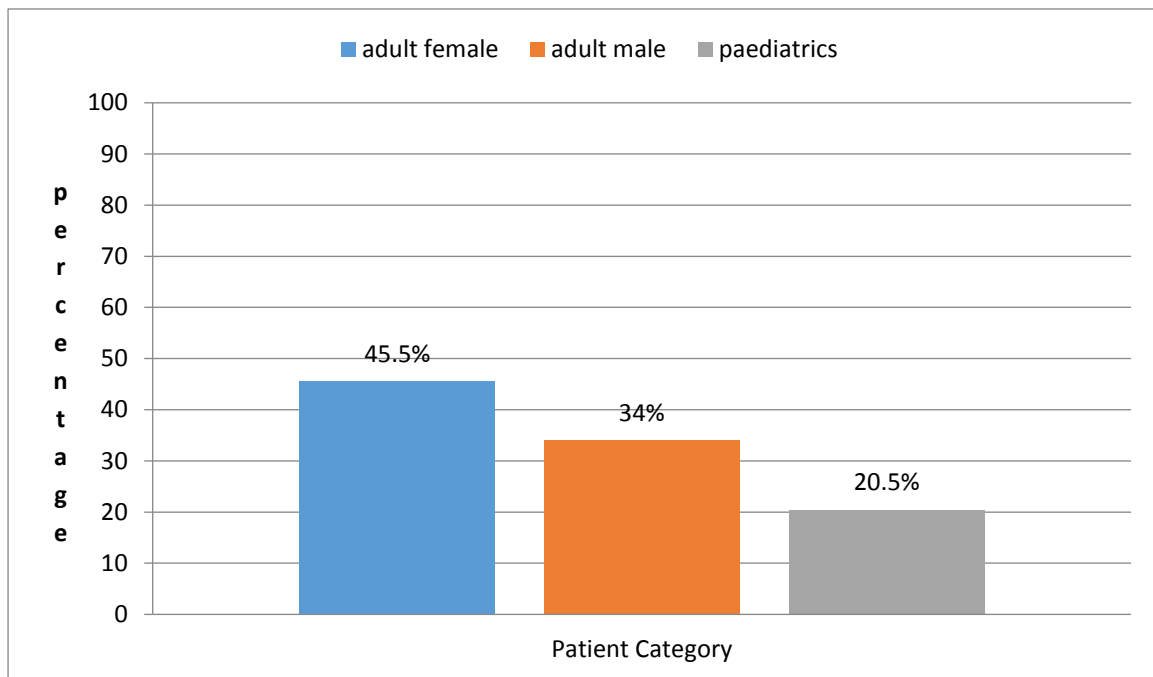


Figure 4.2: Patient category distribution (n=400)

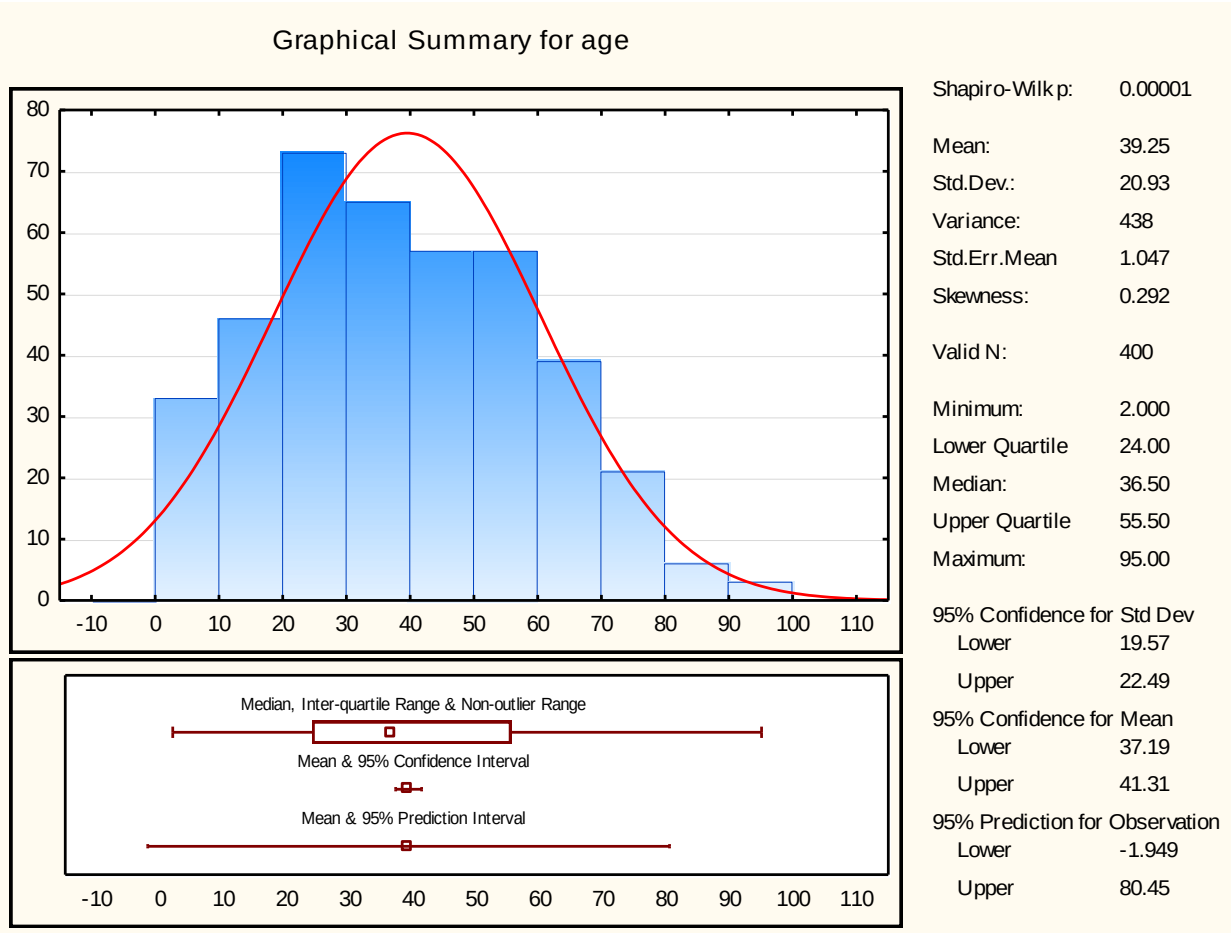


Figure 4.3: Patient age distribution

Patients were divided into six orthopaedic subspecialties (see Figure 4.4). Trauma orthopaedics (excluding paediatric orthopaedic trauma) represented the largest group reviewed with 22.3 %, and paediatric orthopaedics including both traumatic and non-traumatic conditions e.g. neuromuscular conditions represented 20.5 % of the cases reviewed. Arthroplasty, tumours and infections had 19.3 % clinical records reviewed. The Sports and General orthopaedics unit which is comprised of shoulder, knee, foot and ankle had 15.0% of health records reviewed. The Hands unit (comprised of the hand and wrist, excludes upper limb trauma) and Spine unit had 14.8% and 8.3 % of records reviewed, respectively.

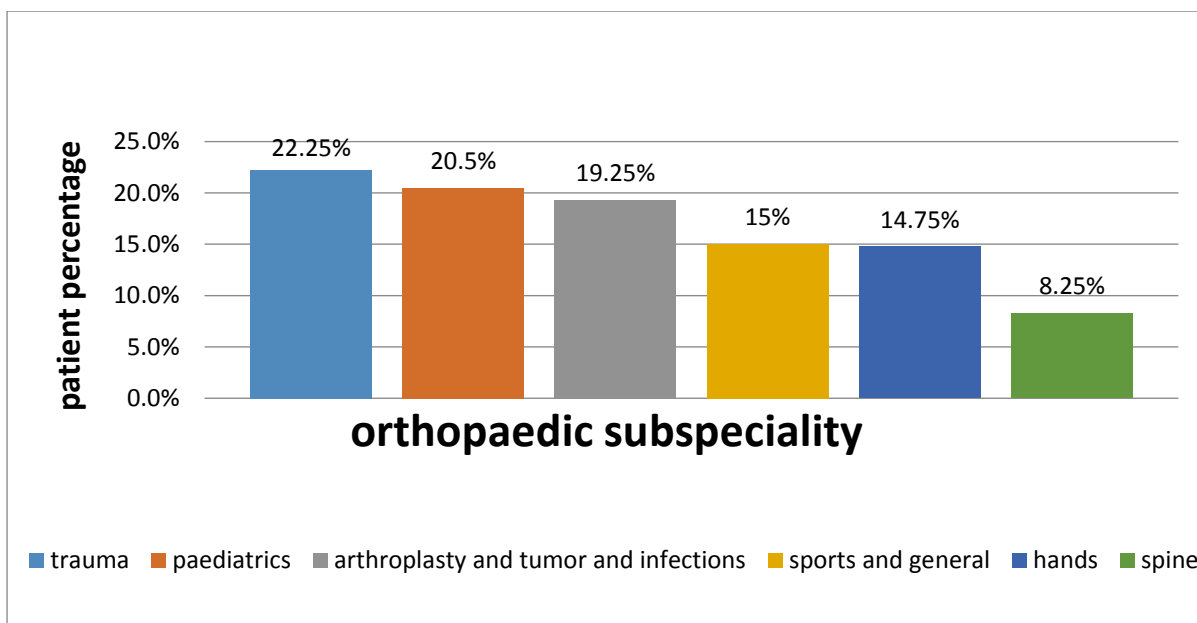


Figure 4.4: Total patients per orthopaedic subspecialty(n=400)

The findings reported here may not reflect adequate compliance by the surgeons as details are usually recorded by the nursing sisters during their checklist in the template stamp and theatre registry.

Table 4.3: Patient demographics percentage

Parameter	Percentage complete
Patient name	400 (100%)
Date of birth	400 (100%)
Hospital number	400 (100%)
Date of operation	394 (98.75%)
Time of operation	365 (91.25%)

The results of the study are demonstrated in Figures 4.5 and 4.6 in comparison with the RCSE guidelines and additional parameters.

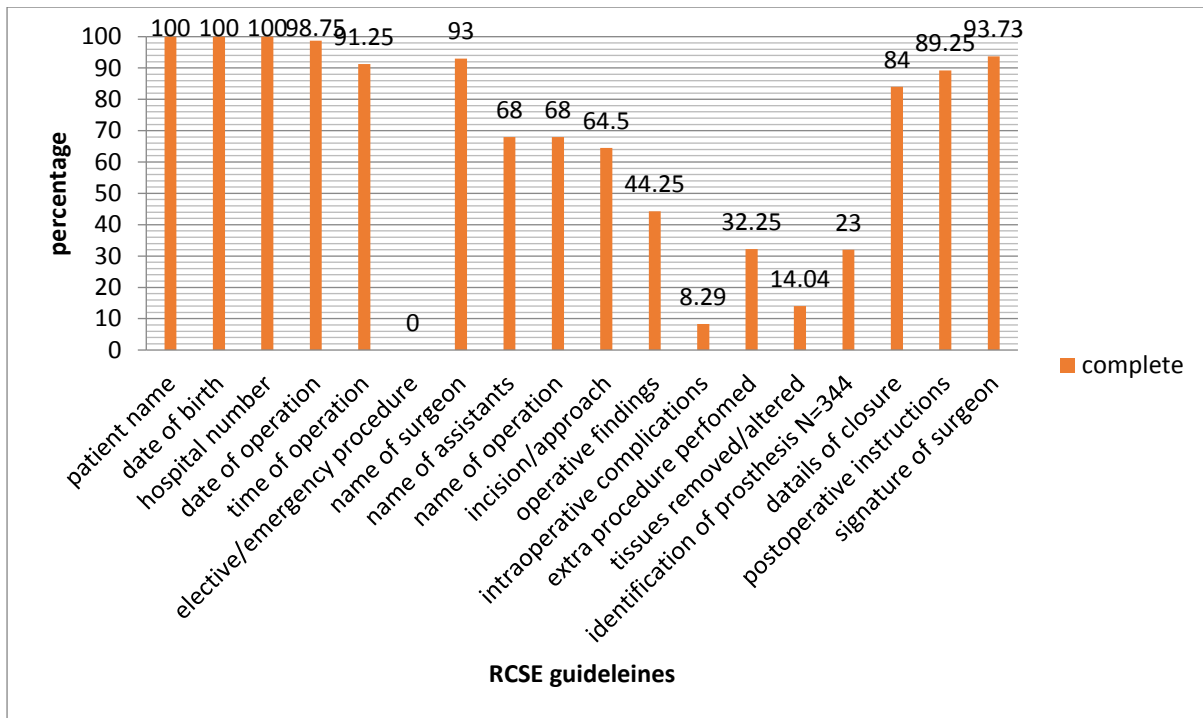


Figure 4.5: Percentage of complete RCSE guidelines

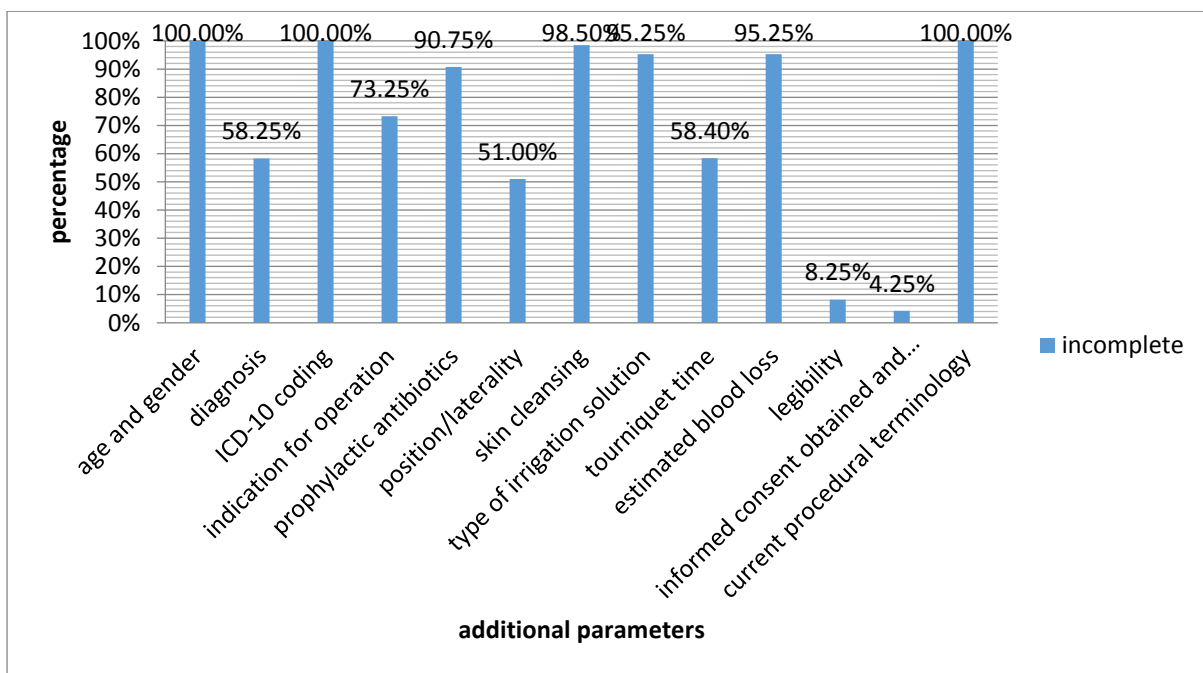


Figure 4.6: Percentage of incomplete additional parameters

4.3. Preoperative details

Preoperative parameters evaluated are demonstrated in Figure 4.7. A diagnosis was written in 55.75% of the operative notes reviewed and none were changed and/or classified based on the intraoperative finding. The study found good documentation of the name of the operating surgeon in 93% of cases, with 23.5% of cases done without an assistant and with no reason given.

The study shows poor reporting on the ICD-10 coding in 99.8 % of the operative notes reviewed. Operations were indicated in 73.3 % of the health records, whereas in 99.8 % of the health records, there was no indication of the type of surgery done, whether emergency or elective.

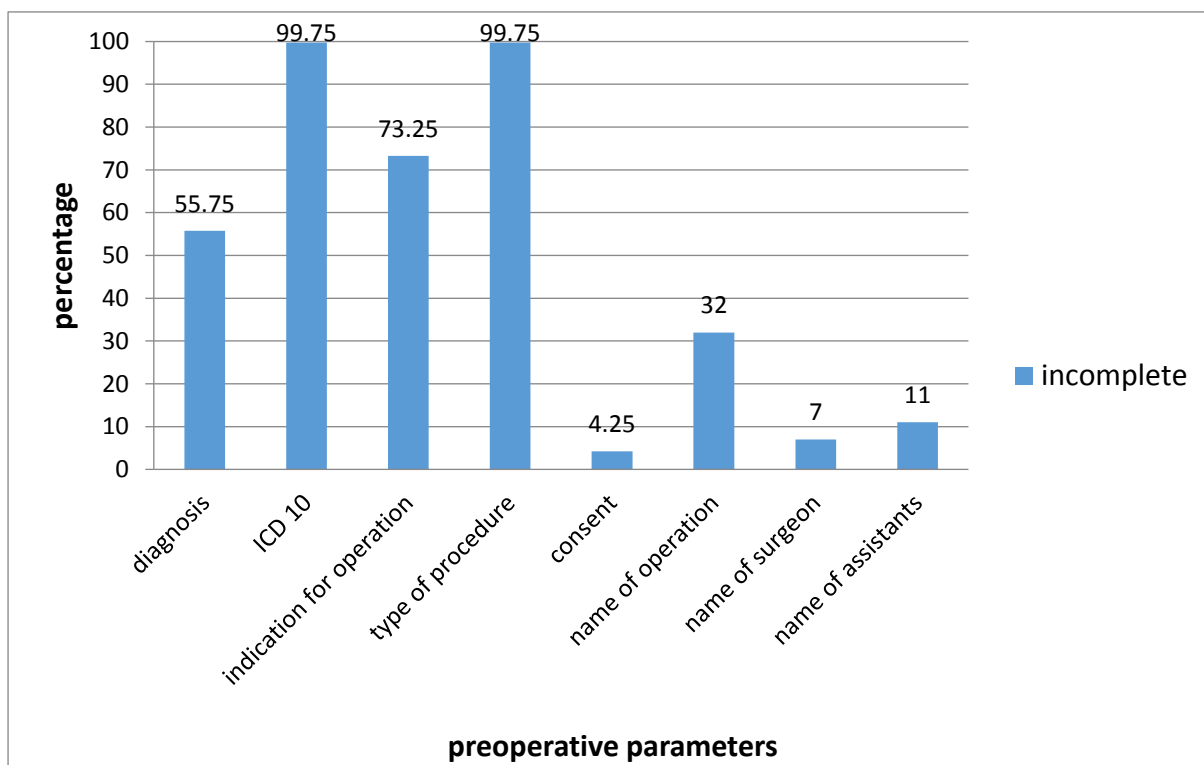


Figure 4.7: Preoperative assessments

Consent forms were completed in 95.8 % of the operations, but it was noted that 78.8 % were obtained by non-operating doctors e.g. interns or medical officers not

involved in the operation (see Figure 4.8). Only 17 % of the consent forms were obtained by the operating or assistant surgeon.

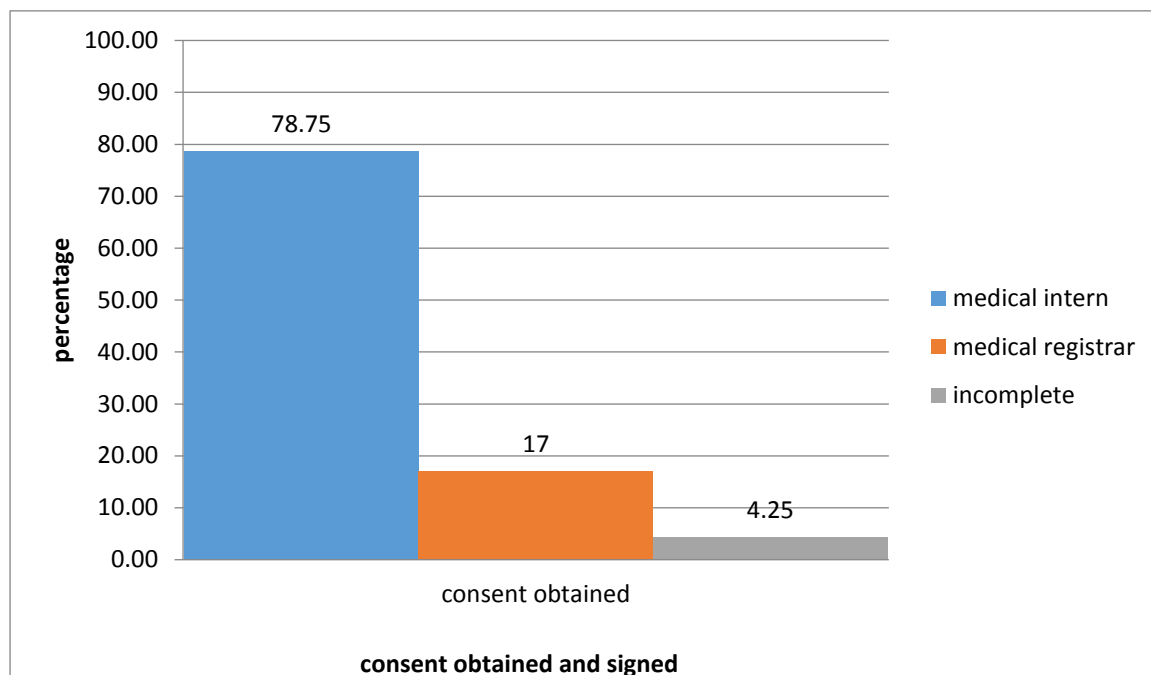


Figure 4.8: Informed consent documentation

Preoperative documentation of a diagnosis was not changed from the initial diagnosis. This seems to be left to the wards clerk or administrator. Up to 99.8 % of the operations were not documented as elective or emergency. This could only be deduced from the date and time of the operation, the theatre used, the orthopaedic surgeons involved and the type of operation done.

Thirty-two percent (32 %) of operations were inadequately documented with regards to what was done on the patient. The names of the surgeon and the surgeon's assistants were completely recorded in 93 % and 68 % of the cases done; and in 23.5 % of the cases, the surgeon assistant(s) were not used (see Figure 4.7).

4.4. Operative details

Table 4.4: Operative procedures

Parameters	Percentage complete
Preparation	
Position/laterality	196 (49%)
Skin cleansing	6 (1.5%)
Prophylactic antibiotics	37 (9.25%)
Tourniquet $n = 262$	109 (41.6%)
Incision/approach	258 (64.5%)
Operation findings	177 (44.25%)
Intraoperative complications	33 (8.29%)
Extra procedure performed and why	129 (32.25%)
Details of tissues removed/altered	56 (14.04%)
Type of irrigation solution	19 (4.75%)
Identification of prosthesis used $n = 356$	84 (23%)
Details of closure technique	336 (84%)
Estimated blood loss	19 (4.51%)
Signature	374 (93.73%)
Legibility of written notes	367 (91.75%)

The tourniquet was used in 261/400 cases of which 71 % were incompletely and inadequately recorded with regards to the duration and amount of pressure applied, as well as whether the tourniquet was deflated and inflated during the surgical procedure.

An overall intraoperative complication rate of 8.3 % was documented. The major concern was the implants documentation that was reported in 32 % of the cases. Most orthopaedic procedures are associated with major blood loss either from soft tissue damage or intramedullary bleeding from the bone during the surgical procedure. Blood loss was estimated in 19 (4.5 %) clinical records and there was no report of blood loss in 381 (95.5 %) health records.

All the notes reviewed were hand-written, of these notes, 91.7 % were easily readable with 8.3 % being poorly visible, and these were compared with details documented in the theatre registry for accuracy and completeness. Up to 93.7 % of the clinical records or notes reviewed had a visible signature of the surgeon or the surgeon's assistant/s.

4.5. Postoperative details

Table 4.5: Postoperative details

Parameters	Percentage complete
Postoperative instructions	357 (89.25%)
Postoperative ward round	59 (14.75%)

A post-operative instruction was well documented in 89.3 % of the clinical records or cases, but of concern was a post-operative ward round which was done in only 14.8 % of the health records (see Table 4.5).

Chapter 5. Discussion

5.1. Introduction

In this chapter, the findings obtained from this study will be discussed in relation to the objectives. Firstly, a general observation of the results will be discussed followed by an in-depth discussion of the following result categories: demographics, pre-operative details, intraoperative details and post-operative details. Lastly, considerations for improving operative notes documentation and recommendations based on the objectives, literature review and findings of this study will be discussed.

5.2. Demographics

The results of this study were collected from 25% of all patients who had orthopaedic surgical procedures performed during the year 2013. These results were based on the data collected from the theatre registry and daily statistics presented to the Orthopaedic surgery department.

The Hands unit had the highest number of patients operated on due to the theatre availability and the largest number of patients seen in the Orthopaedic surgery department. However, few clinical records were available for review as much of operative notes are written in the out-patient files to allow for easier follow-up.

The number of patients operated on depends on the number of theatres available per unit; however, based on mortality and morbidity statistics, some of the reported challenges that might have affected total numbers include fluoroscopy availability, and the availability of equipment such as power tools (drills), and sterile draping towels (linen)lines.

Better compliance was noted in the operative notes written by the Sports and General, and Arthroplasty units and may be due to the availability of consultants throughout the procedures, the number of senior consultants in the unit, low patient volume and the fact that they are mainly involved in elective procedures.

All operative notes reviewed for this study were hand written. Up to 91.75% of the operative notes reviewed were legible; of note was that 8.25% illegible notes were written by the same group of registrars. Lefter et al. (2008) ²⁴ found that hand written notes proved to be non-defensible in a potential complaint in court. Barrit et al. (2010) ³⁹ showed improvements in the adherence to the RCSE parameters and legibility using computerised proforma compared to the handwritten notes. Abbas et al. (2016) ⁴⁴ reported that legibility improved up to 100% with the use of procedure-specific operation notes proformas. The RCSE¹⁴ 2014 operative notes guidelines recommends that operative notes be typed to reduce legibility concerns raised with handwritten notes as shown by some studies. ^{25,29,30} A study by the SARCO group has also found that typed operative notes improves the recording of intraoperative data and the quality of notes keeping ⁵³.

Only 4.25% of the operation notes were written by the consultants. Previous studies also reported that the majority of the operation notes are written by registrars and medical officers, raising concerns about the quality of supervision by seniors and possible financial or reimbursement loss due to poor quality and inadequate operative reports. ^{18, 24,27,31,45} Operative notes written by the consultants had more details compared to the operative notes written by the registrars and medical officer, which then highlights the importance of operative notes documentation teaching by the consultants.

The patient's name, date of birth and hospital number were collected from the theatre registry, due to lack of specific operative notes documentation these were excluded from the detailed analysis and discussion. The study reports good documentation of the date and time of the procedure which was well recorded on the beginning of each page where the notes were written. However, there was no information documented on the start and end times of surgical procedure. This was similar to a study by Kawu et al. (2011) findings ³¹ and several other studies which raised a concern about poor documentation of the time and date of surgery. ^{28,32,33,50}

5.3. Preoperative details

The surgeon has control over several factors within the operating room that may decrease morbidity and overall mortality while improving patient safety and satisfaction. Intraoperative considerations include use of the WHO safety checklist ⁶, control over sterile operative and facility environments, perioperative prophylactic antibiotics and wound management.

A diagnosis was missing in 55.75% of the clinical records and there was no change between the pre- and post-operative diagnosis. Shayah *et al.* (2007) ³³ also reported poor documentation of a diagnosis without the use of aides-memoire and training, with similar studies supporting these findings. ^{30,31,50} No operative notes indicated comorbid disease. The findings reflect poor preoperative assessment of the patients despite overwhelming evidence showing that comorbidities, such as cardiovascular disease, chronic anaemia, rheumatoid arthritis, and chronic immunosuppression, etc have demonstrated increased rates of infections. ⁶⁰⁻⁶²

The study found poor reporting of the ICD-10 coding (about 99.75%) suggesting that the recording of a diagnostic codes on discharge is assigned to the ward clerk. None of the clinical records had Current Procedural Terminology (CPT) indicated and this may be due to the fact that this is done in the billing office. Documentation of the operative notes needs to correspond to the ICD-10 coding and CPT to avoid a delay in the payment of claims, and to avoid a medical negligence lawsuit. ¹ Novitsky *et al.* (2005) ¹⁹ found that 28% of incorrect CPT coding by residents was likely to lead to a 9.7% reimbursement loss. Similarly, Britton *et al.* (2009) ²³ found that coding done by certified professional coders was missing modifiers compared to coding done by consultants, this lead to a loss of revenue if certified professional coders were used. In contrast, Arthur and Nair (2004) ²² found that coding clerks were better at coding than surgeons. Clinical coding is the process by which details on patients' medical conditions, events, procedures, morbidities and complications during treatment are extracted and translated from clinical terminology to an internationally recognised codified language. The Centre for Medicare and Medicaid Services(CMS), the largest health care payer in the United States, exacts monetary penalties for coding fraud under the Health Insurance Privacy and Accountability Act of 1996. ⁶³ Illegitimate diagnosis and procedure coding leads to less compensation for the professional

services the surgeon provides and/or delays in payment while errors are corrected and/or disputes are resolved. ²¹

However, Jones et al. (2008) ⁶⁴ demonstrated improvement in coding through resident instruction with subsequent better record keeping and ultimately the accuracy of claims data suggesting that improving coding accuracy should start upstream where residents and mid-level providers first document clinical information, providing clear and complete language for coders to translate.

Any indication for an operation was incomplete in 73.25% of the clinical records reviewed. Flynn and Allen (2004) ¹⁸ also found that an indication for an operation was one of the commonest pieces of missing information that is required for the reimbursement or delay in a claims payment.

The type of surgical procedure (elective or emergency) was not indicated in 99.75% of the cases, but this can only be deduced from the procedure type, time, theatre registry and surgeon involved. Shayah et al. (2007) ³³, using aides-memoire, and Ali et al. (2015) ²⁸ also reported poor documentation of the type of operation ²⁶. Similarly, a study in Saudi Arabia demonstrated that only 4.7% of the type of procedure was documented despite teaching of the residents ⁵⁰.

However, Singh et al. (2012) ³⁷ showed improvement in documentation of the type of surgical procedure after the introduction of aide-mémoire and surgeon education. Separating elective surgery from emergency surgery could achieve a more predictable workflow, provide excellent training opportunities, increase senior supervision of complex/emergency cases, and could therefore improve the quality of care delivered to patients. ⁶⁵ Many emergency orthopaedic trauma procedures are not performed by a member of the team looking after the patient, therefore operation notes need to be legible and concise with clear post-operative instructions to improve patient continuity of care.

In the current study, consent was well documented in most cases, but of concern was that 78.75% of consent was obtained by the medical intern. This finding is similar to the study by Singh and Mayahi (2004)⁶⁷ where 53% of consent was obtained by a junior doctor in both elective and emergency surgery.

The consenting doctor needs to be aware of the medical and legal responsibilities in taking informed consent. Junior doctors with inadequate orthopaedic experience will not be able to answer specific questions from patients regarding the technicalities of the procedure, the risks and rehabilitation plans. Inadequate informed consent potentially undermines the validity of consent.

The process of obtaining informed consent for surgery includes the following: an introduction and description of the surgeon's role in management, to inform the patient of their pathology and likely disease progression, to inform the patient of the various management options that are available, to make the patient aware of the potential risks and benefits of the procedure and to explain to the patient their right to refuse the operation or seek a second opinion.^{1, 68} If the procedure is being performed in the private medical sector, the cost of any procedure must also be discussed as should any potential conflict of interest which may impact patient care.⁶⁸ With the growing litigious culture in orthopaedic surgery, insufficient consent is a common source of legal complaints.⁶⁹

The right to an informed consent flows from the South African Constitution, the National Health Act, various other statutes, the common law and the HPCSA Guidelines. Health care practitioners are expected to be aware of the law in this regard. The law prescribes the minimum requirements when seeking informed consent from patients.¹ Bhattacharyya *et al.* (2005)⁷⁰ conducted a closed claims analysis on malpractice claims involving an allegation of inadequate informed consent in elective orthopaedic procedures. They found that simple measures such as documentation of consent in patient notes was associated with a decreased indemnity risk and obtaining consent at clinic visit could significantly decrease the risk of malpractice while failure to perform proper and valid consent could also leave the patient confused and apprehensive about their procedure.⁷⁰

The name of the operation and assistants were completed in 68% of the cases. This is similar to the study by Johari *et al.* (2013) ⁵⁰ as they reported that 58.8% of the operative notes had the name of procedure recorded and 52.9% had the name of assistants. Their recordings improved after residents' education and training. Similar improvements were reported by Oladipo *et al.* (2011) ⁴⁰ with the use of standardised operation notes proformas.

In this study, the name of the surgeon was completed correctly in 93% of the cases. Sweed *et al.* (2014) ²⁹ and Shayah *et al.* (2007) ³³ also reported good documentation of 98% and 82% of surgeon and surgeon assistant's names, respectively. Others have shown that the use of procedure specific proformas and surgeon education led to good documentation. ^{26, 37, 44, 55}

5.4. Intraoperative details

Patient position/laterality was missing in 51% of the cases, similar to the findings in a study by SARCO ⁵³. Proper positioning of orthopaedic patients on the operating table is important to provide adequate exposure and minimise risk of perioperative complications. Each position can expose various nerves to the potential for injury, and it is important to be aware of them while positioning the patient as the consequences of improper positioning includes potential malpractice litigation. ^{24, 71, 72}

Skin /surgical site cleansing preparation was poorly documented in 98.5% of the cases. Barrit *et al.* (2010) ³⁹ also reported poor documentation of skin preparation and draping in handwritten notes which improved with the introduction of the computerised RCSE proformas. This is consistent with several studies which show that there is no preferred agent with regards to optimal skin preparation solution to prevent infection and superiority of one agent over the other. ⁷³

Prophylactic antibiotics play a crucial role in the prevention of sepsis in orthopaedic surgery ^{74,75}, but only 9.25% of the cases included in this study had notes documenting that this medication was given. The findings were similar to those of other studies. ^{31, 39, 53} Surprisingly, the majority of the notes did not indicate the dosage used, whether antibiotics were repeated for prolonged surgery (more than 2.5 hours) or in patients

with severe intraoperative blood loss, and there was inconsistency with regards to the antibiotic group used. The use of prophylactic antibiotics in orthopaedic operations is an accepted practice and has been shown to decrease the likelihood of serious morbidity associated with postoperative infection.⁷⁶⁻⁷⁸ Reported surgical site infection after orthopaedic surgery ranges from 0.7% to 22.7% and affects long-term clinical outcomes and subsequent has a substantial impact on health-related quality of life.⁷⁹⁻⁸²

Tourniquet usage in this study was documented as incomplete or missing in 58.4% of the cases. A similar study conducted by Sweed et al. (2014)²⁹ demonstrated similar deficient areas of operative note documentation, in particular the poor documentation of tourniquet time. Other studies also reported poor documentation of tourniquet time and pressure.^{24,27,29} Tourniquet has been used for centuries by surgeons to improve surgical field visibility and reduce blood loss during surgery.⁸¹⁻⁸⁵ In this study, 65.5% of the procedures required tourniquet use, with poor compliance in 58.4% with regards to tourniquet pressure and duration of application. Proposed advantages of tourniquet use include minimising the amount of both intra-operative and post-operative blood loss, producing an intra-operative 'bloodless' visual field, improving the cement-bone inter-digitation and reducing the operation time.⁸⁵⁻⁸⁷ The theoretical disadvantages of tourniquet application include an increased risk of nerve palsy, vascular injury, muscle damage, postoperative swelling and stiffness.^{83, 88-90}

Incision type and /or surgical approach used were documented in 64.5% of the cases. Similarly, Kawu et al. (2011)³¹ reported that incision type was mentioned in 60.8% of the cases^{24,25, 26} and resulted in up to 100% improvement when using procedure specific proformas.⁴⁴ However, others have shown poor documentation of the incision type or surgical approach used.³² Surgical approaches in orthopaedic surgery have been contentious for many years and reported to affect the clinical outcomes, documentation of the surgical approach used in orthopaedic surgery should be emphasised at all times. Vital anatomical structures encountered and complexity of the surgery will be missed if the surgical approach is not documented and lead to difficulty assessing the clinical outcomes and in case of medical negligence lawsuit, it

will be difficult to defend the case if adequate documentation of the anatomical structures encountered and complexity of the surgery is not reported.

Operation findings were missing in 55.75% of the cases included in this study. In a study by the SARCO, it was found that 80.1% of the cases lacked information on the operative findings.⁵³ Several studies also reported poor documentation of operative findings which improved dramatically with the introduction of aides-memoire and procedure specific proformas.^{24,30,32,33,35,44,54} However, Morgan et al. (2009)⁵⁵ reported an improvement from 56% to 67% despite surgeon education and use of a checklist. Similarly, Rodgers and Pleat (1994)⁹¹ reported poor compliance with the use of aides-memoire where some of the RCSE criteria did not apply. It should be emphasised that all parameters should be completed when using aides-memoire or computerised proformas.

Documentation of intraoperative complications was missing in 91.71% of the cases reviewed. This may be related to acts of omission or the fact that the operation was uneventful as shown by Kawu et al. (2011)³¹ who reported 2.5% intraoperative complications. Poor documentation has also been demonstrated by other studies.^{26,32,45,50} Orthopaedic complications documentation and/ or reporting must be emphasised as this is the surgeon own experience which help to identify risk factors for related to treatment failure, play an essential role in the quality control process to improve treatments.^{92, 93}

Extra procedures done, and reasons for the procedure, were missing in 67.75% of the cases reviewed, and details of the tissues removed or added were poorly documented with up to 85.96 % of the cases missing information. Similarly, these details have been poorly reported in other studies.^{26, 31, 32} However, the use of procedure specific proforma has shown good improvement in documentation of the tissue removed and extra procedures done.^{39, 44, 55}

The type of irrigation solution used was missing in 92.25% of the cases. The finding highlights an inconsistency in the literature with regards to acceptable irrigation solutions and techniques. The data on pulsatile lavage versus continuous lavage are

inconclusive, and there are no published or evidence based recommendations. ^{94, 95} Antibiotics appear to be the most commonly used additives in surgical irrigation fluids, despite a shortage of evidence supporting their usage and a growing body of evidence suggesting their usage can have deleterious consequences such as antibiotic resistance. Standardisation and evidence based recommendations regarding intraoperative irrigation must address irrigation solution type, volume, and the method of delivery.

Eighty-nine percent (89%, $n=356$) of the procedures done required the use of implants; however 77% of the cases were missing the identification of prosthesis used. Poor documentation of implant or prosthesis details is still a concern as shown by several studies. ^{24, 30, 53} Coughlan et al. (2015) ²⁷ reported 30% documentation of prosthesis details and argued that orthopaedic specific proforma might improve documentation. The deficiency in operative note documentation was also addressed by Goyal *et al.* (2012) ⁴³. They found that previous operative reports did not provide adequate information necessary for revision arthroplasty surgery and they also recommended standardised procedure specific operative note guidelines. ⁴⁴ Considering that all implants information is readily available during the surgical operation, there is no reason that the operative notes should be incomplete. Poor documentation of the prosthetic implants used reflects the surgeon ignorance or neglect on the importance of the surgical procedure performed and of importance on the quality of prosthetic implants and patient continuity of care principles.

Details of the closure technique were well documented in 84% of the cases, but there were no details of the suture types and few notes mentioned the use of drains. Several studies raised concerns about the insufficient details of closure techniques. ^{29, 31, 32, 53} However, others have shown that surgeon education and training and use of aides-memoire improved operative note reporting of closure techniques and sutures used. ^{26, 27, 50, 55}

Estimated blood loss documentation was missing in 95.49% of the cases reviewed. Zwintscher *et al.* (2012) ⁴⁵ reported up to 67.4% documentation of estimated blood

loss. Poor documentation was also reported in other studies, which improved after surgeon education and the introduction of procedure specific forms.^{40, 50}

Most operative notes had the surgeon or assistant's signature completed (93.73% of the cases). Lefter *et al.* (2014)²⁴ reported that 15.26% of the operative notes were handwritten, and as such proved to be non-defensible in court when combined with other missing parameters.

None of the operative notes documentation reported the use of fluoroscopy despite the high number of cases requiring its use. With a recent increase in the use of fluoroscopy, even in arthroplasty and due advanced surgical techniques such as minimal invasive surgery, surgeons need to be aware of the dangers of exposure to radiation to themselves, patient and the entire operating room theatre staff. Furthermore, protective clothing(gowns), a thyroid shield and eye wear should be used while limiting the duration of radiation exposure using as low as reasonably achievable (ALARA) principles.¹⁰¹

The amount of health risk from radiation is primarily dependent upon intraoperative radiation exposure time, radiation system used, cumulative career exposure, and the effectiveness of utilized protective measures.^{102,103} Giuseppe Mastrangelo *et al.*¹⁰² showed a cumulative career cancer incidence of 29 % in orthopaedic surgeons compared to 4 % in radiation unexposed healthcare workers.

5.5. Post-operative details

The study found that post-operative instructions were written in 89.25% of the cases. This was similar to the previous published study by Ghosh.³⁰ However, others have reported poor documentation.^{24, 28, 29, 40, 45, 50.}

There were poor post-operative ward rounds done, with 85.25% of the patients not seen. Ward rounds are generally poorly conducted in most hospitals around the world as reported in a multi-center study to evaluate the current surgical wards round practices in England which found that 45% were consultant-led compared with 67% weekend rounds, 44% of patients were seen with a nurse present. Recommendations

for daily consultant-led multi-disciplinary ward rounds are poorly implemented in surgical practice, and patients continue to be managed on outlying wards. However, an increasing political focus on patient outcomes at weekends ward rounds may prompt changes in these areas.⁹⁶ An audit of the documentation of post-acute consultant ward round (PACWR) after an introduction of a proforma (standard form) found a statistically significant improvement in the documentation of time and date (37% versus. 72%) and impression (40% versus. 61%) and this will help in avoiding adverse effects on patient care and medico-legal ramifications.⁹⁷

In an environment where there is an increase in medico-legal vulnerability of orthopaedic surgeons, but more importantly, for patient safety, it is imperative that we as a profession make it a paramount objective to achieve complete and correct documentation. It is the responsibility of the operating surgeon to ensure that the patient has received adequate information to provide informed consent. Furthermore, it is the responsibility of the surgeon to properly document preoperative and operative details, both positive or negative findings or minor or major findings.

There is no consensus among the medical council, surgical speciality, nor is there a perfect model that all health authorities, health care professionals and /or statutory bodies adopt on the basic standard requirements of the operative notes documentation in different specialities. Each speciality and/or subspecialty has to be treated differently. With increasing access to the internet and the introduction of electronic health records, health care practitioners have to be aware and comply with the Data protection act and the Protection of Personal Information (POPI) act of their respective countries to ensure that patient privacy and confidentiality is always maintained.

Basic guidelines for each discipline should be set before the introduction of procedure specific guidelines; additional operative notes proforma-standards for such as arthroscopic surgery should be similar to the basic standards. Therefore, based on the findings of the study, recommends the following in our institution to improve the operative notes documentations:

- Introduction of orthopaedic operative notes proforma – paper format or electronic and subsequent audit to ensure compliance

- Teaching of the new members of staff at regular intervals as per rotation schedules
- Regular audits per different subspecialty units, followed by an annual audit to see which unit maintains standards
- Add or attach WHO safety checklist ^{6,98} as shown to reduce surgical mishap
- Introduction of electronic health records when feasible and awareness of the requirements of the HPCSA Good Practice guidelines, National Health Act, Data Protection and POPI Act with regards to patients' records

5.6. Study limitations

The study had several limitations and these are listed below:

- A retrospective observational data study – to avoid selection bias, operative notes reviewed included all the clinical records with operative notes written by consultants, registrars and medical officers
- Clinical records with poor hand writing and incomplete details from theatre registry were also excluded.
- A single hospital was reviewed with different doctors rotating to the other academic hospitals.
- Anaesthetic charts were not reviewed as this sometimes contains more details with regards to prophylactic antibiotics, patient position and tourniquet usage where applicable.
- A pilot study would have provided more clear findings and compliance regarding the objectives of the study.
- Hawthorne effect might have played a role.
- Challenges with regards to clinical records and weekly statistics records: not all morbidity and mortality records were available for consolidation, a diagnosis in theatre records was absent, theatre registers were incomplete, entries were incorrect, and some cases were not recorded
- The experience level of registrar training or medical officers writing operative notes was not assessed to differentiate junior versus senior registrar or medical officer

Compared to previous studies published in the orthopaedic literature, this study covers a wide range of orthopaedic specialities. It is possible that some of the absent data points were omitted due to this information having already been present in the patient's notes or due to the surgeon not recording negative factors. Other absent data may have been considered trivial, such as exposure for superficial incisions.

Chapter 6: Conclusion

The findings of this study confirm poor documentation and a deficiency in the documentation of essential parameters in operative notes that is required for patient safety and continuity of care and highlights lack of consensus on what is required when completing operative notes document. Future research using the orthopaedic operative notes template and/or proformas is recommended to assess completeness of the operative notes documentation.

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Appendix A. Ethics clearance certificate


HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M140135

NAME: Dr NZ Chauke
(Principal Investigator)

DEPARTMENT: Department of Orthopaedic Surgery
CM Johannesburg Academic Hospital

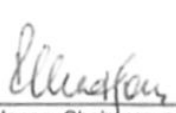
PROJECT TITLE: Audit of Orthopaedic Surgery Operation Notes
at Chris Hani Baragwanath Academic Hospital

DATE CONSIDERED: 31/01/2014

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Prof M Ramokgopa

APPROVED BY: 
Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 24/03/2014

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

DECLARATION OF INVESTIGATORS
To be completed in duplicate and ONE COPY returned to the Secretary in Room 10004, 10th floor, Senate House, University.
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 research protocol as approved, I/we undertake to resubmit the application to the Committee. I agree to submit

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

yearly progress report

Principal Investigator Signature

M140135Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix B: Data collection sheet

RCSE 2008 parameters	Present (1)	Absent (0)	Not applicable(N/A)
Patient name			
Date of birth			
Hospital number			
Date of operation			
Time of operation			
Elective/emergency procedure			
Name of the surgeon			
Name of the assistant			
Name of operation			
The incision			
Operative findings/diagnosis			
Intraoperative complications			
Any extra procedure performed and reason			
Details of tissue removed, added or altered			
Identification of prosthesis or materials used			
Details of closure technique			
Post-operative care instructions			
Signature of surgeon			

Appendix C: Additional parameters not included in the RCSE guidelines

	Present (1)	Absent (0)	Not applicable(N/A)
Age and gender			
ICD – coding			
Indication for operation			
Prophylactic antibiotics			
Preparation: position, skin cleaning solution			
Type of irrigation			
Tourniquet time			
Estimated blood loss			
Legibility			

Appendix D: Data collection categories

DEMOGRAPHICS	Present(1)	Absent(0)	Not applicable(N/A)
Patient name			
Date of birth			
Hospital number			
Date of operation			
Time of operation			
PREOPERATIVE			
Diagnosis			
ICD-10			
Indication for operation			
Type of procedure			
Consent			
Name of operation			
Name of surgeon			
Name of assistants			
OPERATIVE PROCEDURES			
Preparation Position/laterality Skin cleansing			
Prophylactic antibiotics			
Tourniquet			
Incision/approach			
Operation findings			
Intraoperative complications/difficulty			
Extra procedures performed			

Details of tissue altered			
Type of irrigation solution			
Identification of prosthesis			
Details of closure technique			
Estimated blood loss			
Signature			
Legibility			
POST-OPERATIVE			
Post-operative instructions			
Post-operative ward round			

Appendix E: Suggested Orthopaedic Operation notes form

Orthopaedic Surgery Operation Notes	
Patient name	Diagnosis:
Hospital number	Chronic or Comorbid disease:
Date of birth/age	Body mass index:
Gender: M/F	Anaesthetist
OR Patient sticker	Anaesthesia: GA/Regional/Local
	ASA grade:
Date:	Position: Supine/Prone/Lateral
Start time: End time:	
Surgeon:	Prophylactic antibiotics:
	Additional medications:
Assistant(s)	Tourniquet: Yes/No
	On: Off:
	Pressure:
Indications:	Fluoroscopy: Yes/No
Name of the operation(s):	Dose:
External factors code:	Type of surgery: Elective/Emergency
ICD – 10:	Skin preparations:
Procedure codes:	
Modifiers :	
Surgical approach(es) used:	
Description of the procedure:	

Intraoperative findings:
Intraoperative difficulty or complications:
Additional procedures and /or specimen:
Implants used or prosthesis identification:
Estimated blood loss(ml):
Wound closure techniques and /or drains:
Post-operative instructions:
Immediate post-operative assessment in the ward or intensive care:
Discharge instructions and Rehabilitations plans or follow-up:
Surgeon/assistants signature: