

https://dspace.org/

The process of informed consent for obstetric anaesthesia in the Department of Anaesthesia at the University of Witwatersrand, a descriptive cross-sectional study

Senyahale, Wazha Andrew

2025

University of the Witwatersrand, Johannesburg

https://hdl.handle.net/10539/49710

Senyahale, Wazha Andrew . (2025). The process of informed consent for obstetric anaesthesia in the Department of Anaesthesia at the University of Witwatersrand, a descriptive cross- sectional study[Master's dissertation, University of the Witwatersrand, Johannesburg]. WIReDSpace. https://hdl.handle.net/10539/49710

Downloaded from a DSpace repository. https://dspace.org/

The process of informed consent for obstetric anaesthesia in the Department of Anaesthesia at the University of Witwatersrand, a descriptive cross-sectional study

By Wazha Andrew Senyahale, MBChB (UCT), DA(SA)

Student number: 2640699

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

Johannesburg, 2025

Statement

The Research Report comprises a literature review, draft article, study proposal and appendices. The study proposal is included for background reference and is not for examination.

The formatting of this Research Report complies with the University of the Witwatersrand's Style Guide for Theses, Dissertations and Research Reports.

The formatting of the draft article is in keeping with the rest of the research report and complies with the author guidelines of the Southern African Journal of Anaesthesia, the journal to which it is intended to be submitted.

Declaration

I, Wazha Andrew Senyahale, herewith declare that this research report is my own unaided work. It is being submitted for the degree of Master of Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



Signed

22 May 2025

Dedication

This project is dedicated to my beautiful wife, Dimakatso Holele and my son, Wazha L. Senyahale, for their support throughout this process.

Presentations and publications

Presentation: none at present

Publication: none at present

Abstract

Background

Informed consent (IC) constitutes an important part of obstetric anaesthesia services, but the process of informed is not well described. The obstetric patient is deemed competent to make an informed consent despite unique challenges such as time limitations, pain and the effects of narcotic analgesia.

Aim

This study aims to describe the process of obtaining IC for obstetric anaesthesia as reported by anaesthetists at hospitals associated with the University of the Witwatersrand Department of Anaesthesia.

Methods

A descriptive cross-sectional study was conducted, and data was collected using an online self-administered questionnaire using the Redcap® platform. The study collected data from medical offers and registrars in the Department of Anaesthesia at the University of the Witwatersrand between June and July 2023. Data was analysed using SPSS statistical software.

Results

Of the 139 questionnaires sent out, 80 responses were registered, representing a 58% response rate. The majority (52.8%) are confident in their ability to get adequate IC. Eighty-five point one percent (85.1%) most commonly obtain verbal consent. Implied consent is used by 6.8% of the respondents. Only 8.1% use written consent. There is a variation in the risks disclosed to patients with common complications more frequently disclosed than those associated with more severe consequences. The respondents frequently encounter language barriers during the IC process and utilise other patients as translators, use mobile phone translation applications or simplify the English used. Most respondents do not modify their IC process based on whether the surgery is an elective or an emergency.

Conclusion

The process of obtaining IC for obstetric anaesthesia at hospitals associated with the University of the Witwatersrand Department of Anaesthesia varies among anaesthetists with a propensity for verbal consent.

Acknowledgements

I want to thank my supervisors, Dr Dorinka Nel and Dr Cara Redelinghuys, for their unbelievable patience, support, guidance and contributions to my research.

Contents

Statement ..... **ii**
Dedication ..... **iv**
Presentations and publications ..... **v**
Abstract ..... **vi**
Acknowledgements ..... **vii**
List of Figures ..... **x**
List of tables ..... **xi**
List of Abbreviations ..... **xii**
Section 1: Review of the literature **1**
1.1 Introduction ..... **Error! Bookmark not defined.**
1.2 Overview of IC 1
1.3 Ethics of IC 1
1.4 Elements of IC 2
1.5 Types of consent 3
1.6 Shared decision-making 4
1.7 Documentation 5
1.8 Barriers to IC 6
1.9 Regional variations of IC 7
1.10 Summary 8
Section 2: Author's guidelines **15**
Section 3: Draft article **24**
3.1. Abstract 25
3.2. Introduction 26
3.3 Research Methodology 27
3.4 Data Analysis 28
3.5 Results 28
3.6 Discussion 34
3.7 Conclusion 37
3.8. Conflict of interest 37
3.9 Disclosures 38
3.10 References 39
Section 4: Protocol **43**
4.1 Introduction 44
4.2. Problem statement 48
4.3. Aim 48
4.3. Objectives 48

4.4 Research assumption 49
4.5. Demarcation of the study field 49
5.6. Ethical considerations 50
4.7. Research Methodology 50
4.8. Significance of the study 52
4.9. Validity and reliability of the study 52
4.10 Potential limitations of the study 53
4.11 Project outline 54
4.12 References 56
4.13. Appendices 60
5. Section 5: Annexures **77**
5.1. Human Research Ethics Committee (Medical) approval 77
5.2. Graduate Studies Committee Approval 78
5.3. Permission letter by the WITS Anaesthesiology Head of Department 79
5.4. Research Permission Letter by The Deputy Registrar 80
5.5. Information sheet 81
5.6. Questionnaire 82
5.7. Permission to adapt the questionnaire 86
5.8. Turnitin report 87

List of Figures

Section 3 Draft article

Figure 1: The frequency at which anaesthetists quantified risks of spinal anaesthesia……..…….……..31

Figure 2: The frequency at which anaesthetists quantified risks associated with general anaesthesia……..…33

Figure 3: Options used by anaesthetists to overcome language barrier……34

List of tables

Section 3 Draft article

Table I: Demographics of the respondents……...28

Table II: Risks of spinal anaesthesia disclosed by the respondents and frequency of disclosure of the risks……..29

Table III: Risks of general anaesthesia disclosed by the respondents and frequency of disclosure of the risks……..32

List of Abbreviations

AAGBI	Association of Anaesthetists of Great Britain and Ireland
ASIC	Anaesthesia-specific informed patient consent
HPCSA	Health Professional Council of South Africa
IC	Informed consent
NHA	National Health Act
SASA	South African Society of Anaesthesiologists
SDM	Shared decision making
UK	United Kingdom
US	United States

Section 1: Review of the literature

1.1 Overview of IC

IC is a process led by the health care provider to equip the patient with the information needed to assist them in their decision-making. Information about risks, benefits and alternatives to proposed treatment or interventions is shared with the patient. [1] The benefit of IC is that it promotes patient autonomy by involving the patient in the decision-making process and helping them to make rational decisions. It protects the patient from possible coercion and fraud, and it encourages the medical professional to scrutinise their own ideas of what they think is beneficial to the patient. [2]

The anaesthetist has a fiduciary duty to obtain IC before providing a service to the patient. IC is based on legal, moral, and ethical principles and needs to be done effectively despite any potential challenges that may be encountered. [3] South African law states that any procedure or treatment on a patient without proper IC constitutes an assault [4]. IC gives the anaesthetist permission to perform procedures on the patient that may otherwise be impermissible. [2] IC should not be done with the primary objective of avoiding litigation or protecting against accusations and civil suits but rather facilitate patient care. [5]

1.2 Ethics of IC

The four principles of medical ethics, as originally described in The Principles of Biomedical Ethics by Beauchamp and Childress, are autonomy, beneficence, non-maleficence, and justice. Autonomy is defined as the patient's right to self-determination. This self-determination is honoured by consent, confidentiality, privacy, and access to records. [5, 6]

South African laws that govern IC include the National Health Care Act 61 of 2003 (NHA), the Constitution of the Republic of South Africa, The Children's Act 38 of 2005, the Health Professional Council of South Africa (HPCSA) guidelines and various other statutes, as well as the common law. [7] The other statutes that govern IC in the medical field include the

Sterilization Act (Act No. 44 of 1998) for sterilization and the Choice on Termination of Pregnancy Act (No.92 of 1996) for termination of pregnancy. [7]

1.3 Elements of IC

The process of IC can be divided into three elements: threshold elements (or preconditions), information elements and consent elements. Preconditions to valid IC include decision-making capacity or competency and voluntariness. Information elements include adequate disclosure of material information, recommendations and the patient's understanding of the information. Consent elements are the patient's decision and authorisation based on the above elements. [5, 8]

The two main components of legally recognised capacity are age and decisional or mental capacity. [9] Mental capacity to decide requires the decision-maker to understand the proposed decision and communicate it after appropriate deliberations in light of their values and goals. Decisional capacity is, however, not a static concept as one can have the capacity to make a decision or IC about one thing but not capable of making decisions about other things. [5] The anaesthetist is responsible for assessing the patient's capacity to give IC. [8] The anaesthetist assesses decisional-making abilities by determining the patient's ability to understand, express a choice, appreciate the gravity of the situation and reason through their decision. [10] There are often questions about the obstetric patient’s capacity to consent, especially in labour. According to the Association of Anaesthetists of Great Britain and Ireland (AAGBI), the obstetric patient is presumed capable of making informed decisions despite the documented challenges such as opioid usage, pain, sedative effects of analgesics, fatigue, or agitation. Any compromise in capacity due to the above must be severe to be considered incapacitating. [11]

Patients with the mental capacity to make an informed decision encounter instances where this capacity is limited by emotional overwhelm, information overwhelm, or both. [12] Emotional overwhelm occurs when the patient perceives the risks involved as too serious to make a decision. Informational overwhelm is when the patient cannot understand the medical

information and, therefore, cannot make decisions based on that information. [12] Informational overwhelm cannot be solved by using a surrogate because the information that overwhelms the patient can also overwhelm the surrogate decision-maker. It requires a more personal approach, such as shared decision-making. [12] Shared decision-making allows the patients to seek clarity on matters they may not fully understand.

The age of full legal capacity in the Republic of South Africa is 18 years. This means that persons older than 18 are assumed to be able to make decisions independently. [9] Additionally, The Children's Act states that sufficiently mature children of 12 years of age and older are allowed to consent to medical treatment and to consent to surgical operations with the assent of their parent or guardian. [13]

Information disclosure, understanding of information, and authorisation to perform the medical intervention are critical elements of IC. [14] The information on the benefits and material risks related to both general and neuraxial anaesthesia must be discussed with the patient. The lists of risks and benefits can be very long, so there has been a shift towards the “material risk” standard of information disclosure. [14] According to the HPCSA guidelines, information is material if "a reasonable person in the position of the patient, if warned of the risk, would attach significance to it; and the health care practitioner should reasonably be aware that the patient, if warned of the risk, would attach significance to it". [7]

According to a 2009 survey of IC practices in the United Kingdom (UK) for epidural anaesthesia, the most frequently disclosed risks or complications are failed epidural or partially working epidural, headache, drop in blood pressure and temporary nerve blockage. [15] In the same study, the rate of the anaesthetists quantifying the risks was low compared to the disclosure of risks. The most frequently quantified risks were bad headaches and permanent nerve damage. [15]

1.4 Types of consent

Three types of IC for medical procedures are implied, verbal and written consent. Implied consent is based on the principle of "peril invites rescue", where individuals are assumed to have consented to others' efforts made in good faith to assist them. Implied consent must be applied when necessary, not just for convenience. [16] In such a case, there is no discussion regarding consent and no evidence of consent. In other words, implied consent is when the patient passively cooperates without discussion. [17] A patient's apparent compliance or submission to what is being done to them may not constitute consent. [7] Before anaesthesia was established as an independent speciality, consent for anaesthesia was implied in the surgical consent. This has changed, requiring anaesthetists to be responsible for IC for anaesthesia practices. [18] The South African Society of Anaesthesiologists (SASA) states that consent for anaesthesia should never be implied. [19]

Written consent (also known as express consent) comes with the patient's signature and date. This writing is evidence that an agreement was entered in, but it is not binding as the patient can withdraw at any time without requiring the withdrawal to be made in writing [16]

Verbal consent is deemed adequate by the Joint Commission in the United States (U.S.) and the AAGBI, requiring the discussions to be documented in the patient's medical records. [8] Verbal consent entails the assessment of the patient's capacity followed by discussions of the proposed treatment, its benefits and risks, and any other alternative treatments. [8]

Another consideration in IC is broad consent versus narrow specific consent for a stated procedure. In broad consent, the scope of consent is widened to encompass other procedures that may need to be done for a failed initial plan. Broad consent allows for more excellent legal coverage but may compromise the patient's understanding of the information shared. [18]

1.5 Shared decision-making

The approach to obtaining consent for medical procedures has evolved from a paternalistic approach with the healthcare provider being the primary decision-maker to one where patient autonomy is the focus. [3] The paternalistic approach does not consider other factors such as the patient's cultural and religious beliefs, education level and understanding. [20]

Shared decision-making involves information sharing between the clinician and the patient. [3] Shared decision-making represents the middle point between an autonomy approach, "patient knows best", and a paternalistic system of "clinician knows it all". [2] Shared decision-making is a collaborative approach focusing on understanding the patients' circumstances and perspectives to address their needs. [20] The American College of Obstetricians and Gynaecologists Opinion Committee of 2009 considers shared decision-making the highest ethical standard model for IC. [21]

Unlike IC, which focuses on the permission to proceed with a procedure already decided on, SDM includes any situation where the patient's preferences and values need to be accounted for and where there are various options. The proper process of SDM requires time and space for extensive discussions. Time constraints in obstetric anaesthesia may thus hamper true SDM. A further distinction from IC is that shared information is significantly individualised and not set to the reasonable patient or clinician standard. [20]

In anaesthesia, IC still predominates with little progression towards shared decision-making, with time constraint reported as the main barrier to SDM. [22] Decision aids have been used to increase shared decision-making, even though there is no evidence to suggest that more information shared with patients increases the engagement needed for successful shared decision-making. [23]

1.6 Documentation

The entire IC process must be documented. This documentation must include a record of all the risks and possible complications discussed. [24]

Litigations against anaesthetists are less than other specialities, but the lack of clear documentation often leads to adverse findings against anaesthetists. Medicolegal claims related to inadequate consent result in high payouts. Inadequate consent causes patient dissatisfaction and the development of mistrust towards healthcare providers. [25]

1.7 Barriers to IC

A comprehensive review done in Africa on IC practices in obstetric anaesthesia revealed multiple barriers to proper IC. These barriers were classified into four levels: at the women's level, provider level, service level, and societal level. [26] Both surgical and anaesthetic IC were assessed.

At the women's level, young age, low level of education, distrust in the health providers, labour pains and language barriers were cited as barriers. [26] Patients may not have received antenatal education. There is limited time to provide thorough counselling when they present for unplanned emergency interventions. [27] Effective information sharing and consent are difficult during labour due to distractions such as contractions, pain and medication with opioids, but women in labour have the mental capacity to make an informed decision despite these challenges. [9, 28] The informed consent process can become more complex during pregnancy due to the physician's responsibility to consider the health of both the mother and the fetus. Possible conflict ensues when the mother's autonomy endangers the life of the fetus. [11]

Language barriers have been identified as a prevalent barrier, especially among immigrant women. [21] The National Health Act requires doctors to obtain consent in a language the patient understands and that aligns with their literacy level. This is challenging in South Africa, which has eleven official languages and many immigrants. [29]

At the level of the providers, paternalism was implicated, as well as fear of blame and litigation and poor knowledge of IC by healthcare providers. [26] A study done in a South African academic centre found that anaesthetists, even at an academic level, had suboptimal knowledge of South African laws that govern IC. [30]

Poorly designed consent forms and time constraints were identified as service-level constraints. [26] The design flaw identified in the consent forms was that they were written in a language that excluded some patients. [26] Time constraints in the perioperative period are a limitation to IC for obstetric emergency cases due to the fast turnaround time and high number of cases. [23, 26]

At a societal level, cultural and gender norms in the African population significantly influence women's participation in the IC process. Some cultures value vaginal delivery, and this pressurises women to refuse caesarean section. In Nigeria, it was found that the husbands gave the majority of written consent for a caesarean section. [26]

1.8 Regional variations of IC

Europe

A study in Ireland looking at the quality of IC for anaesthesia for elective caesarean deliveries found that patients were not informed of the risks and complications of the anaesthesia plan. The patients were also not offered other viable options, such as epidural or general anaesthesia, as possible plans for caesarean delivery. [31]

A survey of heads of units of anaesthesia in the UK showed significant variations in the reported practices of IC for epidural anaesthesia. [15] For instance, verbal consent was documented in different places such as the clinical notes, anaesthesia charts, separate databases or various other places, including the labour chart or sticky notes. [15]

A survey done in Lithuania, Latvia, and Estonia evaluated the practices and opinions of anaesthesiologists regarding anaesthesia-specific informed patient consent (ASIC). It was found that there was significant variation in the timing for obtaining ASIC and the rate of risk disclosure. The majority of the respondents overstated the risk of intra-operative awareness. It was also found that the responding anaesthesiologists inaccurately represented the incidences of risks. [32] Anaesthesiologists who obtained ASIC in the pre-operative period viewed the risk

and complications shared as adequate compared to those who obtained consent on the day of the surgery. [32]

Africa

A study in a tertiary hospital in Southeast Nigeria found that only 27% of post-caesarean section patients were satisfied with the counselling that they received regarding anaesthesia. [33] Faysal et al. did a literature review on IC in sub-Saharan Africa and found that women received limited or, in some cases, no information on anaesthesia for caesarean section. This study also highlights the lack of research on IC in this region. [26]

South Africa

A South African study in a tertiary hospital found that patients who had already received spinal anaesthesia had limited knowledge about the anaesthetic. [34] The mean score on a knowledge questionnaire was only 53%. Patient's source of information about anaesthesia is other sources other than the anaesthetists, hence the limitation in their knowledge. [34]

An assessment of the IC processes from the perspective of patients undergoing surgery at Inkosi Albert Luthuli Central Hospital found that although most patients interacted with anaesthetists preoperatively, only 55% claimed to have received information about the anaesthetic. [35] In another study that reported on patients' perceptions of IC as practised by doctors and nurses in South Africa, it was found that patients are aware of their right to IC and prefer disclosure of all material risks as well as better communication skills by health care professionals and a shift towards shared decision-making. [14] Healthcare workers often underestimate the amount of information patients want about the proposed therapies to help them decide. [22]

1.9 Summary

The literature reviewed has demonstrated the importance of IC and its many complexities related to ethical considerations. There are vast differences in the processes of IC in terms of

anaesthesia, with an evident paucity of evidence for how IC is obtained. Strategies to improve IC in this vulnerable patient population will need an expansion of information sharing and education that starts early in the antenatal period, where different scenarios are explored and likely changes explained in anticipation of a dynamic period during labour.

References

1. Shah P, Thornton I, Turrin D, Hipskind JE. Informed Consent. StatPearls. Treasure Island (FL)2022. p. 1-8. Available from: https://www.ncbi.nlm.nih.gov/pubmed/28613577.

2. Childress JF, Childress MD. What Does the Evolution From Informed Consent to Shared Decision Making Teach Us About Authority in Health Care? AMA J Ethics. 2020;22(5):423-429. http://dx.doi.org/10.1001/amajethics.2020.423

3. Wilson EH, Burkle CM. The Meaning of Consent and Its Implications for Anesthesiologists. Adv Anesth. 2020;38:1-22. https://doi.org/10.1016/j.aan.2020.07.001

4. Bolton KD. Informed consent. SA Orthop J. 2012 11(3):108-111. Available from: http://www.scielo.org.za/pdf/saoj/v11n3/14.pdf. Accessed 26 May 2022.

5. Hoehner PJ. Ethical Aspects of Informed Consent in Obstetric Anesthesia—New Challenges and Solutions. J Clin Anesth. 2003;15(8):587-600. http://dx.doi.org/10.1016/S0952-8180(02)00505-6

6. Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press; 2001. Available from: https://go.exlibris.link/SJZdgvsW. ISBN 13: 9780195143317.

7. Health Professionals Council of South Africa. Seeking Patients' informed consent: The ethical consideration Booklet 4. HPCSA website: HPCSA; 2016. Available from: https://www.hpcsa.co.za/Uploads/Professional_Practice/Conduct%20%26%20Ethics/Booklet%204%20Informed%20Consent%20September%20%202016.pdf. Accessed 23 June 2022

8. Tait AR, Teig MK, Voepel-Lewis T. Informed consent for anesthesia: a review of practice and strategies for optimizing the consent process. Can J Anaesth. 2014;61(9):832-842. https://doi.org/10.1007/s12630-014-0188-8

9. The Medical Protection Society. Consent-The basics Medical Protection Society 2021 updated 8 Jan 2021. Available from: https://www.medicalprotection.org/southafrica/casebook-and-resources/factsheets/factsheets/sa-consent-the-basics Accessed 20 Nov 2023.

10. Karlawish J. Assessment of decision-making capacity in adults 2024 updated 29 Feb 2024. Available from: https://www.uptodate.com/contents/assessment-of-decision-making-capacity-in-adults?search=mental%20capacity%20assessment&source=search_result&selectedTitle=1%7E150&usage_type=default&display_rank=1#H2075084397. Accessed 13 Jun 2024.

11. Nour S, Griffiths S. Obtaining consent for obstetric procedures. Anaesthesia & Intensive Care Medicine. 2016;17(8):408-410. https://doi.org/10.1016/j.mpaic.2016.05.005

12. Bester J, Cole CM, Kodish E. The Limits of Informed Consent for an Overwhelmed Patient: Clinicians' Role in Protecting Patients and Preventing Overwhelm. AMA J Ethics. 2016;18(9):869-886. http://dx.doi.org/10.1001/journalofethics.2016.18.9.peer2-1609

13. McQuoid-Mason D. Provisions for consent by children to medical treatment and surgical operations, and duties to report child and aged persons abuse: 1 April 2010. S Afr Med J. 2010;100(10):646-648. http://dx.doi.org/10.7196/SAMJ.4278

14. Chima SC. "Because I want to be informed, to be part of the decision-making": Patients' insights on informed consent practices by healthcare professionals in South Africa. Niger J Clin Pract. 2015;18:46-56. http://dx.doi.org/10.4103/1119-3077.170833

15. Middle JV, Wee MY. Informed consent for epidural analgesia in labour: a survey of UK practice. Anaesthesia. 2009;64(2):161-164. https://doi.org/10.1111/j.1365-2044.2008.05679.x

16. Dickens BM, Cook RJ. Types of consent in reproductive health care. Int J Gynaecol Obstet. 2015;128(2):181-184. https://doi.org/10.1016/j.ijgo.2014.11.001

17. Kakar H, Gambhir RS, Singh S, Kaur A, Nanda T. Informed Consent: Corner Stone in Ethical Medical and Dental Practice. J Family Med Prim Care. 2014;3(1):68-71. https://doi.org/10.4103/2249-4863.130284

18. Bárbara F, Sílvia M, Diana A, Sofia D, Miguel R. Informed consent in anesthesiology: an exploratory study. Acta Bioeth. 2022;28(2):281-289. http://dx.doi.org/10.4067/S1726-569X2022000200281

19. South African Society of Anaesthesiologists. SASA Practice Guidelines 2022. SASA; 2022. Available from: https://sasaweb.com/wp-content/uploads/2022/09/SASA-Practice-Guidelines-2022-Consolidated-Final.pdf. Accessed 04 June 2024

20. Lindor RA, Kunneman M, Hanzel M, Schuur JD, Montori VM, Sadosty AT. Liability and Informed Consent in the Context of Shared Decision Making. Acad Emerg Med. 2016;23(12):1428-1433. http://dx.doi.org/10.1111/acem.13078

21. ACOG Committee Opinion No. 819: Informed Consent and Shared Decision Making in Obstetrics and Gynecology. Obstet Gynecol. 2021;137(2 Part 1):34-41. http://dx.doi.org/10.1007/978-3-031-62756-9_44

22. Stubenrouch FE, Mus EMK, Lut JW, Hesselink EM, Ubbink DT. The current level of shared decisionmaking in anesthesiology: an exploratory study. BMC Anesthesiol. 2017;17(1):95-95. https://doi.org/10.1186/s12871-017-0386-3

23. Sturgess J, Clapp JT, Fleisher LA. Shared decision-making in peri-operative medicine: a narrative review. Anaesthesia. 2019;74:13-19. https://doi.org/10.1111/anae.14504

24. Bishop DG, Lucas DN. If it isn't written down, then it didn't happen: documentation in obstetric anaesthesia. South Afr J Anaesth Analg. 2022;28(4):124-130. https://doi.org/10.36303/SAJAA.2022.28.4.2845

25. Broaddus BM, Chandrasekhar S. Informed Consent in Obstetric Anesthesia. Anesth Analg. 2011;112(4):912-915. https://doi.org/10.1213/ane.0b013e31820e777a

26. Faysal S, Penn-Kekana L, Day L, Tripathi V, Khan F, Stafford R, et al. Counseling, informed consent, and debriefing for cesarean section in sub- Saharan Africa: A scoping review. Int J Gynecol Obstet. 2023;00:1-16. https://doi.org/10.1002/ijgo.15079

27. Dyer RH. Informed consent for epidural analgesia in labour. South Afr J Anaesth Analg. 2007;13(1):27-34. https://doi.org/10.1080/22201173.2007.10872462

28. Mahomed K, Chin D, Drew A. Epidural analgesia during labour – maternal understanding and experience – informed consent. J Obstet Gynaecol 2015;35(8):807-809. https://doi.org/10.3109/01443615.2015.1011103

29. Hunter-Adams J, Rother H-A. A Qualitative study of language barriers between South African health care providers and cross-border migrants. BMC Health Serv Res 2017;17(1):97-106. https://doi.org/10.1186/s12913-017-2042-5

30. Mamoojee A, Alli A. Anaesthetists' knowledge of South African Law pertaining to informed consent in an academic centre. South Afr J Anaesth Analg. 2018;24(6):155-164. http://dx.doi.org/10.1080/22201181.2018.1523861

31. Muhammad A. A Study of the Quality of Informed Consent of Anesthesia for Cesarean Deliveries: What and Whatnot was Discussed with Parturients. J Anesth Clin Res. 2014;5(9). http://dx.doi.org/10.4172/2155-6148.1000438

32. Jovaisa T, Norkiene I, Karjagin J, Golubovska I, Gambickas L, Kalinauskaite M, et al. Are We Meeting the Current Standards of Consent for Anesthesia? An International Survey of Clinical Practice. Med Sci Monit. 2020;26:e925905. http://dx.doi.org/10.12659/msm.925905

33. Anikwe CC, Egbuji CC, Ejikeme BN, Ikeoha CC, Egede JO, Ekem NN, et al. The experience of women following caesarean section in a tertiary hospital in SouthEast Nigeria. Afr Health Sci. 2019;19(3):2660-2669. http://dx.doi.org/10.4314/ahs.v19i3.42

34. Möller C. Knowledge and the sources of knowledge of spinal anaesthesia in primiparous women who have received a caesarean section: University of the Witwatersrand; 2015.Available from: https://wiredspace.wits.ac.za/items/e259c3dd-12d9-41e2-8d39-73680103d5d6. Accessed 20 April 2022

35. Naidu S, Goplan P. The informed consent process for anaesthesia: perspectives of elective surgical patients at Inkosi Albert Luthuli Central Hospital, South Africa. South Afr J Anaesth Analg. 2016;22(2):60-64. https://doi.org/10.1080/22201181.2016.1157963

Section 2: Author's guidelines

Southern African Journal of Anaesthesia and Analgesia (SAJAA)

How to submit your paper online:

1. Registered authors must login to submit a paper

1. REGISTER HERE if you do not have a username and password

2. LOGIN HERE if you have already registered with SAJAA

2. Select Author

3. Click on CLICK HERE TO FOLLOW THE FIVE STEPS TO SUBMIT YOUR MANUSCRIPT

4. Follow the five steps to submit your paper

5. To view a video on how to submit a paper online, CLICK HERE

6. To download instructions to authors, CLICK HERE

Review policy and timelines

1. Immediate notification if submitted successfully

2. Notification within 3 weeks if not accepted for further review

3. Notification within 3 months if accepted for publication, if revisions are required or if rejected by both reviewers.

4. Publication within 6 months after submission.

Aims, scope and review policy

The *SA Journal of Anaesthesia and Analgesia* aims to publish original research

and review articles of relevance and interest to the anaesthetist in academia, public sector and private practice. Papers are peer-reviewed to ensure that the contents are understandable, valid, important, interesting and enjoyed. All manuscripts must be submitted online.

SAJAA is accredited by the Department of Education for the measurement of research output of public higher institutions of South Africa (SAPSE accredited). All articles in SAJAA will be peer-reviewed.

Article sections and length

The following contributions are accepted (word counts exclude abstracts, tables and references):

Original Research (2 800 ± 3 200 words / 4-5 pages)

Clinical Reviews (2 400 words / 3-4 pages)

Drug Reviews (2 400 words / 3-4 pages)

Case Studies (1 800 words / 3 pages)

Scientific Letters (2 400 words / 3-4 pages)

Letters to the Editor (400-800 words]

Please see the journal's section policies section policies for further details.

FULL AUTHOR GUIDELINES

Title page

All articles must have a title page with the following information and in this particular order: Title of the article; surname, initials, qualifications and affiliation of each author; The name, postal address, e-mail address and telephonic contact details of the corresponding author and at least 5 keywords.

Abstract

All articles should include an abstract. The structured abstract for an Original Research article should be no more than 300 words and should consist of four paragraphs labelled Background, Methods, Results, and Conclusions. It should briefly describe the problem or issue being addressed in the study, how the study was performed, the major results, and what the authors conclude from these results. The abstracts for other types of articles should be no longer than 230 words and need not follow the structured abstract format.

Keywords

All articles should include keywords. Up to five words or short phrases should be used. Use terms from the Medical Subject Headings (MeSH) of Index Medicus when available and appropriate. Keywords are used to index the article and may be published with the abstract.

Acknowledgements

In a separate section, acknowledge any financial support received or possible conflict of interest. This section may also be used to acknowledge substantial contributions to the research or preparation of the manuscript made by persons other than the authors.

References

Cite references in numerical order in the text, in superscript format (Format> Font> Click superscript). Please do not use brackets or do not use the footnote function of MS Word.

In the References section, references must be typed double-spaced and numbered consecutively in the order in which they are cited, not alphabetically.

The style for references should follow the format set forth in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (http://www.icmje.org) prepared by the International Committee of Medical Journal Editors. Abbreviations for journal titles should follow Index Medicus format. Authors are responsible for the accuracy of all references. Personal communications and unpublished data should not be referenced. If essential, such material should be incorporated in the appropriate place in the text.

List all authors when there are six or fewer; when there are seven or more, list the first three, then ³;et al.´; When citing URLs to web documents, place in the reference list, and use the following format: Authors of document (if available). Title of document (if available). URL. (Accessed [date]).

The following are sample references:

1. Jun BC, Song SW, Park CS, Lee DH, Cho KJ, Cho JH. The analysis of maxillary sinus aeration according to aging process: volume assessment by 3-dimensional reconstruction by high-resolutional CT scanning. Otolaryngol Head Neck Surg. 2005 Mar;132(3):429-34.
2. Polgreen PM, Diekema DJ, Vandeberg J, Wiblin RT, Chen YY, David S, et al. Risk factors for groin wound infection after femoral artery catheterization: a case-control study. Infect Control Hosp Epidemiol [Internet]. 2006 Jan [cited 2007 Jan 5];27(1):34-7. Available from: http://www.journals.uchicago.edu/ICHE/journal/issues/v27n1/2004069/2004069.web.pdf.

More sample references can be found at:

https://www.nlm.nih.gov/bsd/uniform_requirements.html

Tables

Tables should be self-explanatory, clearly organised, and supplemental to the text of the manuscript. Each table should include a clear descriptive title on top and numbered in Roman numerals (I, II, etc) in order of its appearance as called out in text. Tables must be inserted in the correct position in the text. Authors should place explanatory matter in footnotes, not in the heading. Explain in footnotes all non-standard abbreviations.

For footnotes use the following symbols, in sequence: *,†, ‡, § ,||,**, ††, ‡‡

Figures

All figures must be inserted in the appropriate position of the electronic document.

Symbols, lettering, and numbering (in Arabic numerals e.g. 1, 2, etc. in order of appearance in the text) should be placed below the figure, clear and large enough to remain legible after the figure has been reduced. Figures must have clear descriptive titles.

Photographs and images

If photographs of patients are used, either the subject should not be identifiable or use of the picture should be authorised by an enclosed written permission from the subject. The position of photographs and images should be clearly indicated in the text. Electronic images should be saved as either jpeg or gif files. All photographs should be scanned at a high resolution (300dpi, print optimised). Please number the images appropriately.

Permission

Permission should be obtained from the author and publisher for the use of quotes, illustrations, tables, and other materials taken from previously published works, which are not in the public domain. The author is responsible for the payment of any copyright fee(s) if these have not been waived. The letters of permission should accompany the manuscript. The original source(s) should be mentioned in the figure legend or as a footnote to a table.

Review and action

Manuscripts are initially examined by the editorial staff and are usually sent to

independent reviewers who are not informed of the identity of the author(s). When publication in its original form is not recommended, the reviewer's comments (without the identity of the reviewer being disclosed) may be passed to the first author and may include suggested revisions. Manuscripts not approved for publication will not be returned.

Ethical considerations

Papers based on original research must adhere to the Declaration of Helsinki on [3]Ethical Principles for Medical Research Involving Human Subjects; and must specify from which recognised ethics committee approval for the research was obtained.

Conflict of interest

Authors must declare all financial contributions to their work or other forms of conflict of interest, which may prevent them from executing and publishing unbiased research. [Conflict of interest exists when an author (or the author's institution), has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her opinions or actions.] **Modified from: Davidoff F, et al. Sponsorship, Authorship, and Accountability. (Editorial) JAMA 2001: 286(10) The following declaration may be used if appropriate: [3]I declare that I have no financial or personal relationship(s) which may have inappropriately influenced me in writing this paper.´

Submissions and correspondence

All submissions must be made online at www.sajaa.co.za and correspondence regarding manuscripts should be addressed to:

The Editor, SAJAA, E-mail: toc@sajaa.co.za

Note: Ensure that the article ID [reference] number is included in the subject of your email correspondence.

Electronic submissions by post or via email

Authors with no e-mail or internet connection can mail their submissions on a CD to: SAJAA, PO Box 14804, Lyttelton Manor, 0140, Gauteng, South Africa.

All manuscripts will be processed online. Submissions by post or by e-mail must be accompanied by a signed copy of the following indemnity and copyright form.

CLICK HERE to download and save it to your computer.

Submissions by email should be send as an attachment to

Tips on Preparing your manuscript

Please consult the "Uniform requirements for manuscripts submitted to biomedical journals" at www.icmje.org

Please consult the guide on Vancouver referencing methods at:
http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=citmed.TOC&depth=2

The submission must be in UK English, typed in Microsoft Word or RTF with no double spaces after the full stops, double paragraph spacing, font size 10 and font type: Times New Roman.

All author details (Full names, Qualifications and affiliation) must be provided.

The full contact details of corresponding author (Tel, fax, e-mail, postal address) must be on the manuscript.

There must be an abstract and keywords.

References must strictly be in Vancouver format. (Reference numbers must be strictly numerical and be typed in superscript, not be in brackets and must be placed AFTER the full stop or comma.)

It must be clear where every figure and table should be placed in the text. If possible, tables and figures must be placed in the text where appropriate. If too large or impractical, they may be featured at the end of the manuscript or uploaded as separate supplementary files.

All photographs must be at 300dpi and clearly marked according to the figure numbers in the text. (Figure 1, Table II, etc.)

All numbers below ten, without percentages or units, must be written in words.

Figure numbers: Arabic, table numbers: Roman

Section 3: Draft article

The process of informed consent for obstetric anaesthesia in the Department of Anaesthesia at the University of Witwatersrand, a descriptive cross-sectional study

Wazha Andrew Senyahale*, MBChB (UCT), DA(SA) https://orcid.org/0009-0007-4514-2124

Dorinka Nel*, MBChB (UP), DA (SA), FCA(SA) https://orcid.org/0000-0002-8288-7164

Cara Redelinghuys * MBChB (UCT), DCH (SA), DA (SA), FCA (SA), MMed (WITS) https://orcid.org/0000-0002-8506-1106

**Department of Anaesthesiology, School of Clinical Medicine, University of the Witwatersrand, Johannesburg, South Africa*

Corresponding Author

W. A. Senyahale, Department of Anaesthesiology, Chris Hani Baragwanath Academic Hospital, 26 Chris Hani Rd, Diepkloof, Soweto, Johannesburg, 1860

Email: monangagilo@yahoo.co.uk; Contact number: +27 11 933 9335

Data availability statement: The data that supports the finding of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

3.1. Abstract

Background

Informed consent (IC) constitutes an important part of obstetric anaesthesia services, but the process of obtaining informed consent is not well described. The obstetric patient is deemed competent to make an informed consent despite unique challenges such as time limitations, pain and the effects of narcotic analgesia. This study aims to describe the process of obtaining IC for obstetric anaesthesia as reported by anaesthetists at hospitals associated with the University of the Witwatersrand Department of Anaesthesia.

Methods

A descriptive cross-sectional study was conducted, and data was collected using an online self-administered questionnaire using the Redcap® platform. The study collected data from medical offers and registrars in the Department of Anaesthesia at the University of the Witwatersrand between June and July 2023. Data was analysed using SPSS statistical software.

Results

Of the 139 questionnaires sent out, 80 responses were registered, representing a 58% response rate. The majority (52.8%) are confident in their ability to get adequate IC. A significant 85.1% most commonly obtain verbal consent. Implied consent is used by 6.8% of the respondents. Only 8.1% use written consent. There is a variation in the risks disclosed to patients with common complications more frequently disclosed than those associated with more severe consequences. The respondents often encounter language barriers during the IC process and utilise other patients as translators, use mobile phone translation applications or simplify the English used. Most respondents do not modify their IC process based on whether the surgery is an elective or an emergency.

Conclusion

The process of obtaining IC for obstetric anaesthesia at hospitals associated with the University of the Witwatersrand Department of Anaesthesia varies among anaesthetists with a propensity for verbal consent.

Keywords: Anaesthetist, General anaesthesia, Informed Consent, Obstetric anaesthesia, Patient autonomy, Spinal anaesthesia

3.2. Introduction

The anaesthetist has a fiduciary duty to obtain Informed Consent (IC) before providing a service to the patient. This IC must be based on legal, moral, and ethical principles. [1] South African law states that any procedure or treatment on a patient without proper IC constitutes an assault. [2] The primary goal of IC, however, should be to facilitate patient care and not to avoid litigation. [3]

Modern medical ethical principles are based on four fundamental principles: autonomy, beneficence, justice and non-maleficence. [3] IC honours patients' autonomy and protects them from abuse when applied correctly. [3] It also promotes the doctor-patient relationship. [4]

The prerequisites to IC are voluntariness and capacity. [2, 3, 5] Voluntariness implies a decision made without a promise of a reward, coercion, manipulation, or persuasion. [2] The two main components of legally recognised capacity are age and decisional or mental capacity. [6] Mental capacity to decide requires that the decision-maker understands the proposed decision and can communicate their decision after appropriate deliberations in light of their values and goals. It is not a static concept, as one can have the capacity to decide about one thing but not about other things. [3] A woman in labour maintains her decision-making capacity as shown by their information recall despite the pain and the use of opioids. [7]

Information disclosure, understanding of information, and authorisation of consent to the medical intervention are critical elements of IC. [8] The benefits and material risks of general and neuraxial anaesthesia must be discussed. The lists of risks and benefits can be very long, so there has been a shift towards the ‘material risk’ standard of information disclosure. [8] According to the HPCSA guidelines, the risk is deemed material if ‘a reasonable person in the position of the patient, if warned of the risk, would attach significance to it; and the health care practitioner should reasonably be aware that the patient, if warned of the risk, would attach significance to it’. [9]

The approach to obtaining consent for medical procedures has evolved from a paternalistic one to one in which patient autonomy is the focus. [1] The paternalistic approach does not consider other factors such as the patient’s cultural and religious beliefs, their level of education or their level of understanding. [10] Shared decision-making(SDM) is an improvement in that the patient's context and cultural beliefs are considered. [11] SDM requires the patient to have adequate information to participate in decision-making. It is the anaesthetist’s duty to provide the information and ensure the patient’s understanding of the information.

There are three types of IC for medical procedures. Implied consent occurs when the patient passively cooperates without a discussion about the procedure taking place. Verbal consent entails a full discussion around informed consent, but the patient does not sign a specific form. Written consent (also known as express consent) comes with the patient's signature and date. This writing is evidence that an agreement was entered into, but it is not binding as the patient can withdraw at any time without requiring the withdrawal to be made in writing. [12]

A study done at a South African academic hospital assessed postoperative patients' recall of the information they received about spinal anaesthesia. The mean score on a 15-point knowledge scale was only 53%, and only 34% of participants claim to have received the information from the anaesthetist. [13] It is unclear whether anaesthetists' process of obtaining IC contributes to this finding as there is a paucity of data in South Africa.

This study aims to describe the process of obtaining IC for obstetric anaesthesia as reported by anaesthetists at hospitals associated with the University of the Witwatersrand Department of Anaesthesia.

3.3 Research Methodology

Research design

A descriptive cross-sectional study was conducted with ethical approval from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand (M-230522).

Study population

The study population consisted of medical officers and registrars in the Department of Anaesthesia at the University of the Witwatersrand. At the hospitals in this study, obstetric anaesthesia is primarily a service rendered by medical officers and registrars with distant consultant supervision; hence, the point of contact with the patient is the medical officers and registrars. For this reason, the consultants were excluded from the sample population.

Study sample

A convenience sampling method was used. This involves selecting the most readily available people for a study.

Sample size

In consultation with a biostatistician, a sample size was determined based on a pool of 131 medical offices and registrars. Interns and consultants were excluded from the study. The questionnaire was distributed to the entire registrar and medical officer population through REDCap®. The RedCap® platform was set up to send emails with the questionnaire link to the study participants. Consent for the study was via an acceptance button at the bottom of the information and consent sheet.

A population proportion of 90% was assumed to achieve a maximum 95% confidence interval margin of error of 5%, and the sample size of 68 respondents was determined to be sufficient. Incomplete questionnaires were included in the response rate calculations but not in the statistical analysis.

Questionnaire Development

The questionnaire was developed based on a questionnaire originally used in a similar study surveying IC practices for epidural analgesia in labour in the United Kingdom (UK). [7] Permission was obtained to use relevant parts of the original questionnaire. The questionnaire was modified to satisfy the study objectives. A panel of experts in anaesthesia and bioethics reviewed the newly composed questionnaire for validity. Changes were made based on their recommendations. The questionnaire consisted of demographic questions and content questions.

Data Collection

Participation in the study was voluntary, and the participants were given an information sheet upon accessing the REDCap® link shared with them. The questionnaire was distributed via email. Follow-up reminders via email and social media were sent weekly for three weeks.

3.4 Data Analysis

Data was downloaded onto a Microsoft Excel spreadsheet from REDCap® and analysed using SPSS Statistics Software (v.25; IBM SPSS) with assistance from a biostatistician. Descriptive and inferential statistics were used. Numbers and percentages were used to describe categorical data, and associations were sought between calculated parameters using the Pearson correlation coefficient. The Chi-squared test of independence was used to test whether two categorical variables were related. For the Likert scale data, the data were represented in graphical form to illustrate the distribution of the responses.

3.5 Results

Of the 139 questionnaires sent out, 80 responses were registered, representing a 58% response rate. Of the 80 responses, six were left entirely blank and excluded from the analysis, leaving a denominator of 74. The demographics of the respondents are shown in **Table I**.

Table I: Demographics of the respondents

		n	%
Gender	Male	31	41.9
	Female	43	58.1
Designation/rank	Medical officer	18	24.3
	Registrar	56	75.7
Work experience	Up to 1 year	5	6.8
	Up to 2 years	8	10.8
	Up to 3 years	16	21.6
	More than 4 years	45	60.8
Highest anaesthetic qualification	No formal anaesthetic training	1	1.4
	Diploma in Anaesthetics	5	6.8
	FCA ‡ Part 1	66	89.2
	FCA ‡ Part 2	2	2.7

‡ Fellowship of the College of Anaesthesiologists of South Africa

Respondents were asked to judge the adequacy of their IC process, and 52.8% deemed their IC process adequate, while 29.7% admitted to deficiencies in their processes. The majority always introduce themselves by name (96.0%), and three out of the 74 (4.1%) respondents only occasionally give patients their names. More than two-thirds (68.9%) ‘never’ or ‘rarely’ introduced themselves by rank.

Verbal consent was the most common used IC used by 85.1% of the respondents. Implied consent is used by 6.8% of the respondents, while only 8.1% use written consent. Of those that used verbal IC, 49.2% either often or always documented IC, and 22.2% never documented this process. Verbal consent is documented in the anaesthetic chart (76.2%), the patient’s file (6.4%) and the surgical consent form (3.2%).

Only 23.0% of respondents ‘often’ or ‘always’ offer both spinal and general anaesthesia (GA), while 48.7% of respondents ‘never’ or ‘seldom’ offer both.

The risks of spinal anaesthesia and the frequency at which the anaesthetists disclose is shown in Table II. Death (77.1%), cardiac arrest (78.1%) and anaphylaxis (74.3%) were the least likely risks to be disclosed, as shown by those who selected never or seldom. Risk factors that were most frequently disclosed are nausea and vomiting (79.7%), the need to convert to general anaesthesia (73.2%) and post-puncture headaches (51.4%), as shown by those who selected often or always. The other complications mentioned by the respondents that were not listed in the questionnaire are infections, patchy/partial block, hypotension, failed spinal, needle breakage, dizziness and change in sensation below the block level.

Table II: Risks of spinal anaesthesia disclosed by the respondents and frequency of disclosure of the risks

Risk of spinal anaesthesia	% Never/Seldom	% Occasionally	% Often/Always
Anaphylaxis	74.3	14.9	10.8
Cardiac arrest	78.1	12.3	9.6
Compression from a vertebral canal haematoma	41.9	18.9	39.2
Compression from an epidural abscess/ meningitis	47.3	17.6	35.1
Death	77.1	16.2	6.8
High (total) spinal	36.5	33.8	29.7
Local anaesthesia systemic toxicity	62.2	17.6	20.3
Nausea and vomiting	4.1	16.2	79.7
Need to convert to general anaesthesia	5.4	21.6	73.2
Post-dural puncture headache	20.3	28.4	51.4
Post spinal backache	46.0	24.3	29.8
Pruritus	56.7	20.3	23.0
Shivering	36.5	24.3	39.2
Transient neurologic symptoms	52.7	18.9	28.4
Nerve injury	29.8	32.4	37.9
Urinary retention	60.8	23.0	16.2

Other	89.0	4.1	6.8

Figure 1 shows how often the above risks associated with spinal anaesthesia, are quantified. Local anaesthetic systemic toxicity (51.3%), urinary retention (54.1%) and anaphylaxis (52.7%) are the least likely to be quantified. The most often or always quantified risks are post-dural puncture headache (39.2%), the need to convert to GA (47.3%) and nausea and vomiting (56.8%).

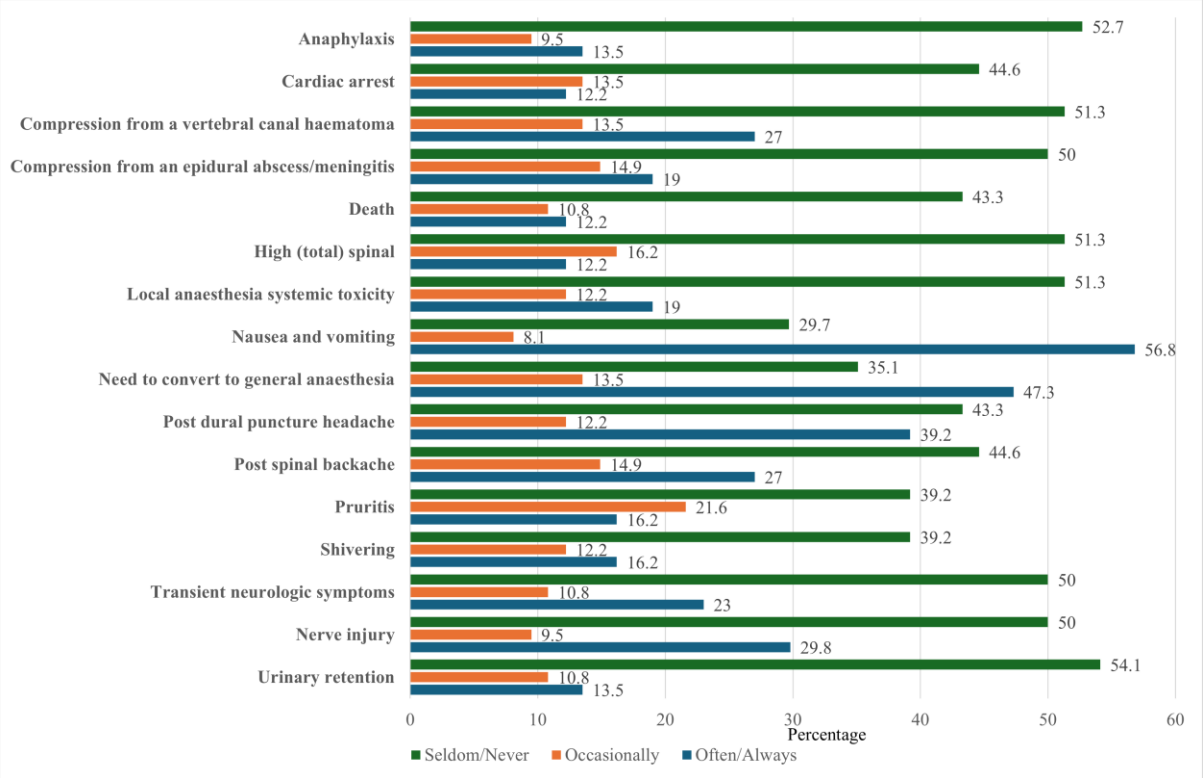


Figure 1. The frequency at which anaesthetists quantified risks of spinal anaesthesia

Table III shows the risks of general anaesthesia disclosed by the anaesthetists. The risk of aspiration of gastric contents (76.7%), depression of the foetus with narcotics (59.9%), and airway and dental trauma (60.2%) are the most frequently disclosed risks of general anaesthesia. Risks that are least likely to be disclosed to the patients about general anaesthesia are anoxia and brain damage (67.1%), increased risk of post-partum haemorrhage (60.3%), and drug toxicity/side effects (43.8%). Risks disclosed that were not listed include the tocolytic effect of anaesthetic volatiles, post-operative confusion, post-operative pain, sore throat, and inability to witness the delivery of the baby.

Table III: Risks of general anaesthesia disclosed by the respondents and frequency of disclosure of the risks

Risks of general anaesthesia	% Never/Seldom	% Occasionally	% Often/Always
Airway and dental trauma	19.1	20.5	60.2
Anoxia and brain damage	67.1	16.4	16.4
Aspiration of gastric contents and its consequences	6.8	16.4	76.7
Awareness under general anaesthesia	41.1	19.2	39.7
Depression of the foetus with narcotics	19.2	20.5	59.9
Drug toxicity/side effects	43.8	20.5	35.6
Increased risk of post-partum haemorrhage	60.3	16.4	23.3
Loss of airway control (failed intubation) and the need for surgical airway	30.1	27.4	42.4
Post-operative nausea and vomiting	19.2	27.4	53.4

Figure 2 shows how often the risks associated with GA were quantified. The most quantified risks of GA were postoperative nausea and vomiting (37.8%), aspiration of gastric contents (39.2%) and airway and dental trauma risk (39.2%). The least quantified risks of GA were drug toxicity or side effects (58.1%), anoxia and brain damage (52.7%), failed intubation and need for a surgical airway (50.0%).

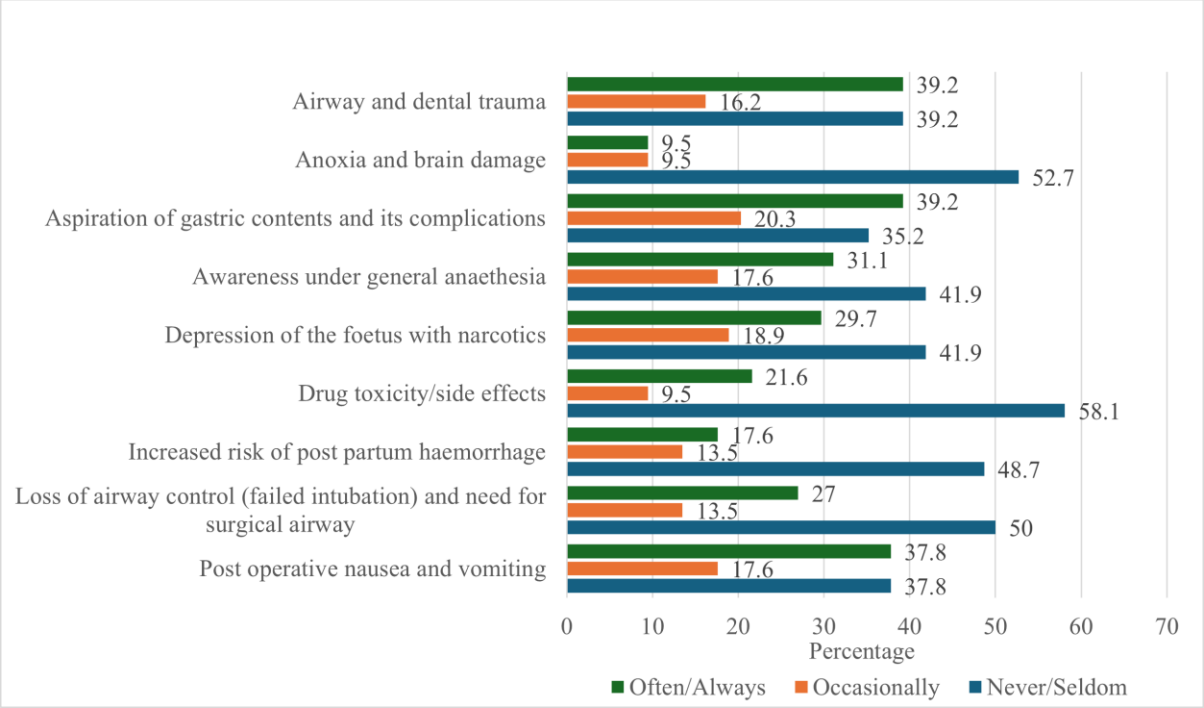


Figure 2: The frequency at which anaesthetists quantified risks associated with general anaesthesia

Almost three-quarters (73%) of respondents often or always obtain IC in the patient's preferred language. Most anaesthetists surveyed (89%) 'occasionally' or 'often' encounter language barriers in their IC process. Figure 3 shows the methods used by anaesthetists to overcome language barriers if encountered during the process of IC. Other methods to overcome the language barrier include contacting the patient's family members or using another medical professional to translate. The majority (64.9%) of the respondents indicated that their IC process was unaffected by whether the case was an emergency or an elective.

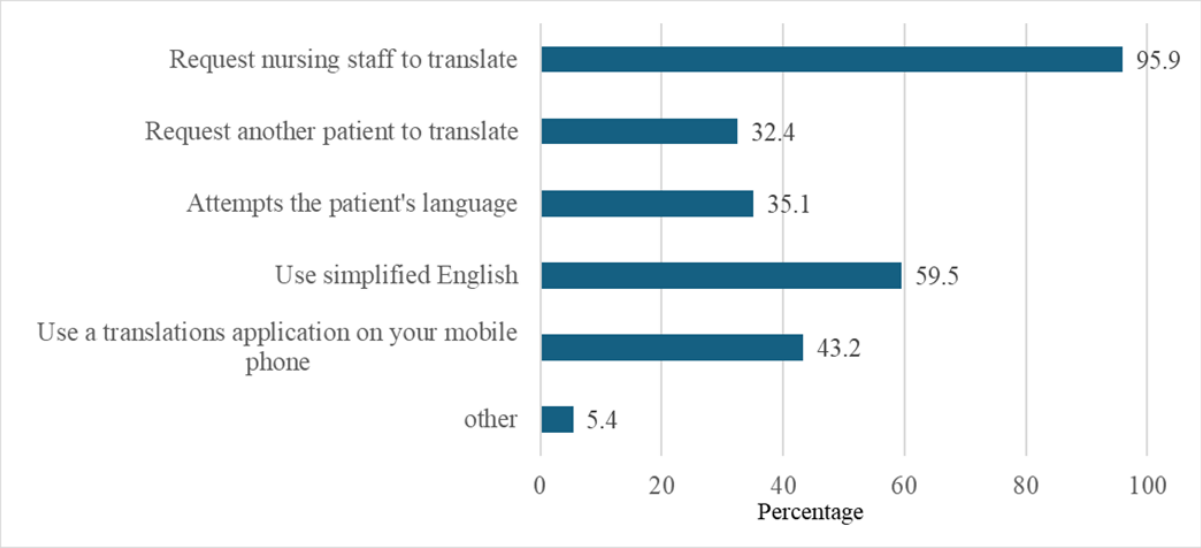


Figure 3: Options used by anaesthetists to overcome language barrier.

A weak positive correlation exists between the anaesthetic experience and the frequency with which IC is obtained in the patient's preferred language, rho = 0.24, p = 0.04. Those with more experience are more likely to address the patients in their preferred language.

There is a correlation between anaesthetic experience and using another patient as a translator when obtaining IC, Fisher's exact = 8.91, p = 0.02. A weak positive correlation exists between experience and discussing risks for GA, rho=0.24, p=0.04. More experienced respondents more readily discussed risks with the patients.

3.6 Discussion

The study shows that the IC process for obstetric anaesthesia at hospitals associated with the University of Witwatersrand is variable.

In the question regarding self-assessment of the adequacy of IC, 'adequacy' was deliberately not defined to assess the respondent's subjective view of their practices. More than half of the respondents felt that their IC process was adequate. Poor compliance with general and vital aspects of IC, such as documented written consent, suggests a false sense of adequacy. Since ethics training forms part of the undergraduate and postgraduate curricula, their perception of adequacy is an example of overconfidence bias rather than a lack of knowledge. [14]

The Patients' Rights Charter stipulates that patients have the right to be treated by a named healthcare provider. [15] There is good compliance in our study as 83.8% 'always' introduce themselves by name. This is much better

than in other Sub-Saharan countries such as Eritrea, where a study found that only 15% of anaesthetists introduced themselves and in Ethiopia, where 23.5% introduced themselves. [16, 17]

Despite the South African Society of Anaesthesiologists (SASA) guidelines recommending that patients be informed of their anaesthetist's qualifications and experience level [18], the majority (68.9%) 'never' or 'rarely' introduce themselves by rank. Rank generally denotes the level of experience or expertise that affects the service quality. A study done in Mthatha found that the rate of failed spinal is associated with the level of experience of the anaesthetist. [19] A study at Inkosi Albert Luthuli Hospital found that 42% of the patients preferred to know the level of experience of their anaesthetist. [14] South African ethics experts were asked to validate a consent form in its development phase, and they did not find rank essential for the IC process, as shown by a content validity index (CVI) of less than 0.8. [20] The influence of rank on the adequacy of informed consent is thus not clearly defined.

According to HPCSA practice guidelines as outlined in booklet 4, consent must always be expressed and never implied. [9] It is concerning that 6.8% of the respondents used implied consent for an invasive procedure. The definition of implied consent was provided in the questionnaire to eliminate confusion about its meaning.

The SASA guidelines stipulate that IC must be written or that some record or note be made in the patient file. [18] Written IC is needed if the proposed treatment is complex or carries significant risks. [9, 21] Only 8.1% use written consent and less than half of those who use verbal consent document it in the patient's record. Undocumented verbal consent is invalid.

There is no dedicated anaesthetic consent form at the hospitals where respondents work. This is likely the reason for the low usage of written consent and the low documentation of verbal consent. A recent quality improvement study at a South African university indicates that a standardised anaesthetic consent form increases the documentation rate. [22]

GA and spinal anaesthesia are seldom offered together as viable options for caesarean section (CS). This is in keeping with a previous study finding that 95% of the postpartum women knew that spinal anaesthesia was an option for CS versus only 43% who knew GA was also an option. [13] This indicates that anaesthetists are still applying a paternalistic approach in choosing the mode of obstetric anaesthesia.

In the literature, high-frequency and high-morbidity side effects and complications or those with implications for adverse foetal outcomes are most frequently disclosed. [23] Nausea and vomiting, conversion to GA, and post-puncture headaches were the most frequently disclosed risks in this study, while death and cardiac arrest were

the least likely to be mentioned. This is similar to a North American study where death and cardiac arrest were also less frequently disclosed compared to headache, local pain or discomfort and the risk of infection. [24] The SASA practice guidelines require rare but catastrophic complications such as death and paralysis to be mentioned to the patient. [18] A possible reason why anaesthetists are reluctant to disclose these risks is to decrease patient anxiety. The respondents frequently disclose conversion to GA, possibly because it changes the patient's entire experience of the birth of her baby. A study in a South African academic institution found the incidence of failed spinal anaesthesia to be 11.7%. [19] Disclosure of this risk is thus warranted.

Respondents continue to show a bias towards spinal anaesthesia as they omit to mention GA. This may be because spinal anaesthesia is safer for the mother and baby. General anaesthesia is associated with higher rates of perioperative haemorrhage and a greater risk of neonatal depression. Respondents disclosed the risk of aspiration of gastric contents significantly more than other complications. This might be because aspiration is easier to explain, and prevention is relatively well established.

SASA recommends that common risks, as well as material risks, be fully explained. [18] Quantification of risks is vital to delineate the common risks from the rare ones. [18] While some risks are more often quantified than others, achieving a 100% quantification rate is difficult. This limitation is often due to the absence of specific data for the specific institutions. Accurate risk assessment requires data relevant to the specific healthcare system and population. [7] The lack of quantification may reflect the lack of such data.

Anaesthetists frequently encounter language barriers. It is in keeping with the findings of a scoping review that described counselling, IC and debriefing in sub-Saharan Africa and found language differences to be a barrier to effective counselling. [25] Despite this barrier, most respondents claimed to address patients in the patient's preferred language, demonstrating the diversity in their language capabilities.

Respondents use informal interventions to overcome language barriers. Nursing staff are frequently used to translate. They are ideally placed to be translators due to their medical knowledge and being bound by patient confidentiality. A significant advantage of the artificial intelligence era is that various translation applications are available and are commonly used by respondents. The Association of Anaesthetists (ASA) advises against using family members to interpret as it risks the patient being coerced and inaccurate information being relayed between the patient and the anaesthetist. It also compromises the patient’s right to privacy and confidentiality. [26]

Work experience was associated with the use of other patients as translators, as well as a tendency to disclose more complications. An Ethiopian study assessing the practices and factors associated with IC found that work experience of more than ten years was positively associated with adequate practice of IC. [27]

Most respondents do not adjust their IC when dealing with elective or emergency surgery. Due to an overburdened obstetric service at the hospitals where respondents work, it is common for most CS to be done as emergencies. Elective CS are often unscheduled and performed between emergencies. They arrive in the operating theatre in the same manner as emergencies. Patients in both categories are interviewed upon arrival at the operating theatre. The emergency setting is characterised by time pressure and high stakes, as any delay can compromise the mother or baby. The process of IC may be rushed under those circumstances. It is concerning that even elective cases are treated in the same manner, especially given the other findings of this study that point to an inadequate process of IC.

The strength of this study is that it serves as the basis for further research into the IC process and measures to improve IC for obstetric anaesthesia. It also contributes to a body of evidence pointing to the inadequacy of IC in obstetric anaesthesia. Anonymity allowed for frank reflection of the practices of individuals without fear of retribution for wrongdoing.

This study must be read against certain limitations. This study is not generalisable as it only targeted anaesthetic registrars and medical officers associated with the University of Witwatersrand. Self-reported studies pose the risk of social desirability bias, a form of self-report bias where respondents give answers to paint themselves in a better light than reality. [28] The lack of clear guidelines for IC makes it challenging to determine the IC process objectively. Using a 5-point Likert scale meant that a significant portion of respondents chose the middle category of ‘occasionally’, thus not committing to what their actual practice is.

Quality improvement projects can include the use of patient leaflets, informational videos, and dedicated anaesthetic consent forms. The development and use of written consent tools require further research. Research on the use of medical translation applications is also needed.

3.7 Conclusion

The process of obtaining IC for obstetric anaesthesia at hospitals associated with the University of the Witwatersrand is variable. Undocumented verbal consent obtained by named anaesthetists in the patient’s preferred language is the most common practice. Quality improvement strategies are recommended.

3.8. Conflict of interest

The authors declare that we have no financial or personal relationships which may have inappropriately influenced the writing of this paper.

3.9 Disclosures

This research was done in partial fulfilment of a Master of Medicine degree.

3.10References

1. Wilson EH, Burkle CM. The Meaning of Consent and Its Implications for Anesthesiologists. Adv Anesth. 2020;38:1-22. https://doi.org/10.1016/j.aan.2020.07.001

2. Bolton KD. Informed consent. SA Orthop J. 2012 11(3):108-111. Available from: http://www.scielo.org.za/pdf/saoj/v11n3/14.pdf. Accessed 26 May 2022.

3. Hoehner PJ. Ethical Aspects of Informed Consent in Obstetric Anesthesia—New Challenges and Solutions. J Clin Anesth. 2003;15(8):587-600. http://dx.doi.org/10.1016/S0952-8180(02)00505-6

4. Bárbara F, Sílvia M, Diana A, Sofia D, Miguel R. Informed consent in anesthesiology: an exploratory study. Acta Bioeth. 2022;28(2):281-289. http://dx.doi.org/10.4067/S1726-569X2022000200281

5. Bester J, Cole CM, Kodish E. The Limits of Informed Consent for an Overwhelmed Patient: Clinicians' Role in Protecting Patients and Preventing Overwhelm. AMA J Ethics. 2016;18(9):869-886. http://dx.doi.org/10.1001/journalofethics.2016.18.9.peer2-1609

6. The Medical Protection Society. Consent-The basics Medical Protection Society 2021 updated 8 Jan 2021. Available from: https://www.medicalprotection.org/southafrica/casebook-and-resources/factsheets/factsheets/sa-consent-the-basics Accessed 20 Nov 2023.

7. Middle JV, Wee MY. Informed consent for epidural analgesia in labour: a survey of UK practice. Anaesthesia. 2009;64(2):161-164. https://doi.org/10.1111/j.1365-2044.2008.05679.x

8. Chima SC. "Because I want to be informed, to be part of the decision-making": Patients' insights on informed consent practices by healthcare professionals in South Africa. Niger J Clin Pract. 2015;18:46-56. http://dx.doi.org/10.4103/1119-3077.170833

9. Health Professionals Council of South Africa. Seeking Patients' informed consent: The ethical consideration Booklet 4. HPCSA website: HPCSA; 2016. Available from: https://www.hpcsa.co.za/Uploads/Professional_Practice/Conduct%20%26%20Ethics/Booklet%204%20Informed%20Consent%20September%20%202016.pdf. Accessed 23 June 2022

10. Lindor RA, Kunneman M, Hanzel M, Schuur JD, Montori VM, Sadosty AT. Liability and Informed Consent in the Context of Shared Decision Making. Acad Emerg Med. 2016;23(12):1428-1433. http://dx.doi.org/10.1111/acem.13078

11. Childress JF, Childress MD. What Does the Evolution From Informed Consent to Shared Decision Making Teach Us About Authority in Health Care? AMA J Ethics. 2020;22(5):423-429. http://dx.doi.org/10.1001/amajethics.2020.423

12. Dickens BM, Cook RJ. Types of consent in reproductive health care. Int J Gynaecol Obstet. 2015;128(2):181-184. https://doi.org/10.1016/j.ijgo.2014.11.001

13. Möller C. Knowledge and the sources of knowledge of spinal anaesthesia in primiparous women who have received a caesarean section: University of the Witwatersrand; 2015.Available from: https://wiredspace.wits.ac.za/items/e259c3dd-12d9-41e2-8d39-73680103d5d6. Accessed 20 April 2022

14. Naidu S, Goplan P. The informed consent process for anaesthesia: perspectives of elective surgical patients at Inkosi Albert Luthuli Central Hospital, South Africa. South Afr J Anaesth Analg. 2016;22(2):60-64. https://doi.org/10.1080/22201181.2016.1157963

15. Health Professionals Council of South Africa. Guidelines for good practice in the health care professionals national patients' rights charter Booklet 3. Health Professionals Council of South Africa, Department of Health; 2008. Available from: https://www.hpcsa.co.za/Uploads/professional_practice/ethics/Booklet_3_Patients_Rights_Charter_September_2016v2.pdf. Accessed 12 December 2023

16. Gebremedhn EG, Nagaratnam V. Assessment of patient satisfaction with the preoperative anesthetic evaluation. Patient Relat Outcome Meas. 2014;5(0):105-110. https://doi.org/10.2147/PROM.S66737

17. Andemeskel YM, Elsholz T, Gebreyohannes G, Tesfamariam EH. Patient satisfaction with peri-operative anesthesia care and associated factors at two National Referral Hospitals: a cross sectional study in Eritrea. BMC Health Serv Res. 2019;19(1):669. https://doi.org/10.1186/s12913-019-4499-x

18. South African Society of Anaesthesiologists. SASA Practice Guidelines 2022. SASA; 2022. Available from: https://sasaweb.com/wp-content/uploads/2022/09/SASA-Practice-Guidelines-2022-Consolidated-Final.pdf. Accessed 04 June 2024

19. Alabi AA, Adeniyi OV, Adeleke OA, Pillay P, Haffajee MR. Factors associated with failed spinal anaesthesia for Caesarean sections in Mthatha general hospital, Eastern Cape, South Africa. S Afr Fam Pract. 2017;59(4):128-132. https://doi.org/10.1080/20786190.2017.1292696

20. San Pedro K. Development and validation of an anaesthetic consent form [unpublished thesis]. University of the Witwatersrand2021.Available from: https://wiredspace.wits.ac.za/server/api/core/bitstreams/0df0da90-b9c3-46e7-8614-4b42f39c0fb6/content. Accessed 05 June 2024

21. Gelb AW, Morriss WW, Johnson W, Merry AF, Gelb AW, Merry AF, et al. World Health Organization-World Federation of Societies of Anaesthesiologists (WHO-WFSA) International Standards for a Safe Practice of Anesthesia. Can J Anesth/J Can Anesth. 2018;65(6):698-708. https://doi.org/10.1007/s12630-018-1111-5

22. Burger R, Smit M, Plenge U, Gibbs M. Informed consent for peripheral nerve blocks at a tertiary level hospital in South Africa: a quality improvement project. S Afr J Anaesth Analg. 2024;30(2):62-72. https://doi.org/10.36303/SAJAA.3061

23. Broaddus BM, Chandrasekhar S. Informed Consent in Obstetric Anesthesia. Anesth Analg. 2011;112(4):912-915. https://doi.org/10.1213/ane.0b013e31820e777a

24. Brull R, McCartney CJL, Chan VWS, Liguori GA, Hargett MJ, Xu D, et al. Disclosure of Risks Associated With Regional Anesthesia: A Survey of Academic Regional Anesthesiologists. Reg Anesth Pain Med. 2007;32(1):7-11. https://doi.org/10.1016/j.rapm.2006.07.005

25. Faysal S, Penn-Kekana L, Day L, Tripathi V, Khan F, Stafford R, et al. Counseling, informed consent, and debriefing for cesarean section in sub- Saharan Africa: A scoping review. Int J Gynecol Obstet. 2023;00:1-16. https://doi.org/10.1002/ijgo.15079

26. McCombe K, Bogod D. Regional anaesthesia: risk, consent and complications. Anaesthesia. 2021;76:18-26. https://doi.org/10.1111/anae.15246

27. Negash W, Assefa N, Baraki N, Wilfong T. Practice and Factors Associated with Informed Consenting Process for Major Surgical Procedures Among Health-Care Workers, South Eastern Ethiopia. Int J Gen Med. 2021;14:7807-7817. https://doi.org/10.2147/IJGM.S338243

28. Bauhoff S. Self-Report Bias in Estimating Cross-Sectional and Treatment Effects. In: Michalos AC, editor. Encyclopedia of Quality of Life and Well-Being Research. Dordrecht: Springer Netherlands; 2014. p. 5798-5800. Available from: https://doi.org/10.1007/978-94-007-0753-5_4046.

Section 4: Protocol

The process of IC for obstetric anaesthesia in the Department of Anaesthesia at the University of Witwatersrand, a descriptive cross-sectional study

Name: Wazha Andrew Senyahale

Student number: 2640699

Supervisor: Dr Dorinka Nel

Department of Anaesthesiology

Co-supervisor: Dr Cara Redelinghuys

Department of Anaesthesiology

4.1 Introduction

The anaesthetist has a fiduciary duty to obtain Informed Consent (IC) before providing a service to the patient. This IC is based on legal, moral, and ethical principles, which need to be done effectively despite any potential challenges that may be encountered. [1] South African law states that any procedure or treatment on a patient without proper IC constitutes an assault. [2] IC gives the anaesthetist permission to perform procedures on the patient that may otherwise be impermissible. [3] For anaesthetists, IC should not be to avoid litigation or protect against accusations and civil suits but rather facilitate patient care. [4]

South African laws which govern IC include the National Health Care Act 61 of 2003 (NHA), the Constitution of the Republic of South Africa, The Children's Act 38 of 2005, the Health Professional Council of South Africa guidelines and various other statutes, as well as the common law. [5] A study to determine the knowledge of anaesthetists at the University of the Witwatersrand reveals gaps in their knowledge and a need for interventions to improve the depth and understanding of consent law among anaesthetists. [6] The surveyed anaesthetists performed the worst at questions assessing knowledge of the Children's Act and National Health Act. [6] Both these acts are fundamental for IC to promote patients' autonomy.

IC is a process led by the health care provider for the patient's benefit in which information about risks, benefits and alternatives to proposed treatment or interventions are shared with the patient to assist in their decision-making. [7] It promotes individual autonomy, protects patients, avoids fraud and coercion, encourages self-scrutiny by medical professionals, promotes rational decisions, and involves the public in decision-making. [3]

Information disclosure, understanding of information, and authorisation of consent to the medical intervention are critical elements of IC. [8] The benefits and material risks related to both general and neuraxial anaesthesia must be discussed with the patient. The lists of risks and benefits can be very long, so there has been a shift towards the "material risk" standard of information disclosure. [8] According to the Health Professional Council of South Africa

guidelines, information is material if "a reasonable person in the position of the patient, if warned of the risk, would attach significance to it; and the health care practitioner should reasonably be aware that the patient if warned of the risk, would attach significance to it ". [5]

The prerequisites to IC are capacity and voluntariness. [2, 9] Voluntariness implies a decision made without a promise of a reward, coercion, manipulation, or persuasion [2]

Patients with the mental capacity to make an informed decision encounter instances where this capacity is limited by emotional overwhelm, information overwhelm, or both. Emotional overwhelm occurs when the patient perceives the risks involved as too serious to make a decision. Informational overwhelm is when the patient cannot understand the medical information and, therefore, cannot make decisions based on that information. [9] Informational overwhelm cannot be solved by using a surrogate because the information that overwhelms the patient can also overwhelm the surrogate decision-maker. It requires a more personal approach, such as shared decision-making [9]. Shared decision-making allows the patients to ask questions about things they do not understand.

The approach to obtaining consent for medical procedures has evolved from a paternalistic approach with the healthcare provider being the primary decision-maker to one where patient autonomy is the focus. [1] The paternalistic approach does not consider other factors such as the patient's cultural or religious beliefs, their level of education or their level of understanding. [10]

Shared decision-making involves information sharing between the clinician and the patient. [1] Shared decision-making represents the middle point between an autonomy approach, "patient knows best", and a paternalistic system of "clinician knows it all". [3] Shared decision-making is a collaborative approach focusing on understanding the patients' circumstances and perspectives to address their needs. [10] The American College of Obstetricians and Gynaecologists Opinion Committee of 2009 considers shared decision-making the highest ethical standard model for IC. [11]

In anaesthesia, IC still predominates with little progression towards shared decision-making. [12] Decision aids have been used to increase shared decision-making even though there is no evidence to suggest that more information shared with patients increases the engagement needed for successful shared decision-making. A proposed hindrance is the patients' focus on the IC given for surgery and not deeming anaesthetic consent as critical. Time constraint in the perioperative period is another proposed limitation. [13]

In the United States of America (USA), the professional practice standard is the standard of information disclosure, which focuses on the information the health care provider shares rather than the patient's understanding. [3] The patient either accepts or rejects the proposed course of treatment. [14]

The pregnant and labouring woman presents a unique set of challenges in obtaining IC. Patients may not have received antenatal education. During unplanned emergency interventions, there is limited time to provide extensive education. [15] Effective information sharing and consent are difficult during labour due to distractions such as contractions, pain and medication with opioids. [16]

Additional obstacles include language barriers, especially for immigrant women. [11] The National Health Act requires doctors to obtain consent in a language the patient understands, which aligns with their literacy level. This is challenging in South Africa, which has eleven official languages and many immigrants. [17]

Despite these challenges, women in labour can make decisions even when disagreeing with the clinician or family members. They must participate fully in shared decision-making and give IC for treatments proposed. [4, 11] A 2019 literature review concluded that there is insufficient data to determine whether labouring women maintain their capacity to give consent. [18] The interests of the family, the woman's partner and what is deemed best for the foetus are competing interests that a labouring mother may need to consider in making an informed decision. [19]

A 2009 survey in the United Kingdom (UK) of the practice of anaesthetists in obtaining IC for epidural anaesthesia shows variations in the information and risks mentioned and the incidence of those risks. [19, 20] This is attributed to some risks being poorly documented in the literature with no reliable incidence data. [15] The onus is on the anaesthetists to be updated on the latest figures to enable better information sharing. [15]

In the African context, a study conducted in Nigeria in 2015 shows that only a third of the anaesthetists surveyed obtained IC before performing epidurals on their patients. [21] A survey of the access to safe obstetric anaesthesia in five East African countries from 2013 to 2014 finds that 85% of the clinicians surveyed say they checked preoperative consent including consent for both surgery and anaesthesia. [22] Both these studies were not explicit about how IC is obtained.

A study by Möller at Chris Hani Baragwanath shows that only a third of primigravidas got information about spinal anaesthesia from the anaesthetist. Anaesthetists are the experts concerning spinal anaesthesia and, ideally, should be the source of information for all parturients. [23]

A University of KwaZulu Natal (UKZN) study assessing the process of IC from the patient's perspective reveals a dismal amount and depth of information shared with patients preoperatively. It also shows a lack of standardisation of the process. [24]

According to the 2020/2021 Health Professional Council of South Africa annual report, IC constitutes 1.6% of complaints lodged with the statutory body about health care providers in South Africa. [25] This small number may underestimate the extent of the problems as it only represents cases reported to the Health Professional Council of South Africa. [26]

Taking into consideration available evidence that the knowledge of the laws governing IC is lacking and IC from the patient's perspective is lacking, this study aims to understand the process of obtaining IC for obstetric anaesthesia as reported by the anaesthetists at hospitals associated with the University of the Witwatersrand Department of Anaesthesiology.

4.2. Problem statement

The current practice in South Africa, as evaluated from a patient's perspective at a tertiary hospital in KwaZulu Natal, showed serious inadequacies regarding the information shared with patients by the anaesthetist before administering anaesthesia. The researchers suggested that a standardised process of obtaining IC for anaesthesia might alleviate some of the weaknesses in the process. [24] Currently, there is no data on how IC is obtained and what information is discussed by anaesthetists when consenting patients for anaesthesia in obstetrics in South Africa. Medical practitioners are ideally positioned to provide information for obstetric anaesthesia. [23] There is evidence that anaesthetists lack knowledge of IC laws, so an investigation of the current processes of IC is necessary. [6]

4.3. Aim

This study aims to describe the process of obtaining IC for obstetric anaesthesia as reported by anaesthetists at hospitals associated with the University of the Witwatersrand Department of Anaesthesiology.

4.3. Objectives

The objectives of this study are to:

Describe the demographics (age, gender and years of experience) of anaesthetists obtaining consent for obstetric anaesthesia.

Describe the documentation of IC

Describe the information provided to the patient

Describe language use in the process of IC

Describe the perception of anaesthetists regarding the adequacy of their IC process

Describe the process of IC in relation to years of anaesthetic training.

4.4 Research assumption

The following definitions will be used in this study:

Anaesthetists: Any qualified doctor working in the Department of Anaesthesiology. For this study, an anaesthetist will refer to medical officers and registrars.

Respondents: Anaesthetists who will complete the survey questionnaire

Implied consent: Refers to when a patient passively cooperates in a process without discussion. There is no documentation by either the patient or clinician.

Verbal consent: Consent in which a patient verbally states their agreement to a procedure but does not sign any written form. The clinician must document that verbal consent has been obtained.

Written consent: Consent when both the patient and the clinician sign and date a document to show their agreement.

4.5. Demarcation of the study field

The study will be conducted in Johannesburg in the Department of Anaesthesia at the University of the Witwatersrand. The staff complement of the department that will be sent a questionnaire consists of 119 registrars and 21 medical officers.

5.6. Ethical considerations

Ethics approval will be obtained from the Human Research Ethics Committee (Medical) and the University of the Witwatersrand Graduate Studies Committee before data collection. Approval to conduct the study will be obtained from Prof. Motshabi, the Academic Head of the Department of Anaesthesiology of Wits (Appendix A). Permission to collect data will be obtained from the Head of Department of Anaesthesia at each hospital (Appendix B).

To ensure confidentiality, respondents will be allocated a unique study number. The data will be analysed without identifying information; only the researcher and supervisors can access raw data. Data will be stored securely electronically on a password-protected database for six years after completion of the study.

Consent is implied if a respondent completes the questionnaire after reading the study information letter (Appendix C).

4.7. Research Methodology

Research design

A descriptive survey study will be conducted. Primary data will be collected using a newly adapted questionnaire (Appendix D). The questionnaire will utilise Likert-type scale responses and multiple-choice questions to be completed by the respondent on RedCap®. Only invited respondents may complete the survey, and the respondents' identities are concealed.

Study population

The study population comprises medical officers and registrars in the Department of Anaesthesiology at the University of the Witwatersrand.

Study sample

Sample method

A voluntary response sample will be used where respondents can either respond or ignore the questionnaire.

Sample size

Based on a pool of 131 anaesthetists and assuming a population proportion of 90% to achieve a maximum 95% confidence interval margin of error of 5%, the sample size will be 68 respondents. This sample size was calculated using an online calculator at www.calculator.net [27].

An initial email will be sent out, followed by reminders on the departmental social media platforms to encourage participation. Reminder emails will be resent depending on response rates. If the online response fails to reach the required sample size, hard copies of the questionnaire will be distributed to respondents who have not yet completed the online questionnaire.

Inclusion criteria

All medical officers and registrars working in the Department of Anaesthesiology at the time of the study will be included. All questionnaires, including partially completed questionnaires, will be included in the data analysis.

Exclusion criteria

Interns are excluded from the study because they rotate through the department every two months. The interns within the department at the time of data collection will not be a representative sample of all the interns. Consultants will be excluded due to their lack of involvement in daily obstetric anaesthesia.

Data collection

An online self-report questionnaire will be used as the primary data collection tool. A link to the questionnaire will be emailed to the target population after approval by the Human Research Ethics Committee. The questionnaire will take 10 minutes to complete.

Questionnaire validation

The adapted questionnaire is based on previous work by Middle and Wee and has been validated for internal and content validity by a panel of experts in South Africa. [20] Permission has been obtained to use the questionnaire (Appendix E). The validation process will ensure that the survey is reproducible. [28]

Data analysis

Descriptive statistics will describe the survey data. These statistics include frequency and measures of central tendency such as mean, median and mode, and dispersion measures such as standard deviation and range, as well as a percentage.

A biostatistician was consulted in the development of the research protocol and will be consulted for data analysis. SPSS will be used as the data management software for data analysis.

4.8. Significance of the study

This study will document how IC is obtained for obstetrics anaesthesia. This data will inform other quality improvement projects aimed at optimising the interaction of the anaesthetist and the patient to obtain IC for obstetric anaesthesia.

4.9. Validity and reliability of the study

Bias and confounding factors

Nonresponse bias is a severe threat to this study as the population targeted are busy and focused on other things. To counter this, sufficient time will be given for respondents to participate, and the emails will be sent from a reputable source such as the Faculty Office or Head of the Department. Respondents will be reminded to participate after the initial email. Hard copies will be available to respondents who did not complete the online questionnaire.

Random error is minimised by selecting the correct sample size representative of the population. Selection bias is addressed by including all registrars and medical officers and excluding medical interns and consultants

Surveys that require clinicians to report on their practices are predisposed to self-report bias, where respondents may try to underreport perceived bad practices. This will be addressed by maintaining anonymity and confidentiality.

4.10 Potential limitations of the study

This study will depend on the response rate of the participants and may be limited by a poor response rate. Responses given may not be truthful. This descriptive study is specific to the Department of Anaesthesia at the University of the Witwatersrand, so the results may not reflect the practice of the province or country.

4.11 Project outline

Year	2022-2023											
Months	J	F	M	A	M	J	J	A	S	O	N	D
Literature review												
Preparing protocol												
Protocol assessment												
Ethics application												
Collecting Data												
Data analysis												
Writing up thesis												
Writing up paper												

Financial plan

The cost will be kept at a minimum. The University of the Witwatersrand will subsidise printing costs.

RedCap® is an open source free online platform; therefore, it will not incur any monetary costs.

Item	Price per page	Number of pages	Copies	Total
Proposal	2	20	10	R 400
Ethics	2	20	25	R1000
Postgraduate form	2	2	6	R24
Complete report	2	100	4	R 800
Total				R 2224

4.12 References

1. Wilson EH, Burkle CM. The Meaning of Consent and Its Implications for Anesthesiologists. Adv Anesth. 2020;38:1-22. https://doi.org/10.1016/j.aan.2020.07.001

2. Bolton KD. Informed consent. SA Orthop J. 2012 11(3):108-111. Available from: http://www.scielo.org.za/pdf/saoj/v11n3/14.pdf. Accessed 26 May 2022.

3. Childress JF, Childress MD. What Does the Evolution From Informed Consent to Shared Decision Making Teach Us About Authority in Health Care? AMA J Ethics. 2020;22(5):423-429. http://dx.doi.org/10.1001/amajethics.2020.423

4. Hoehner PJ. Ethical Aspects of Informed Consent in Obstetric Anesthesia—New Challenges and Solutions. J Clin Anesth. 2003;15(8):587-600. http://dx.doi.org/10.1016/S0952-8180(02)00505-6

5. Health Professionals Council of South Africa. Seeking Patients' informed consent: The ethical consideration Booklet 4. HPCSA website: HPCSA; 2016. Available from: https://www.hpcsa.co.za/Uploads/Professional_Practice/Conduct%20%26%20Ethics/Booklet%204%20Informed%20Consent%20September%20%202016.pdf. Accessed 23 June 2022

6. Mamoojee A, Alli A. Anaesthetists' knowledge of South African Law pertaining to informed consent in an academic centre. South Afr J Anaesth Analg. 2018;24(6):155-164. http://dx.doi.org/10.1080/22201181.2018.1523861

7. Shah P, Thornton I, Turrin D, Hipskind JE. Informed Consent. StatPearls. Treasure Island (FL)2022. p. 1-8. Available from: https://www.ncbi.nlm.nih.gov/pubmed/28613577.

8. Chima SC. "Because I want to be informed, to be part of the decision-making": Patients' insights on informed consent practices by healthcare professionals in South Africa. Niger J Clin Pract. 2015;18:46-56. http://dx.doi.org/10.4103/1119-3077.170833

9. Bester J, Cole CM, Kodish E. The Limits of Informed Consent for an Overwhelmed Patient: Clinicians' Role in Protecting Patients and Preventing Overwhelm. AMA J Ethics. 2016;18(9):869-886. http://dx.doi.org/10.1001/journalofethics.2016.18.9.peer2-1609

10. Lindor RA, Kunneman M, Hanzel M, Schuur JD, Montori VM, Sadosty AT. Liability and Informed Consent in the Context of Shared Decision Making. Acad Emerg Med. 2016;23(12):1428-1433. http://dx.doi.org/10.1111/acem.13078

11. ACOG Committee Opinion No. 819: Informed Consent and Shared Decision Making in Obstetrics and Gynecology. Obstet Gynecol. 2021;137(2 Part 1):34-41. http://dx.doi.org/10.1007/978-3-031-62756-9_44

12. Stubenrouch FE, Mus EMK, Lut JW, Hesselink EM, Ubbink DT. The current level of shared decisionmaking in anesthesiology: an exploratory study. BMC Anesthesiol. 2017;17(1):95-95. https://doi.org/10.1186/s12871-017-0386-3

13. Sturgess J, Clapp JT, Fleisher LA. Shared decision-making in peri-operative medicine: a narrative review. Anaesthesia. 2019;74:13-19. https://doi.org/10.1111/anae.14504

14. Kunneman M, Montori VM. When patient-centred care is worth doing well: informed consent or shared decision-making. BMJ Qual Saf. 2017;26(7):522-524. https://doi.org/10.1136/bmjqs-2016-005969

15. Dyer RH. Informed consent for epidural analgesia in labour. South Afr J Anaesth Analg. 2007;13(1):27-34. https://doi.org/10.1080/22201173.2007.10872462

16. Mahomed K, Chin D, Drew A. Epidural analgesia during labour – maternal understanding and experience – informed consent. J Obstet Gynaecol 2015;35(8):807-809. https://doi.org/10.3109/01443615.2015.1011103

17. Hunter-Adams J, Rother H-A. A Qualitative study of language barriers between South African health care providers and cross-border migrants. BMC Health Serv Res 2017;17(1):97-106. https://doi.org/10.1186/s12913-017-2042-5

18. Wada K, Charland LC, Bellingham G. Can women in labor give informed consent to epidural analgesia? Bioethics. 2019;33(4):475-486. https://doi.org/10.1111/bioe.12517

19. Smith MK, Levy KS, Yudin MH. Informed Consent During Labour: Patient and Physician Perspectives. J Obstet Gynaecol Can. 2018;40(5):614-617. https://doi.org/10.1016/j.jogc.2017.12.013

20. Middle JV, Wee MY. Informed consent for epidural analgesia in labour: a survey of UK practice. Anaesthesia. 2009;64(2):161-164. https://doi.org/10.1111/j.1365-2044.2008.05679.x

21. Olatosi JO, Adekola OO, Anaegbu NC, Adesida A, Rotimi MK. Anaesthetists' attitudes and practice of informed consent in Nigeria. J West Afr Coll Surg. 2016 6(4):83-103. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5667723/. Accessed 03 August 2022.

22. Epiu I, Tindimwebwa JVB, Mijumbi C, Chokwe TM, Lugazia E, Ndarugirire F, et al. Challenges of Anesthesia in Low- and Middle-Income Countries: A Cross-Sectional Survey of Access to Safe Obstetric Anesthesia in East Africa. Anesth Analg. 2017;124(1):290-299. https://doi.org/10.1213/ANE.0000000000001690

23. Möller C. Knowledge and the sources of knowledge of spinal anaesthesia in primiparous women who have received a caesarean section: University of the Witwatersrand; 2015.Available from: https://wiredspace.wits.ac.za/items/e259c3dd-12d9-41e2-8d39-73680103d5d6. Accessed 20 April 2022

24. Naidu S, Goplan P. The informed consent process for anaesthesia: perspectives of elective surgical patients at Inkosi Albert Luthuli Central Hospital, South Africa. South Afr J Anaesth Analg. 2016;22(2):60-64. https://doi.org/10.1080/22201181.2016.1157963

25. Health Professionals Council of South Africa. HPCSA ANNUAL REPORT 2020/2021. Report. Health Professionals Council of South Africa; 2021 30 September 2021. Available from: https://www.hpcsa.co.za/Uploads/Publications/2021/Annual%20Report/HPCSA%20FY2020-21%20Annual%20Report%20Approved%20Final.pdf. Accessed 10 October 2022

26. Govender K. Sign here! Do we know the law on informed consent? SAJAA. 2018 24(6). Available from: https://www.sajaa.co.za/index.php/sajaa/article/view/2159. Accessed 11 November 2018.

27. sample size calculator www.calculator.net 2022. Available from: https://www.calculator.net/sample-size-calculator.html?type=2&cl2=95&ss2=100&pc2=60&ps2=131&x=83&y=6#findci. Accessed 02 June 2022.

28. Story DA, Tait AR. Survey Research. Anesthesiology. 2019;130(2):192-202. https://doi.org/10.1097/aln.0000000000002436

4.13. Appendices

Appendix A: Permission from the Head of Department of Anaesthesiology

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
FACULTY OF HEALTH SCIENCES
WITS SCHOOL OF CLINICAL MEDICINE
DEPARTMENT OF ANAESTHESIOLOGY
Tel.(011)488 4344

08 August 2022

Postgrad Office

School of Clinical
Medicine Faculty of
Health Sciences
University of the
Witwatersrand

To Whom It May Concern

Permission To Conduct Research: Dr Wazha Andrew Senyahala- Student Number: 2640699

This is to confirm that I have read and given permission for **Dr Wazha Andrew Senyahale** toconduct research at in the Department of Anaesthesiology towards his/her

Mmed project titled ***"The process of IC for obstetric anaesthesia in the Department of Anaesthesia at the University of Witwatersrand: a descriptive cross-sectional study"***

Thank you.

Assoc. Prof. P Motshabi Chakane

Ass Prof P. Motshabi Chakane
HOD Wits Anaesthesia
HOU Cardiac Anaesthesia

Tel: +27 (0)11 488 4344
Cell: 083 432 1994
Email: palesa.motshabi@wits.ac.za
Website: www.wits.ac.za

WITS UNIVERSITY

WITS SCHOOL OF CLINICAL MEDICINE

FACULTY OF HEALTH SCIENCES

Charlotte Maxeke Johannesburg Academic Hospital, 6th Floor, Area 361/16, Jubilee Road, Parktown, Johannesburg

Appendix B: Request for permission to conduct research at various hospitals in the Department of Anaesthesia

University of the Witwatersrand,

Department of Anaesthesiology

Head of Department Anaesthesia

Charlotte Maxeke Johannesburg Academic Hospital (CMJAH)

Chris Hani Baragwanath Academic Hospital (CHBAH)

Helen Joseph Hospital (HJH)

Rahima Moosa Mother and Child Hospital(RMMCH)

27 July 2022

Dear Sir/Madam,

Re: Permission to conduct research in your department

My name is Dr Wazha Andrew Senyahale.

I am studying for a Master of Medicine in Anaesthesiology at the University of the Witwatersrand. I am seeking permission to do research in your department.

I am researching the process of IC for obstetric anaesthesia. This study documents how IC for obstetrics anaesthesia is obtained, including challenges encountered during the process.

The research will collect data from medical officers and registrars in the Department of Anaesthesiology. If they agree, they will be asked to complete an online questionnaire via

RedCap®. The questionnaire will take less than 10 minutes to complete. The participants will be able to complete the questionnaire at any time they choose.

By completing the questionnaire, consent to participation will be implied. Their responses will be treated confidentially, and identities (their names and the name of the organization) will be anonymous unless otherwise expressly indicated. Individual privacy will be maintained in all published and written data from the study.

The results will be communicated via master's thesis or published in academic journals.

The research participants will not be advantaged or disadvantaged in any way. They will be reassured that they can withdraw their permission at any time during this project without any penalty. There are no foreseeable risks in participating in this study. The participants will not be paid for this study.

All research data will be stored securely in a password-protected platform for six years.

I, therefore, request permission in writing to conduct my research at your organization.

Please let me know if you require any further information. I look forward to your response as soon as is convenient.

Yours sincerely,

Cara Redelinghuys

076 738 5493

carared003@gmail.com

Dr Wazha Andrew Senyahale

071 506 2499

2640699@students.wits.ac.za

Supervisor's name

Dr Dorinka Nel

083 362 3061

neldorinka@gmail.com

Please sign below to grant permission (cross out the rest)

CMJAH	CHBAH	HJH	RMMCH
Prof E Oosthuizen	Dr P Mogane	Dr B Gardner	Dr T Kleyenstuber
.....	.....	.....	.....

Appendix C: Information letter

Dear colleague,

My name is Wazha Andrew Senyahale. I am a registrar in the Department of Anaesthesiology at the University of the Witwatersrand.

I invite you to participate in my Master of Medicine in Anaesthesia research study entitled: The process of IC for obstetric anaesthesia at hospitals associated with the University of Witwatersrand; a descriptive cross-sectional study. This will be achieved by describing the demographics (age, gender and years of experience) of the anaesthetists obtaining consent for obstetric anaesthesia, describing documentation of IC, describing the information provided to the patient, describing the impact of language on the IC process and describing the perception of anaesthetists regarding the adequacy of their IC process.

I would like you to participate by completing the attached questionnaire.

The questionnaire is anonymous, and all responses obtained will be stored in a secure, confidential, password-protected manner. The only people who will access the raw data will be my supervisors and me. No identifying data will be requested or captured. If, at any stage, you feel uncomfortable participating in the questionnaire, you are welcome to withdraw from the study. Participation in this study is entirely voluntary, and consent will be implied by completing the questionnaire.

Answering this questionnaire should take less than 10 minutes. No incentives will be offered to complete this questionnaire.

If you have any questions about this study, please get in touch with me, Dr Wazha Andrew Senyahale, or either of my supervisors, Dr Cara Redelinghuys (+27 76 738 5493) or Dr Dorinka Nel (+27 83 362 3061).

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. The role of this committee is to protect the dignity and rights of all research participants. If you have any queries about the conduct of this study, please get in touch with the chairperson of the Human Research Ethics Committee, Professor Clement Penny, who may be contacted via:

- Email: Clement.Penny@wits.ac.za
- Telephone number: 011 717 2301

Telephone numbers for the Committee secretaries are 011 717 2700/1234, and the email addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for your time and participation.

Kind Regards,

Dr Wazha Andrew Senyahale

071 506 2499

monangagilo@yahoo.co.uk

Appendix D: Questionnaire

1. Demographics

   a. What is the year of your birth?

   b. Gender

   - Male
   - Female
   - Other
   - Decline to answer

   c. Designation/rank

   - Medical officer
   - Registrar

   d. Total anaesthetic experience?

   - ≤ 1 year
   - ≤ 2 years
   - ≤ 3 years
   - > 3 years

   e. What is your highest anaesthetic qualification?

   - No formal anaesthetic qualification
   - Diploma in Anaesthetics
   - FCA part 1
   - FCA part 2

3. In your opinion, do you regard your process of IC for the obstetric patient as adequate?

   - Strongly agree
   - Agree

- Undecided
- Disagree
- Strongly disagree

4. Do you introduce yourself by name prior to getting IC obstetric anaesthesia?
    - Never
    - Seldom
    - Occasionally
    - Often
    - Always

5. Do you introduce yourself by your rank (medical officer or registrar) prior to getting IC for obstetric anaesthesia?

    - Never
    - Seldom
    - Occasionally
    - Often
    - Always

6. What type of IC do you use most commonly in obstetric anaesthesia?
    - Implied consent (Refers to when a patient passively cooperates in a process without discussion.)
    - Verbal consent (Consent where a patient states their agreement to a procedure verbally but does not sign any written form.)
    - Written consent (Consent when both the patient and the clinician sign and date a document to show their agreement.)

7. In the event of verbal consent, do you document the verbal consent? (branching logic on Redcap)

- Never
- Seldom
- Occasionally
- Often
- Always

If yes, where do you document it? (Branching logic on Redcap)

- Patient's file
- Anaesthetic chart
- Surgical consent form
- Dedicated anaesthetic consent form

Other: Please specify (branching logic on Redcap)

8. In the event of written IC, where is it documented? (branching logic on Redcap)

- Patient's file
- Anaesthetic chart
- Surgical consent form
- Dedicated anaesthetic consent form
- Other: Please specify (branching logic on Redcap)

9. How often do you offer both spinal anaesthesia and general anaesthesia as viable options for caesarean section?

- Never
- Seldom

- Occasionally
- Often
- Always

10. How often do you discuss the following risks of spinal anaesthesia?

Risks	Always	Often	Sometim	Rarely	Never
Anaphylaxis					
Cardiac arrest					
Compression from a vertebral canal haematoma					
Compression from an epidural abscess/ meningitis					
Death					
High(total) spinal					
Hypotension					
Inadequate analgesia					
Local anaesthetic systemic toxicity					
Nausea and vomiting					
Need to convert spinal to general anaesthesia					
Post dural puncture headache					
Post spinal backache					
Pruritis					
Shivering					
Transient neurologic symptoms					
Nerve injury					
Urinary retention					
Other (branching logic on Redcap) Describe…… ……					

11. How often do you quantify the risk of the following complications of spinal anaesthesia? Choose "Not Applicable" for those complications that you never discuss with patients.

Risks	Always	Often	Sometimes	Rarely	Never	Not Applicable
Anaphylaxis						
Cardiac arrest						
Compression from a vertebral canal haematoma						
Compression from an epidural abscess/ meningitis						
Death						
High(total) spinal						
Hypotension						
Inadequate analgesia						
Local anaesthetic systemic toxicity						
Nausea and vomiting						
Need to convert spinal to general anaesthesia						
Post dural puncture headache						
Post spinal backache						
Pruritis						
Shivering						
Transient neurologic symptoms						
Nerve injury						
Urinary retention						
Other (branching logic on Redcap) Describe…… ……						

12. How often do you discuss the following risks of general anaesthesia?

Risk	Always	Often	Sometimes	Rarely	Never
Airway and dental trauma					
Anoxia and brain damage					
Aspiration of gastric contents and its consequences					
Awareness under general anaesthesia					
Depression of the foetus with narcotics					
Drug toxicity/side effects					
Increased risk of post-partum haemorrhage					
Loss of airway control (failed intubation) and need for surgical airway					
Post-operative nausea and vomiting					
Other(branching logic on Redcap)Describe……..					

13. How often do you quantify the risk of the following complications of general anaesthesia? Choose "Not Applicable" for those complications that you never discuss with patients.

Risk	Always	Often	Sometimes	Rarely	Never	Not applicable
Airway and dental trauma						
Anoxia and brain damage						
Aspiration of gastric contents and its consequences						
Awareness under general anaesthesia						
Depression of the foetus with narcotics						
Drug toxicity/side effects						
Increased risk of post-partum haemorrhage						
Loss of airway control (failed intubation) and need for surgical airway						
Post-operative nausea and vomiting						

14. How often do you obtain IC from obstetric patients in their preferred/home language?

- Never
- Seldom
- Occasionally
- Often
- Always

15. a. How often do you encounter a language barrier in the process of obtaining IC from obstetric patients? Tick one

- Never
- Seldom
- Occasionally
- Often
- Always

b. Once you encounter a language barrier do you use any of the options below to over the language barrier? Tick all options that apply (branching logic)

- Use nursing staff as a translator
- Use another patient as a translator
- Attempt the patient's language
- Use simplified English
- Use a translational application on your mobile device
- Other: Please describe (branching logic on Redcap)

16. Does your process of IC for obstetric anaesthesia change with elective cases versus emergency cases?

- Yes
- No

Appendix E: Permission to use questionnaire

Re: Permission to adapt parts of your questionnaire

From: Michael Wee (michaelwee533@gmail.com)

To: monangagilo@yahoo.co.uk

Date: Sunday, 13 February 2022 at 12:44 GMT+2

Dear Senyahale,

Thank you for contacting me. Please feel free to adapt our questionnaire for your dissertation provided you give proper acknowledgement to our publication. If possible, can you also send me a copy of your questionnaire with a statement that it was adapted from ours. I wish you very best wishes in your academic endeavours.

Kind regards

Prof. Michael Wee

On Sun, 13 Feb 2022 at 08:28, monanga gilo <monangagilo@yahoo.co.uk> wrote:

> Good day
>
> I am Wazha Senyahale currently a first year registrar in the department of Anaesthetics at Chris Hani Baragwanath Academic Hospital affiliated with the University of Witwatersrand in Johannesburg, South Africa.
>
> In February 2009 you published a study in Anaesthesia: Perioperative medicine, critical care and pain journal volume 64, Issue 2 pages 119 to 234. I would like to use themes from your questionnaire and some questions to formulate a new questionnaire for my dissertation study on the process of informed consent at my institution for obstetric anaesthesia.
>
> Could you please permit me to use parts of your work.
>
> I am looking forwad to hearing from you or your team.
>
> Kind regards
>
> Dr Wazha Senyahale
> MBChB, DA(SA)
> +27 71 506 2499
> Student number 2640699

5. Section 5: Annexures

5.1. Human Research Ethics Committee (Medical) approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Wazha Senyahale

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M230205 MED22-09-119

NAME: (Principal Investigator)	Dr Wazha Senyahale
DEPARTMENT:	Anaesthesia
PROJECT TITLE:	*The process of informed consent for obstetric anaesthesia in the Department of Anaesthesia at the University of Witwatersrand, a descriptive cross-sectional study*
DATE CONSIDERED:	24/02/2023
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr D. Nel and Dr C. Redelinghuys
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	23/05/2023 **EXPIRY DATE:** 23/05/2028

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 Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions.Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **February** and will therefore be due in the month of **February** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature — Date: 30/07/2023

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

5.2. Graduate Studies Committee Approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

06 January 2023
Person No: 2640699
PAG

Dr WA Senyahale
45 Hospital road
Brakpan,Ekurhuleni
Aeroton
2013
South Africa

Dear Dr Wazha Senyahale

Master of Medicine in Anaesthesia: Approval of Title

We have pleasure in advising that your proposal entitled *The process of informed consent for obstetric anaesthesia in the Department of Anaesthesia at the University of Witwatersrand, a descriptive cross-sectional study* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

5.3. Permission letter by the WITS Anaesthesiology Head of Department

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG | FACULTY OF HEALTH SCIENCES | WITS SCHOOL OF CLINICAL MEDICINE

DEPARTMENT OF ANAESTHESIOLOGY
Tel.(011)488 4344

08 August 2022

Postgrad Office

School of Clinical Medicine

Faculty of Health Sciences

University of the Witwatersrand

To Whom It May Concern

Permission To Conduct Research: Dr Wazha Andrew Senyahala- Student Number: 2640699

This is to confirm that I have read and given permission for **Dr Wazha Andrew Senyahale** to conduct research at in the Department of Anaesthesiology towards his/her Mmed project titled ***"The process of informed consent for obstetric anaesthesia in the Department of Anaesthesia at the University of Witwatersrand: a descriptive cross-sectional study"***

Thank you.

Assoc. Prof. P Motshabi Chakane

Ass Prof P. Motshabi Chakane
HOD Wits Anaesthesia
HOU Cardiac Anaesthesia
Tel: +27 (0)11 488 4344
Cell: 083 432 1994
Email: palesa.motshabi@wits.ac.za
Website: www.wits.ac.za
Charlotte Maxeke Johannesburg Academic Hospital, 6th Floor, Area 361/16, Jubilee Road, Parktown, Johannesburg

WITS UNIVERSITY | WITS SCHOOL OF CLINICAL MEDICINE | FACULTY OF HEALTH SCIENCES

5.4. Research Permission Letter by The Deputy Registrar

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

OFFICE OF THE DEPUTY REGISTRAR

02 June 2023

Wazha Senyahale
Student Number (2640699)
Master of Medicine in Anaesthesia
Faculty of Health Sciences

TO WHOM IT MAY CONCERN

"The process of informed consent for obstetric anaesthesia in the Department of Anaesthesia at the University of Witwatersrand, a descriptive cross-sectional study."

This letter serves to confirm that the above project has received permission to be conducted on University premises, and/or involving staff and/or students of the University as research participants. In undertaking this research, you agree to abide by all University regulations for conducting research on campus and to respect participants' rights to withdraw from participation at any time.

If you are conducting research on certain student cohorts, year groups or courses within specific Schools and within the teaching term, permission must be sought from Heads of School or individual academics.

Ethical clearance has been obtained. (Protocol number: M230205 MED22-09-119)

Research Expiration: (23 May 2028)

Nicoleen Potgieter
University Deputy Registrar

Private Bag 3, WITS, 2050, South Africa | **T** +27 11 717 1204/8 | **E** nicoleen.potgieter@wits.ac.za | www.wits.ac.za
IYUNIVESITHI YASEWITWATERSRAND | YUNIVESITHI YA WITWATERSRAND

5.5. Information sheet

The process of informed consent for obstetric anaesthesia in the Department of Anaesthesia at the University of Witwatersrand, a descriptive cross-sectional study

Dear colleague,

My name is Wazha Andrew Senyahale. I am a registrar in the Department of Anaesthesiology at the University of the Witwatersrand.

I invite you to participate in my Master of Medicine in Anaesthesia research study titled: The process of informed consent for obstetric anaesthesia at hospitals associated with the University of Witwatersrand; a descriptive cross-sectional study. This will be achieved by describing the demographics (age, gender and years of experience) of the anaesthetists obtaining consent for obstetric anaesthesia, describing documentation of informed consent, describing the information provided to the patient, describing the impact of language on the informed consent process and describing the perception of anaesthetists regarding the adequacy of their informed consent process.

I would like you to participate by completing the attached questionnaire,.

The questionnaire is anonymous, and all responses obtained will be stored in a secure and confidential, password-protected manner. The only people who will access the raw data will be my supervisors and me. No identifying data will be requested or captured. If, at any stage, you feel uncomfortable participating in the questionnaire, you are welcome to withdraw from the study. Participation in this study is entirely voluntary, and consent will be implied by your completion of the questionnaire.

Answering this questionnaire should take less than 15 minutes. No incentives will be offered for the completion of this questionnaire.

If you have any questions about this study, please get in touch with me, Dr Wazha Andrew Senyahale (cell phone +27 71 506 2499), or either of my supervisors, Dr Cara Redelinghuys (+27 76 738 5493) or Dr Dorinka Nel (+27 83 362 3061).

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. The role of this committee is to protect the dignity and rights of all research participants. If you have any queries about the conduct of this study, please get in touch with the chairperson of the Human Research Ethics Committee Professor Clement Penny, who may be contacted via:

Email: Clement.Penny@wits.ac.zaTelephone number: 011 717 2301Telephone numbers for the Committee secretaries are 011 717 2700/1234, and the email addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this participant information sheet.

Click 'Next Page' to proceed

5.6. Questionnaire

The process of informed consent for obstetric anaesthesia in the Department of Anaesthesia at the University of Witwatersrand, a descriptive cross-sectional study

Demographics	
How old are you in years?	_____
What is your gender?	◯ Male ◯ Female ◯ Other ◯ Decline to answer
What is your designation/rank?	◯ Medical officer ◯ Registrar
Total anesthetic experience?	◯ ≤ 1 year ◯ ≤ 2 years ◯ ≤ 3 years ◯ > 4 years
What is your highest anaesthetic qualifications?	☐ No formal anaesthetic qualification ☐ Diploma in Anaesthetics ☐ FCA part 1 ☐ FCA part 2

Content questions	
In your opinion, do you regard your process of informed consent for the obstetric patient as adequate?	◯ Strongly agree ◯ Agree ◯ Undecided ◯ Disagree ◯ Strongly disagree
Do you introduce yourself by name prior to getting informed consent for obstetric anaesthesia?	◯ Never ◯ Seldom ◯ Occasionally ◯ Often ◯ Always
Do you introduce yourself by your rank (medical officer or registrar) prior to getting informed consent for obstetric anaesthesia?	◯ Never ◯ Seldom ◯ Occasionally ◯ Often ◯ Always

Local anaesthesia systemic toxicity	○	○	○	○	○
Nausea and vomiting	○	○	○	○	○
Need to convert to general anaesthesia	○	○	○	○	○
Post dural puncture headache	○	○	○	○	○
Post spinal backache	○	○	○	○	○
Pruritis	○	○	○	○	○
Shivering	○	○	○	○	○
Transient neurologic symptoms	○	○	○	○	○
Nerve injury	○	○	○	○	○
Urinary retention	○	○	○	○	○
Other	○	○	○	○	○

Please specify.

_____

How often do you quantify the risk of the following complications of spinal anaesthesia? Choose "Not Applicable" for those complications that you never discuss with patients.

	Never	Seldom	Occasionally	Often	Always	Not Applicable
Anaphylaxis	○	○	○	○	○	○
Cardiac Arrest	○	○	○	○	○	○
Compression from a vertebral canal haematoma	○	○	○	○	○	○
Compression from an epidural abscess/ meningitis	○	○	○	○	○	○
Death	○	○	○	○	○	○
High (total) spinal	○	○	○	○	○	○
Local anaesthesia systemic toxicity	○	○	○	○	○	○
Nausea and vomiting	○	○	○	○	○	○
Need to convert to general anaesthesia	○	○	○	○	○	○
Post dural puncture headache	○	○	○	○	○	○
Post spinal backache	○	○	○	○	○	○
Pruritis	○	○	○	○	○	○
Shivering	○	○	○	○	○	○
Transient neurologic symptoms	○	○	○	○	○	○
Nerve injury	○	○	○	○	○	○

Urinary retention	○	○	○	○	○	○

How often do you discuss the following risks of general anaesthesia?

	Never	Seldom	Occasionally	Often	Always
Airway and dental trauma	○	○	○	○	○
Anoxia and brain damage	○	○	○	○	○
Aspiration of gastric contents and its consequences	○	○	○	○	○
Awareness under general anaesthesia	○	○	○	○	○
Depression of the foetus with narcotics	○	○	○	○	○
Drug toxicity/side effects	○	○	○	○	○
Increased risk of post-partum haemorrhage	○	○	○	○	○
Loss of airway control (failed intubation) and need for surgical airway	○	○	○	○	○
Post operative nausea and vomiting	○	○	○	○	○
Other	○	○	○	○	○

Please specify.

_____

How often do you quantify the risk of the following complications of general anaesthesia? Choose "Not Applicable" for those complications that you never discuss with patients.

	Never	Seldom	Occasionally	Often	Always	Not Applicable
Airway and dental trauma	○	○	○	○	○	○
Anoxia and brain damage	○	○	○	○	○	○
Aspiration of gastric contents and its consequences	○	○	○	○	○	○
Awareness under general anaesthesia	○	○	○	○	○	○
Depression of the foetus with narcotics	○	○	○	○	○	○
Drug toxicity/side effects	○	○	○	○	○	○
Increased risk of post-partum haemorrhage	○	○	○	○	○	○

Loss of airway control (failed intubation) and need for surgical airway	○	○	○	○	○	○
Post operative nausea and vomiting	○	○	○	○	○	○

How often do you obtain informed consent from obstetric patients in their preferred/home language?

- ○ Never
- ○ Seldom
- ○ Occasionally
- ○ Often
- ○ Always

How often do you encounter a language barrier in the process of obtaining informed consent from obstetric patients?

- ○ Never
- ○ Seldom
- ○ Occasionally
- ○ Often
- ○ Always

Once you encounter language barrier do you use any of the options below to get over the language barrier? Tick all options that apply

- ☐ Use nursing staff as a translator
- ☐ Use another patient as a translator
- ☐ Attempt the patient's language
- ☐ Use simplified English
- ☐ Use a translations application on your mobile phone
- ☐ Other

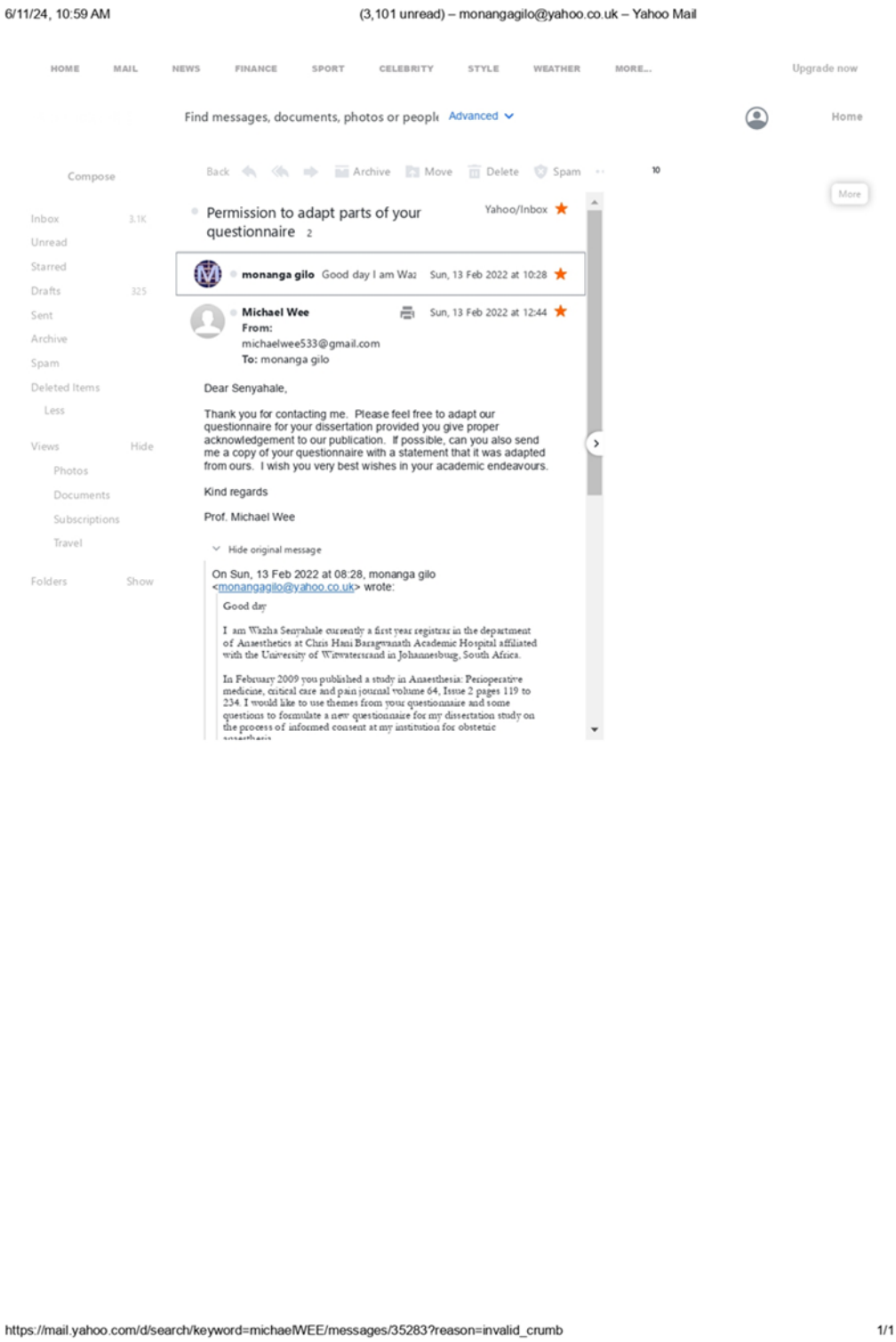
You have selected the option "other" as a means to get over language barrier. Please describe.

_____

Does your process of informed consent for obstetric anaesthesia change with elective cases versus emergency cases?

- ○ Yes
- ○ No

5.7. Permission to adapt the questionnaire



6/11/24, 10:59 AM (3,101 unread) – monangagilo@yahoo.co.uk – Yahoo Mail

HOME MAIL NEWS FINANCE SPORT CELEBRITY STYLE WEATHER MORE... Upgrade now

Find messages, documents, photos or people Advanced Home

Compose

Back Archive Move Delete Spam More

Inbox 3.1K
Unread
Starred
Drafts 325
Sent
Archive
Spam
Deleted Items
Less
Views Hide
Photos
Documents
Subscriptions
Travel
Folders Show

Permission to adapt parts of your questionnaire 2

Yahoo/Inbox

monanga gilo Good day I am Wa Sun, 13 Feb 2022 at 10:28

Michael Wee Sun, 13 Feb 2022 at 12:44
From: michaelwee533@gmail.com
To: monanga gilo

Dear Senyahale,

Thank you for contacting me. Please feel free to adapt our questionnaire for your dissertation provided you give proper acknowledgement to our publication. If possible, can you also send me a copy of your questionnaire with a statement that it was adapted from ours. I wish you very best wishes in your academic endeavours.

Kind regards

Prof. Michael Wee

Hide original message

On Sun, 13 Feb 2022 at 08:28, monanga gilo <monangagilo@yahoo.co.uk> wrote:

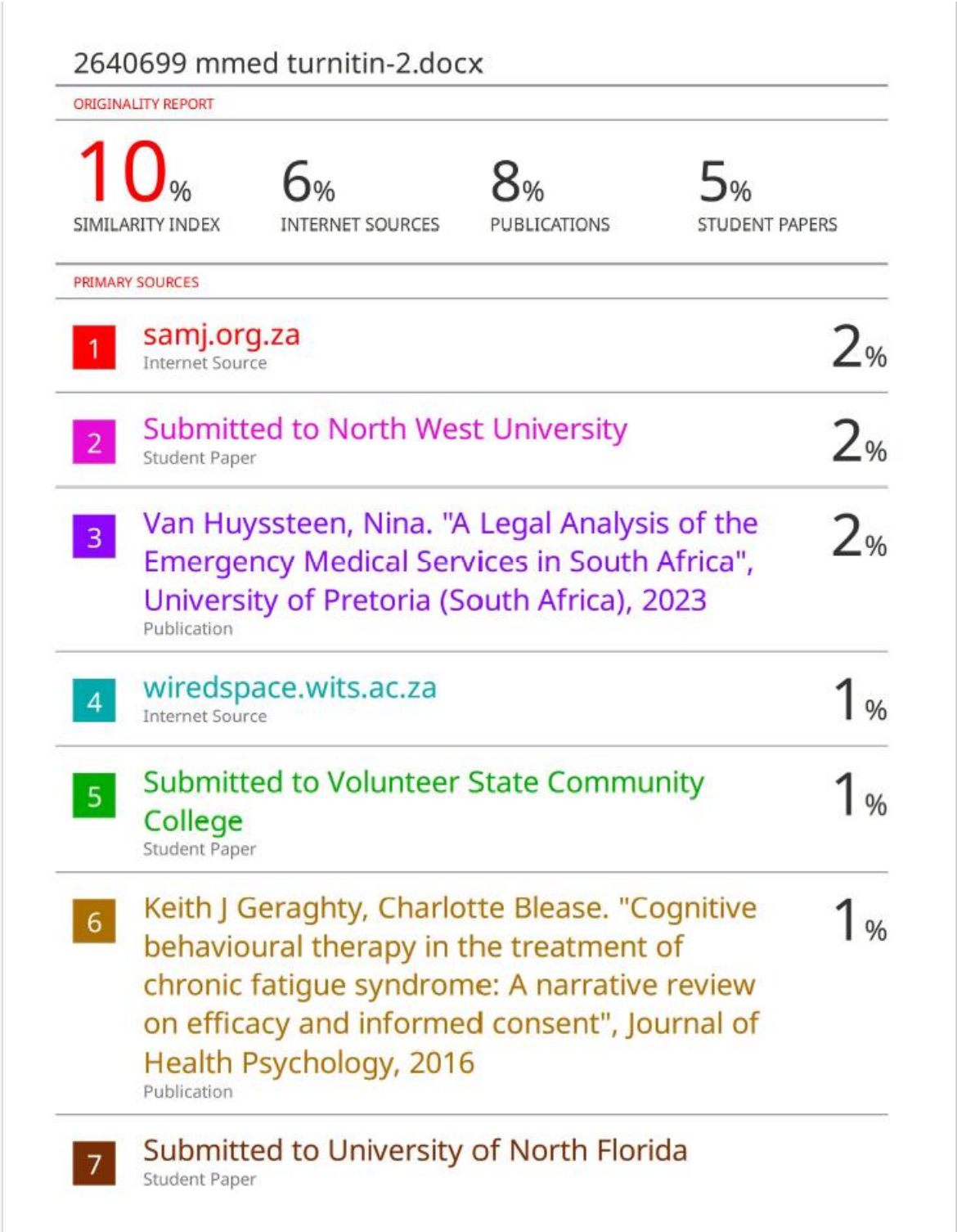
Good day

I am Wazha Senyahale currently a first year registrar in the department of Anaesthetics at Chris Hani Baragwanath Academic Hospital affiliated with the University of Witwatersrand in Johannesburg, South Africa.

In February 2009 you published a study in Anaesthesia: Perioperative medicine, critical care and pain journal volume 64, Issue 2 pages 119 to 234. I would like to use themes from your questionnaire and some questions to formulate a new questionnaire for my dissertation study on the process of informed consent at my institution for obstetric

https://mail.yahoo.com/d/search/keyword=michaelWEE/messages/35283?reason=invalid_crumb 1/1

5.8. Turnitin report



2640699 mmed turnitin-2.docx

ORIGINALITY REPORT

10%	6%	8%	5%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	samj.org.za Internet Source	2%
2	Submitted to North West University Student Paper	2%
3	Van Huyssteen, Nina. "A Legal Analysis of the Emergency Medical Services in South Africa", University of Pretoria (South Africa), 2023 Publication	2%
4	wiredspace.wits.ac.za Internet Source	1%
5	Submitted to Volunteer State Community College Student Paper	1%
6	Keith J Geraghty, Charlotte Blease. "Cognitive behavioural therapy in the treatment of chronic fatigue syndrome: A narrative review on efficacy and informed consent", Journal of Health Psychology, 2016 Publication	1%
7	Submitted to University of North Florida Student Paper	

		1 %
8	www.scielo.org.za Internet Source	1 %

Exclude quotes	On	Exclude matches	< 8 words
Exclude bibliography	On		