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Adequacy of consenting patients for computed tomography (CT) scans in a developing country: a survey of two academic hospitals in Johannesburg, South Africa

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Adequacy of Consenting Patients for Computed Tomography (CT) Scans in a Developing Country: A Survey of Two Academic Hospitals in Johannesburg, South Africa

Dr Thandaza Shayingca

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

Johannesburg, 2014

Declaration

I, Thandaza Shayingca declare that this research report is my own work. It is being submitted for the degree of MMed (Diagnostic Radiology) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Dr Thandaza Shayingca

On this 5th day of April 2014.

In loving memory of my late sister,

Samukelisiwe Shayingca

A constant reminder that life is a precious gift

Publications and presentations

This work has never been published or presented at a congress.

Abstract

INTRODUCTION

South Africa presents a complex scenario with regard to patients consenting for medical procedures, because of the differing profiles of the population and the health care workers who perform the consenting procedures.

AIM

To evaluate consenting practice for CT scanning, within the South African tertiary referral setting and to determine if there are any associations between patient demographic profile and the level of understanding with the adequacy of consent.

METHOD

A prospective survey regarding consenting practices for CT scanning was performed in a form of an interview questionnaire in patients presenting to Chris Hani Baragwanath Academic and Charlotte Maxeke Johannesburg Academic hospitals. Determination of any associations between patient age, racial group, language and education was made with the level of understanding and adequacy of consent.

RESULTS

The survey was conducted on 117 patients; 86 from Charlotte Maxeke Johannesburg Academic Hospital and 31 from Chris Hani Baragwanath Academic Hospital. We found no significant association between gender and age category (p=0.11), racial group (p=0.17), education (p=0.26), home language (p=0.21) or residential area type (p=0.70).

There was a significant, weak, association between age category and education (p=0.043; Cramer's V=0.29). There was a significant, moderate association between the understanding of the language of consent and the home language of the patients (p=0.0013; phi coefficient=0.43). There was also some association between education and age. Just over 50% of patients felt that they had been given enough information and had had an opportunity to ask questions and only 33% had been offered an alternative to the CT scan. There was a significant difference in the mean adequacy of consent score with regards to racial group (p<0.0001), home language (p=0.0073), residential area type (p<0.0001) and level of education (p<0.0001).

CONCLUSION

Language differences between patients and personnel performing the consent procedure proved to be a major barrier in offering adequate consenting for CT Scans.

Acknowledgements

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My family, friends & colleagues

Charlotte Maxeke Johannesburg Academic & Chris Hani Baragwanath Academic Hospitals

The patients

I thank you

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1. Introduction

Consent for CT scanning in radiology is undertaken so that patients are made aware of the risks of contrast administration, radiation (especially for pregnant females) and anaesthesia or sedation. In addition this serves to protect the practitioner against any medico legal action in the event of an incident affecting the patient negatively. The practice of consenting, even though well described and documented, is not supervised or monitored and often becomes a routine procedure without meeting the intended purposes. South Africa presents a complex scenario with regard to consenting because of the varied nature of the population and the traditional profile of health care workers.

There are 11 official languages with the main medical language being English whereas the widest spoken languages of lay people are isiZulu and Setswana. Patients in this developing country presenting to state health institutions often have a limited education and language proficiency in English and often have little background knowledge about their disease and the advanced imaging interventions which they have been referred for. Doctors on the contrary, who should take responsibility for consenting patients referred for complex imaging procedures, have traditionally been from different racial groups, language and educational background. This mismatch of medical personnel performing the consenting procedure with patients being consented is an important contributor to inadequate consenting procedure, which must be quantified and rectified. This research aims to determine the adequacy of consenting for CT scanning in two large referral hospitals in Gauteng South Africa taking language, education, racial group and consenting procedure into consideration.

Radiologists and clinicians alike differ in opinions on the need to consent patients for CT scanning (1). Some sectors view the informed consent procedure as means to protect the doctor against a lawsuit, rather than as a tool to involve, inform and empower the patient to actively partake in the decision-making regarding their management (1-3). In facilitating the informed consent procedure one needs to select a method that will be suitable for patients, that is in keeping with the laws of the country, that upholds ethical principles and that is efficient for the doctor (3).

Informed consent should reflect shared decision making between the patient and the doctor and it must meet the basic minimum requirements: The patient must be of sound mind, be capable of understanding the information provided and be able to use that information to come to a knowledgeable decision (4). The information provided to the patient must include but not be limited to the nature of the proposed procedure, benefits of the proposed procedure, risks associated with the proposed procedure, alternatives to the procedure and the risks and the benefits associated with the alternative (3, 5-8). In situations where the patient is a minor or an adult who lacks the capacity to make knowledgeable decision a representative who has the patient's best interests should make the decision on behalf of the patient. In cases where such a person cannot be identified and life saving procedure is necessary the attending doctors may proceed with the procedure based on a doctrine to save lives (9). The doctor patient relationship should naturally facilitate the informed consent procedure. The patient-radiologist relationship tends to be very brief if at all, which further highlights why referring clinicians are better suited to consenting patients for CT scans.

There is lack of comprehensive data as to how suited/ trained referring doctors are at consenting patients for CT scans in the South African setting. Studies in the United States of America have documented that the referring doctors have some knowledge on the adverse reactions associated with IV contrast but have no real knowledge on radiation exposure doses (6). Interestingly, even Radiologists had very little knowledge on how much radiation patients were exposed to for different imaging procedures (6).

Written consent has been shown to be better than oral consent; a combination of the two has been shown to increase recall of information given and understanding (10). Written consent has the benefit of being reproducible, allows for documentation and standardizes the communication between the doctor and the patient regarding the procedure (11). There are three described models of informed consent:

I. 'Reasonable doctor standard- what information would a reasonable doctor give to a patient under similar circumstances?
II. Reasonable patient standard- what would a reasonable patient want to know from his/ her doctor to be able to make an informed decision?
III. Subjective standard- this standard requires the doctor to tailor-make the information for each patient; the doctor must use his/ her discretion to decide what would this particular patient want to know to be able to make an informed decision' (9).

Old studies have reported that information about risks associated with procedures increases the incidence of complications by placing patients under undue anxiety, however in recent studies it has been widely documented that improving patients level of

understanding reduces anxiety (10, 12). Patients expressed a desire to be informed of the risks involved during a procedure in one study (12). Current practice does not lay out a standard and thus the attending doctor decides what and how he/ she gives information to the patient, if any (13). Routine consenting procedure in South Africa does not include information on radiation doses and possible associated risks as part of the consenting documentation.

CT scans are fast, relatively simple and accurate diagnostic tools, which are widely used and continue to gain popularity worldwide. In the US it is reported that CT accounts for about 13% of imaging procedures in radiology but contributes to more than 70% of radiation exposure to patients (6). No data is available for South Africa as yet. The typical surface radiation dose from CT for adults has been estimated to be 30-70 mGy for a head scan series and 20-50 mGy for an abdominal series, with a CT of the abdomen said to deliver 200-300 times the radiation of a chest radiograph (14). Recent studies have documented that the effective dose from CT scans are within the range of exposure of those received within 2 km of the epicentre of the Japanese atomic bomb. Survivors of this event are reported to have a small but statistically significant increased risk (above baseline) of developing cancer (6, 11). It is, however, the use of IV contrast during CT scanning that is the main reason for consenting patients because of the well-documented acute risks associated with this.

It is well documented that patients want to be educated about medical issues so that they are better equipped to partake in medical discussions regarding their care. Clinical studies have over the years demonstrated that very little of the information passed on to the

patient can be recalled or retained by the patients (2, 10, 15). Multiple factors such as language differences, cultural differences, illiteracy, age, the patient identifying the situation as being stressful or poor communication skills on the part of the healthcare provider are barriers to effective communication, which is critical for rendering safe, good quality health care to our patients (16).

In South Africa the absence of effective communication is the norm rather than the exception where doctors who only speak English or Afrikaans attend to patients with limited or no understanding of either language. An added problem arises when the patient has the belief that she/ he has an adequate command of the English language or when the attending doctor is of the belief that he/ she has a good command of the patient's native language. The use of untrained interpreters has also been shown to lead to misinterpretation and often incomplete, inaccurate information is relayed because the interpreters lack the medical understanding. This compromises the quality of care (17).

One's culture greatly affects how one perceives the world (16). Cultural differences are also often associated with language differences. Cultural differences are therefore a major contributor to communication breakdown and can be responsible for the poor understanding, retention and recall of information during the informed consenting procedure. In some cultures paternalistic medical practice is still prevalent so the patients are willing to accept whatever the doctor chooses for them (4), as they firmly believe he/ she has their best interest at heart. Even within the same culture or society, patients' preferences differ with regard to how much information they need. In some parts of the world and in certain cultures patients always need to consult with family first before they

can consent to medical procedures because for them, family relationships are more important than one's personal interests (9).

The correlation between the patient's level of education and their ability to retain and recall information is well documented. Patients with a higher education level generally have a better grasp of the information and are better participants in the decision-making regarding their care (7). It has been reported that educated, younger patients are more likely to want more information compared to older, sickly patients (9).

This research aims to evaluate consenting practice for CT scanning, within the South African tertiary referral setting, and to correlate this with patient profile with regard to racial group, language, education and geographic place of residence.

1.1. Study objectives

This study aims to:

- Determine what proportion of patients undergoing a CT scanning had signed consent for the study
- Determine the profile of patients referred to CT with regard to age, gender, language preference, cultural / racial group, level of education and geographic habitat.
- Determine the language in which the consenting procedure for CT was undertaken, in relation to the language preference of the patient.
- Determine the level of understanding of: the purpose of the visit to the department, what procedure was requested, the body part to be evaluated, the need for an injection, the risks of doing the procedure, and the benefits of doing the procedure.
- Determine if the patients were made aware of the alternative forms of investigation and their associated risks and benefits; if they were afforded time to ask questions and if they were given enough time to consider their options.
- Determine the overall adequacy of the consent for CT according to a composite score of the above questions and to correlate patients' level of education and cultural background with this score.
- Compare results between the two major referral centres studied, which differ in geographic location, and socio-economic status of patients.

2. Materials and Methods

2.1. Introduction

This was a prospective survey of patients presenting for CT scanning at two tertiary referral centres Chris Hani Baragwanath Academic (CHB) and Charlotte Maxeke Johannesburg Academic (CMX) hospitals in Johannesburg, South Africa.

2.2. Research Design

On selected days patients presenting for CT scanning at the abovementioned hospitals were approached to partake in the study. The survey was in a form of a questionnaire (Appendix B), conducted by the primary investigator, in the form of an interview. In the event where the investigator and the participants did not speak the same language a translator was used. The data collection part of the study was conducted over a period of three months.

2.3. Population and Sample

Sample size was calculated at a minimum of 100 participants based on Cohen's tables, which are the standard reference for statistical power. A sample size of 100 means that the correlation tests (r) achieves a power of 0.80 to 0.90 and when using a chi-square test it will give a power of 0.80, for the 0.05 level of significance (95% CI) for detecting a medium effect size. The population was all patients who presented to both institutions for CT Scanning. The sample was selected at random, on random days of the week.

2.4. Inclusion and Exclusion Criteria

Inclusion criteria

Male and female patients aged 18 years and above presenting for CT scan at any of the two hospitals were eligible for the study.

Exclusion criteria

Patients on life support

Trauma patients

Patients who were consented by the medical manager

Patients who were mute, confused or unconscious

2.5. Data Collection

Data was collected to create patient profiles and to gather *relevant information on the consenting practice. The collected data was categorised as follows.*

2.5.1. Demographics

2.5.2. Language of consenting in relation to patients' proficiency

2.5.3. Level of understanding of the consent form

2.5.4. Level of information/ alternative given during consenting

2.5.5. Overall adequacy of consenting for CT scanning

2.5.6. Overall satisfaction with the information provided and how well delivered

2.6. Data analysis and Interpretation

Results were expressed as frequencies and percentages for categorical variables.

Data analysis was carried out using SAS (statistical analysis software system) version 9.3 for Windows; a statistical software package by SAS Institute Inc.

The X^2 test was used to assess the relationships between two categorical variables. Fisher's exact test was used for 2 x 2 tables or where the requirements for the X^2 test could not be met. The strength of the associations was measured by Cramer's V and the phi coefficient respectively.

For Cramer's V and the phi coefficient, the following scale of interpretation was used:

0.50 and above	high/strong association
0.30 to 0.49	moderate association
0.10 to 0.29	weak association
<0.10	little if any association

The t-test for independent samples was used to assess the relationship between a categorical variable with two groups and a continuous variable. In the case of a categorical variable with more than two groups, one-way Analysis of Variance (ANOVA) was used. In both cases, the effect size was measured by Cohen's d.

For Cohen's d, the following scale of interpretation was used:

0.80 and above	large effect
0.50 to 0.79	moderate effect
0.20 to	0.49 small effects
< 0.20	zero or near zero effect

The 0.05 significance level was used throughout, unless specified otherwise.

Age, population group, gender, place of residence and education level was correlated with the overall adequacy and each item. Comparison of the two institutions was made in relation to the overall scores

.

3. Results

3.1. The sample

The survey was conducted on 117 patients; 86 (74%) from CMX and 31 (26%) from CHB.

3.2. Demographics

3.2.1. Gender

47% of the patients were male. There was no significant difference in the gender composition of the patients between the two hospitals (p=0.68).

3.2.2. Age

The overal age mean was 45.8y. There was a marginally significant difference in the mean age of the patients from CMX (46.4±3.3y) compared to CHB (40.3±4.8y) (p=0.055). The distribution of ages is demonstrated in figure 3.1. For further analysis, the ages of the patients were categorised as shown in figure 3.2. There was a significant, moderate, association between age category and hospital (p=0.018; Cramer's V=0.32): There was a higher proportion of patients in the 31-40y age group (and a lower proportion of patients in the 61y+group) at CHB compared to CXM.

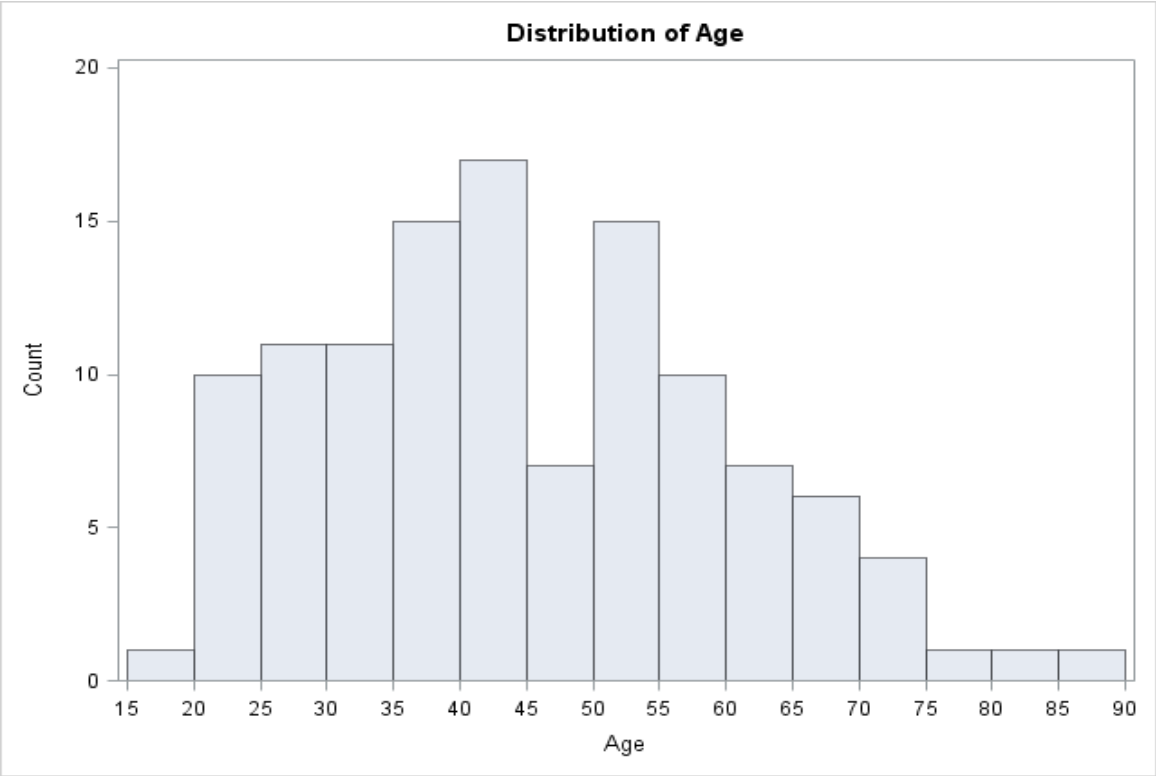


Figure 3.1. Overall age distribution of respondents

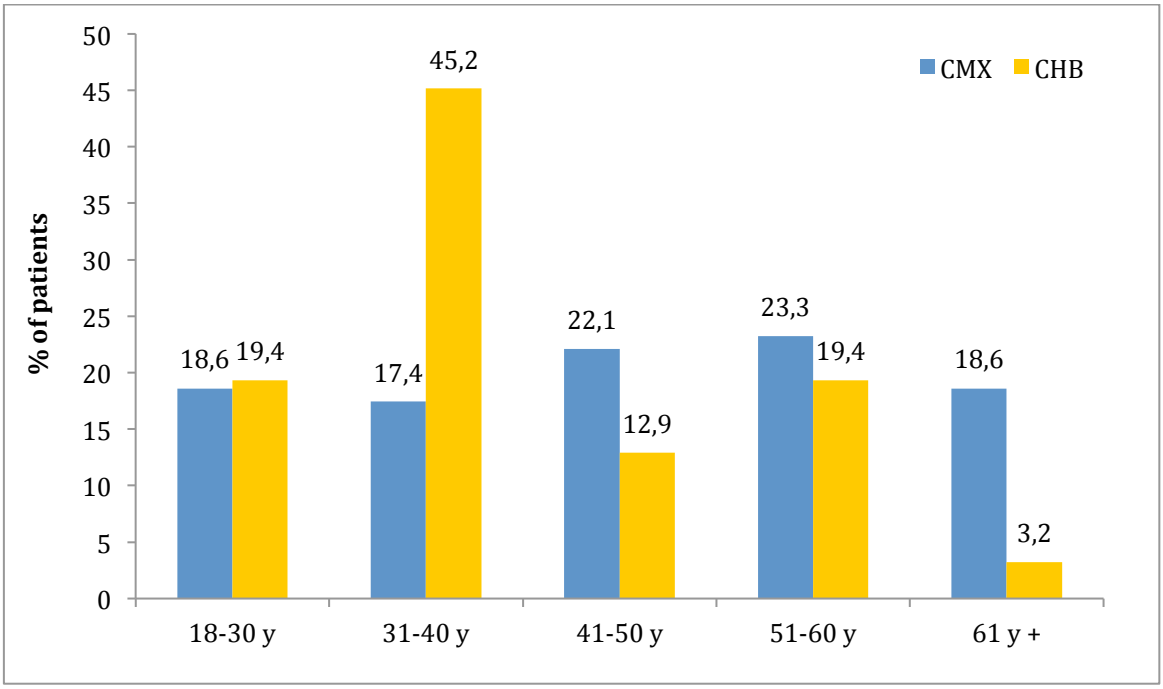


Figure 3.2. Mean age of patients from CMX compared to CBH

3.2.3. Racial group

The majority of the patients (73%) were black. Figure 3.3. summarises the distribution.

There was no significant difference between the hospital groups (p=0.42).

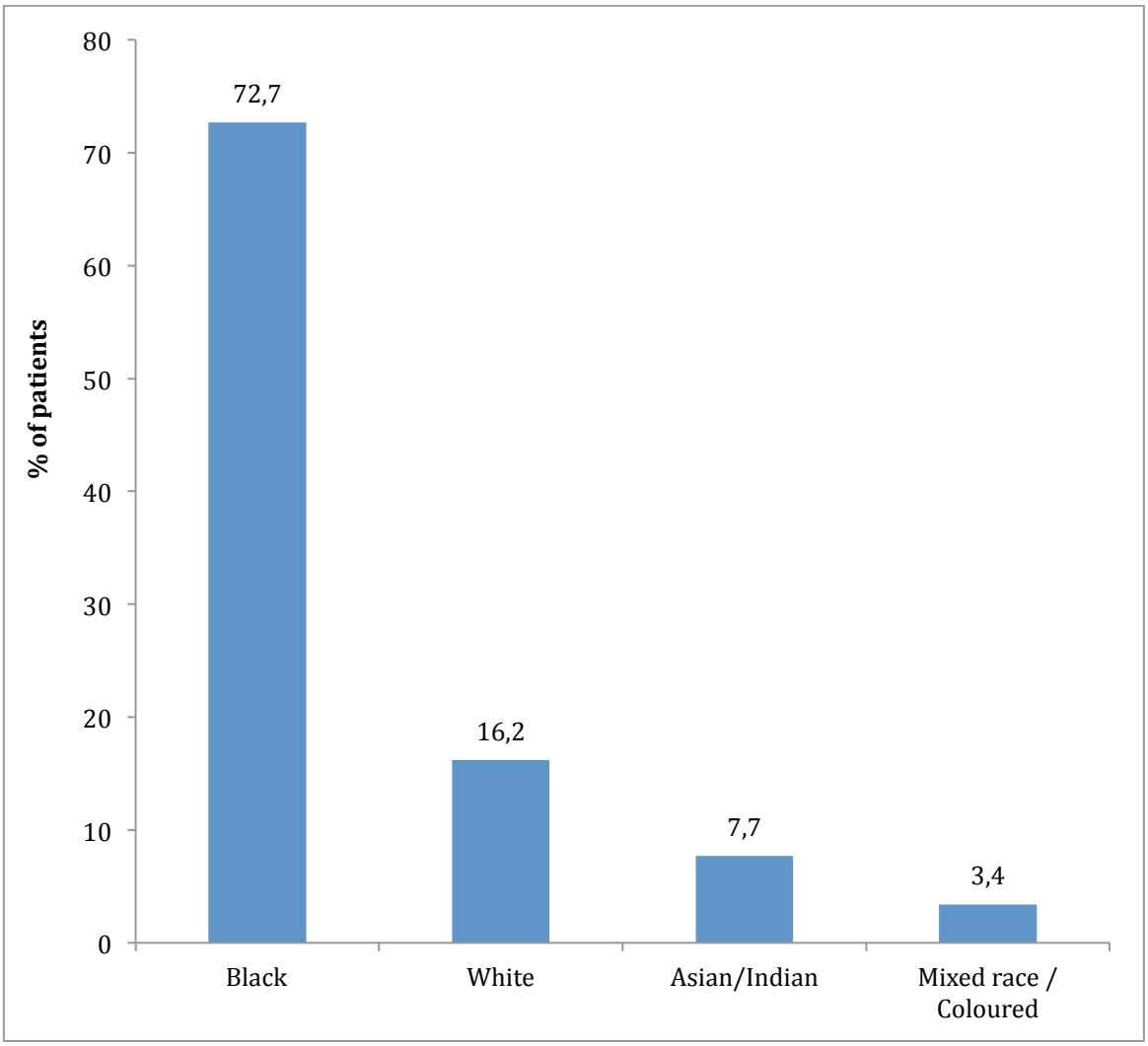


Figure 3.3. Overall racial grouping of respondents

3.2.4. Home language

The frequency distribution of the home languages spoken by the patients in the study is shown in figure 3.4. IsiZulu was the most common language, followed by English and IsiXhosa. There was no significant difference between the language profiles of the patients between the two hospitals (p=0.60).

The category 'Other' was omitted from further analysis.

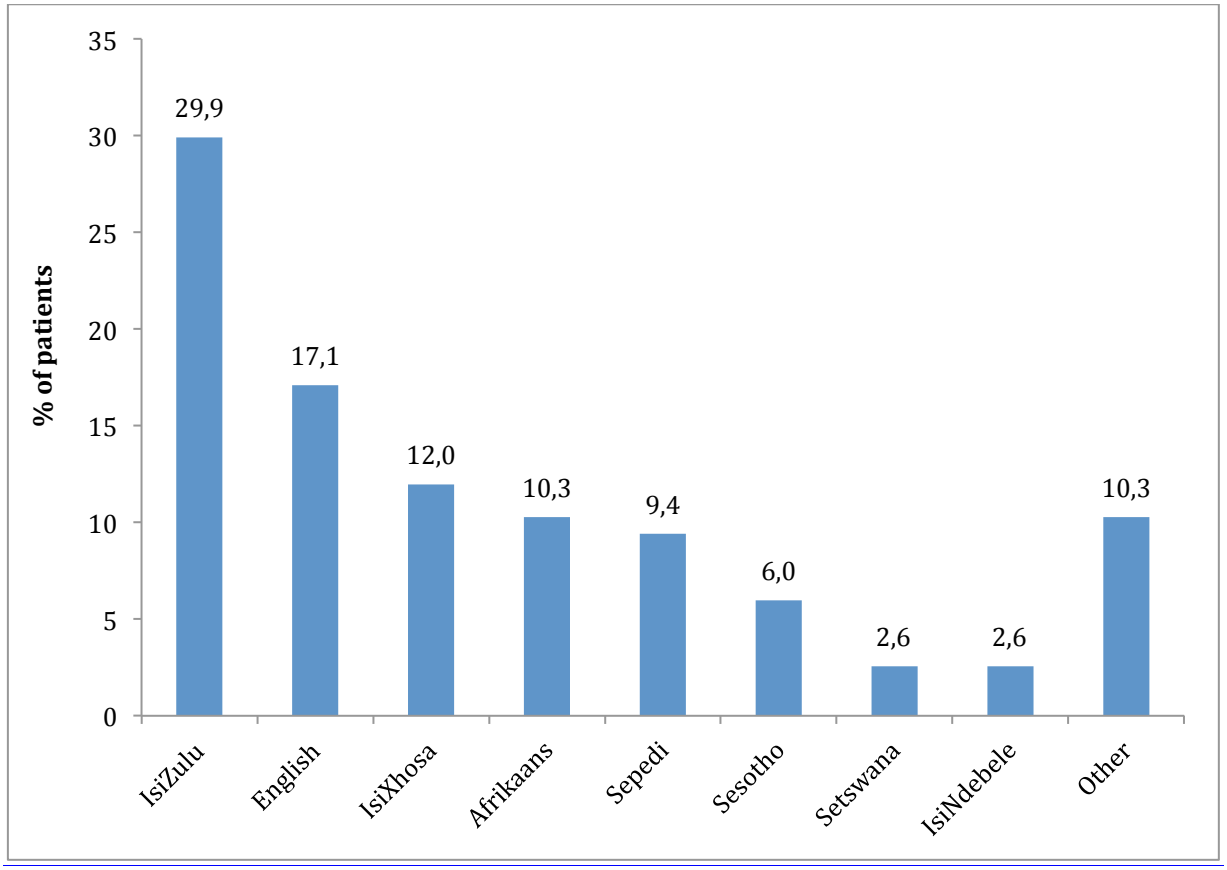


Figure 3.4. Frequency distribution of the home languages spoken by the respondents

3.2.5. Residential area type

The majority (55%) of the patients in the study resided in a township, while a further 38% resided in a suburb. Only 7% of the patients indicated that they had come from a rural area (see figure 3.5.). There was no significant difference between the residential area profiles of the patients between the two hospitals (p=0.47).

The category 'Other' was omitted from further analysis.

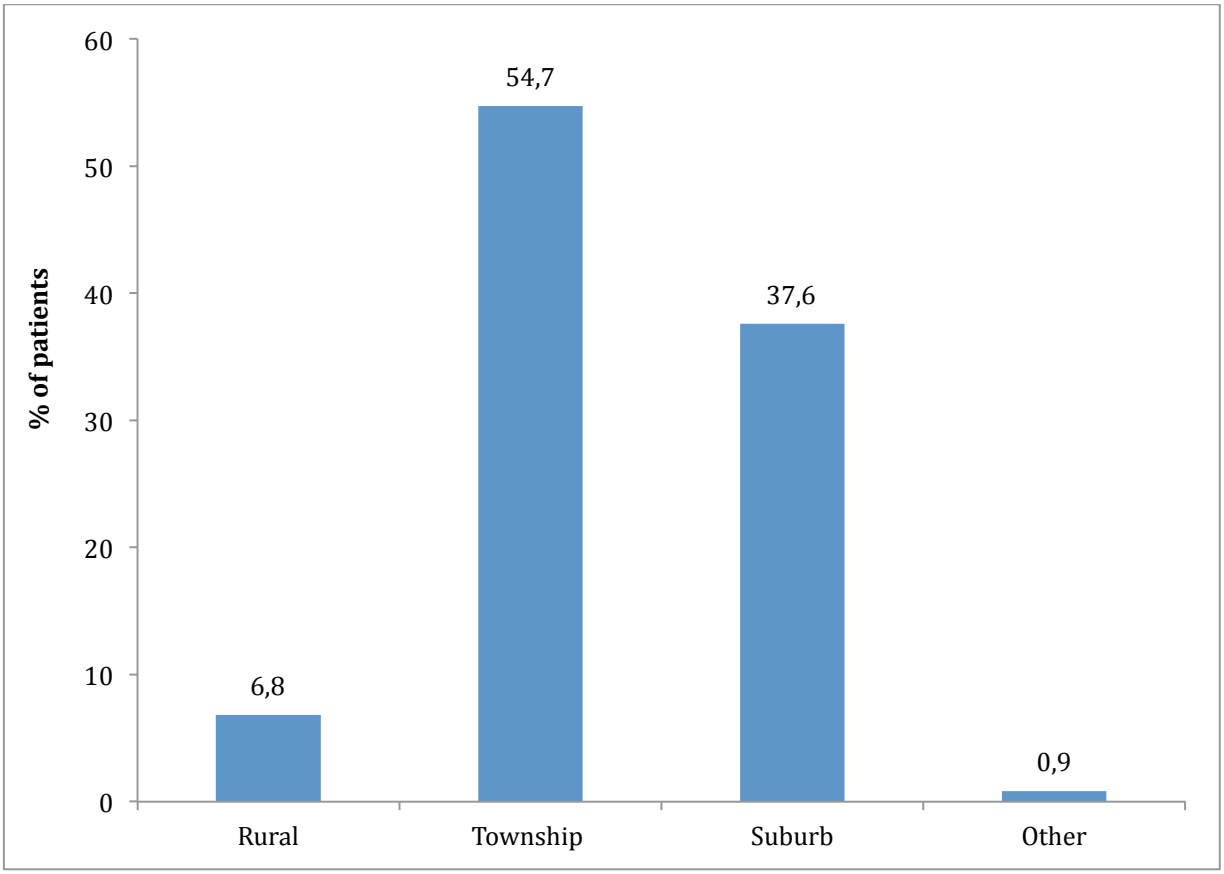


Figure 3.5.Overall residential area profiles of the respondents

3.2.6. Education

The majority of patients in the study (62%) had either some high school education or had completed matric, and an additional 16% had tertiary education as shown in figure 3.6. There was no significant difference between the educational profiles of the patients between the two hospitals (p=0.27).

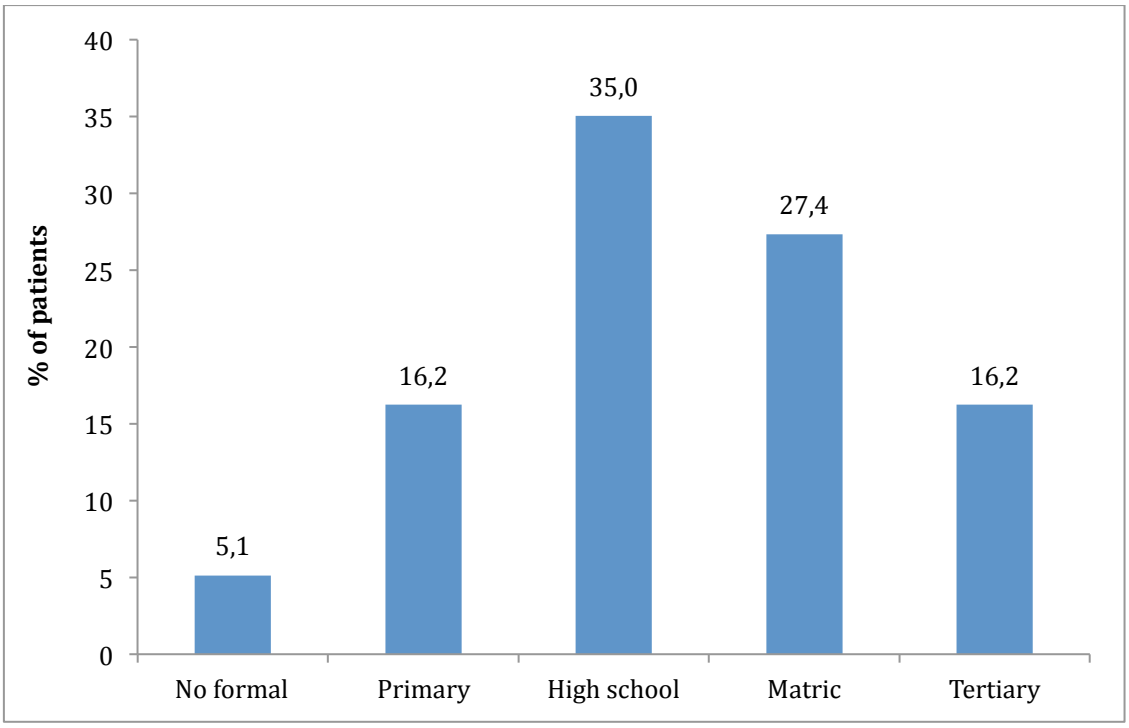


Figure 3.6. Overall educational profiles of the respondents

Considering the association of the demographic variables with each other, we found that:

- There was no significant association between **gender** and age category (p=0.11), cultural background (p=0.17), education (p=0.26), home language (p=0.21) or residential area type (p=0.70).

There was no significant association between **age** category and cultural background (black & white only; other categories excluded due to low cell counts in the cross-tabulation) (p=0.77), home language (0.49) or residential area type (p=0.30). There was a significant, weak, association between age category and education (p=0.043; Cramer's V=0.29), as shown in figure 3.7. For this analysis, ages were categorised as 18-40 y / 41y+ (otherwise the frequencies in the cross-tabulation are too low for analysis). Amongst the younger patients (18-40y), higher levels of education (matric and tertiary education) were evident compared to the older (41y+) patients

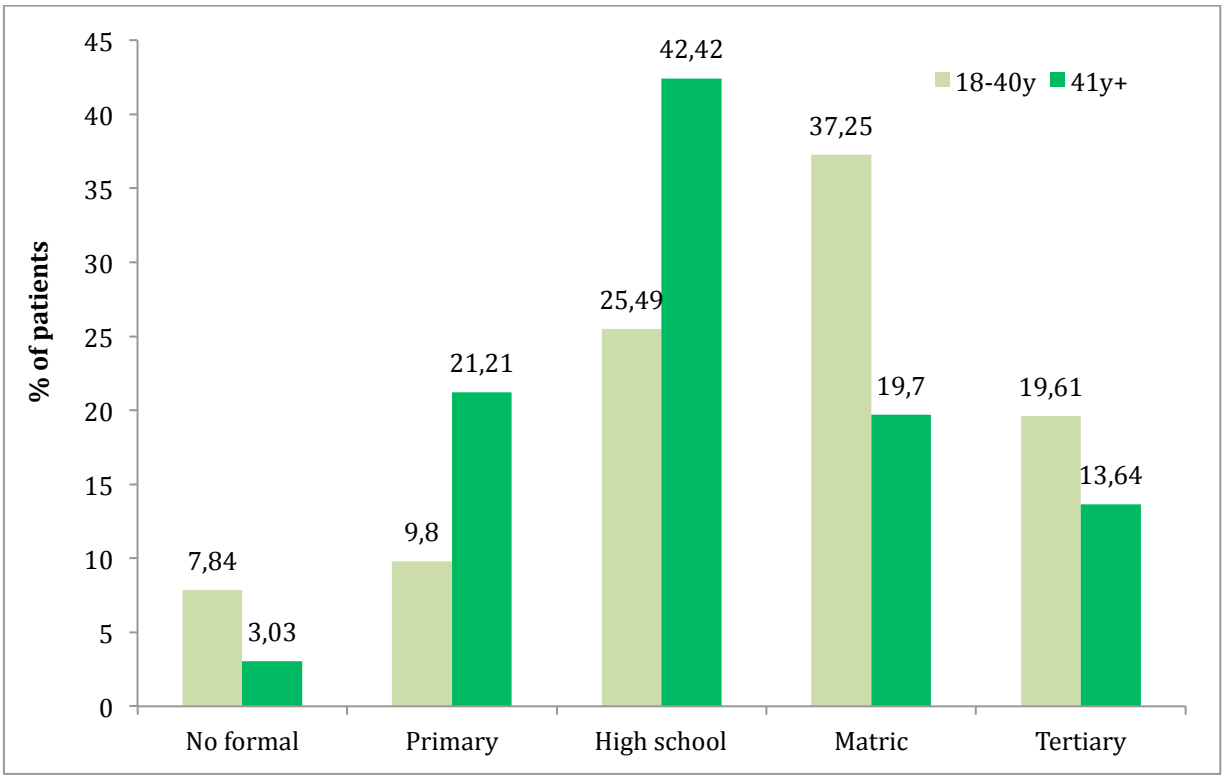


Figure 3.7. Overall association between age category and education

There was a significant, moderate, association between **racial group** (black & white only) and education (p=0.037; phi coefficient=0.32), shown in figure 3.8. A lower level of education was evident amongst black patients compared to white patients.

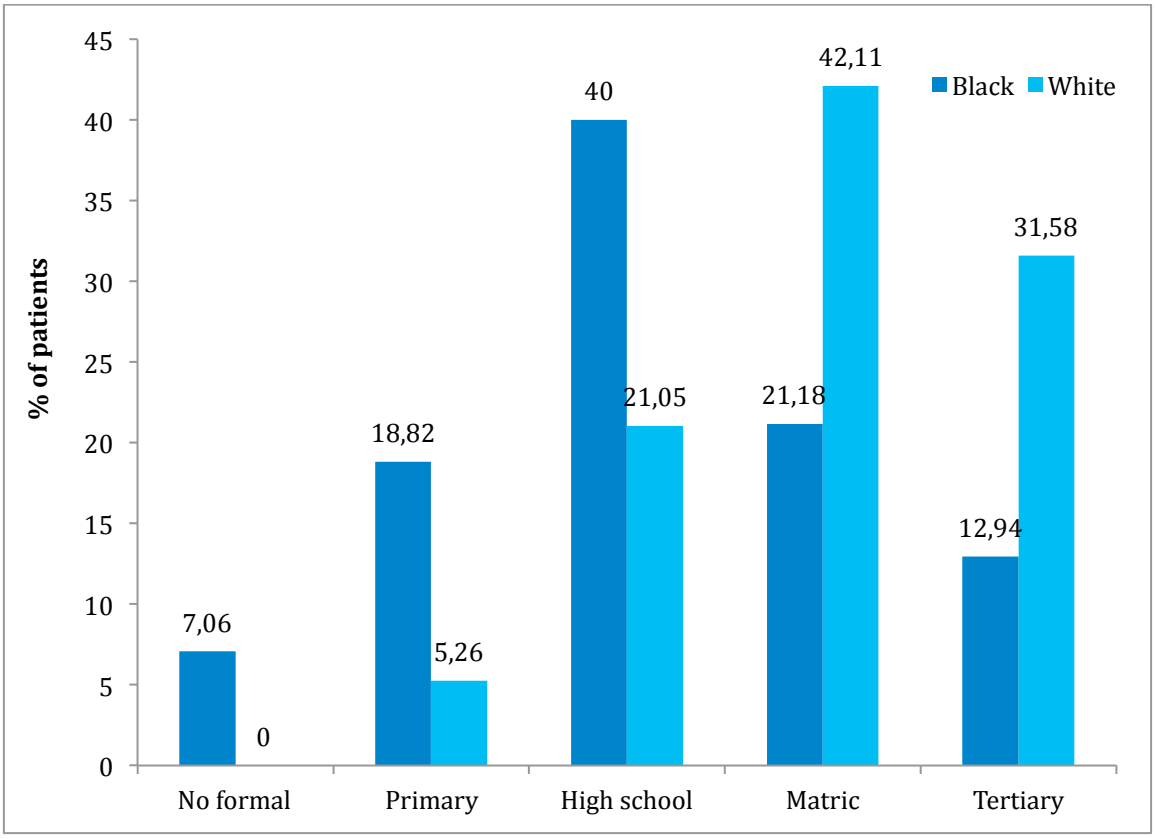


Figure 3.8. Association between racial group (black & white only) and education

Cultural background and home language were almost completely confounded – see table 3.1

Table 3.1. Association between racial group and home language

Race	Home Language								
	IsiZulu	English	IsiXhosa	Afrikaans	Sepedi	Sesotho	Se-tswana	Isi Nde-bele	Total
Black	35	1	14	-	11	7	3	3	74
White	-	11	-	7	-	-	-	-	18
Asian / Indian	-	8	-	1	-	-	-	-	9
Mixed Race / Coloured	-	-	-	4	-	-	-	-	4
Total	35	20	14	12	11	7	3	3	105

There was a significant, strong, association between racial group (black & white only) and residential area type (p<0.0001; Cramer's V=0.68), see figure 3.9. The white patients came exclusively from the suburbs while the black patients came from all three residential area types, but mostly from townships.

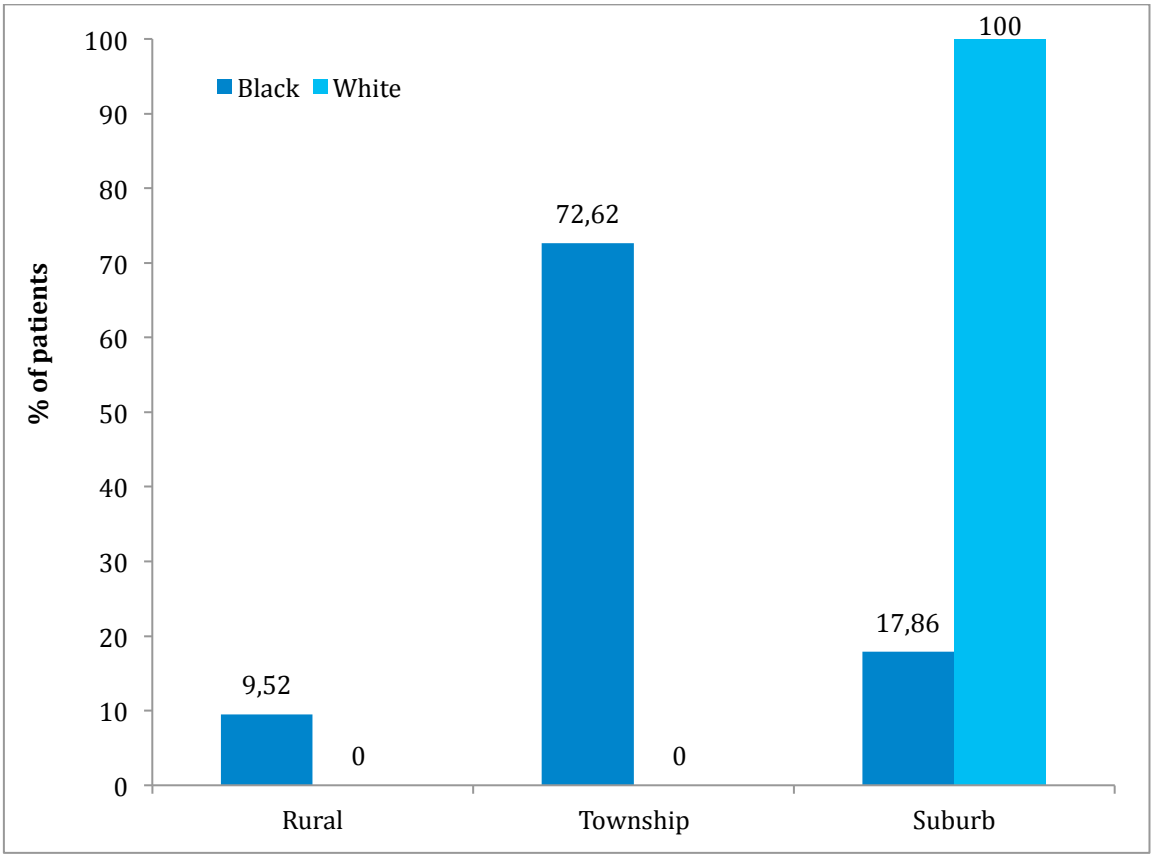


Figure 3.9. Association between racial group (black & white only) and residential area

There was no significant association between home language (top 3 languages only; other categories excluded due to low cell counts in the cross-tabulation) and education (p=0.074).

There was a significant, strong, association between home language (top 3 languages only) and residential area type ($p<0.0001$; Cramer's $V=0.74$), see figure 3.10. The English-speaking patients came mostly from the suburbs while the Zulu- and Xhosa-speaking patients came mostly from townships.

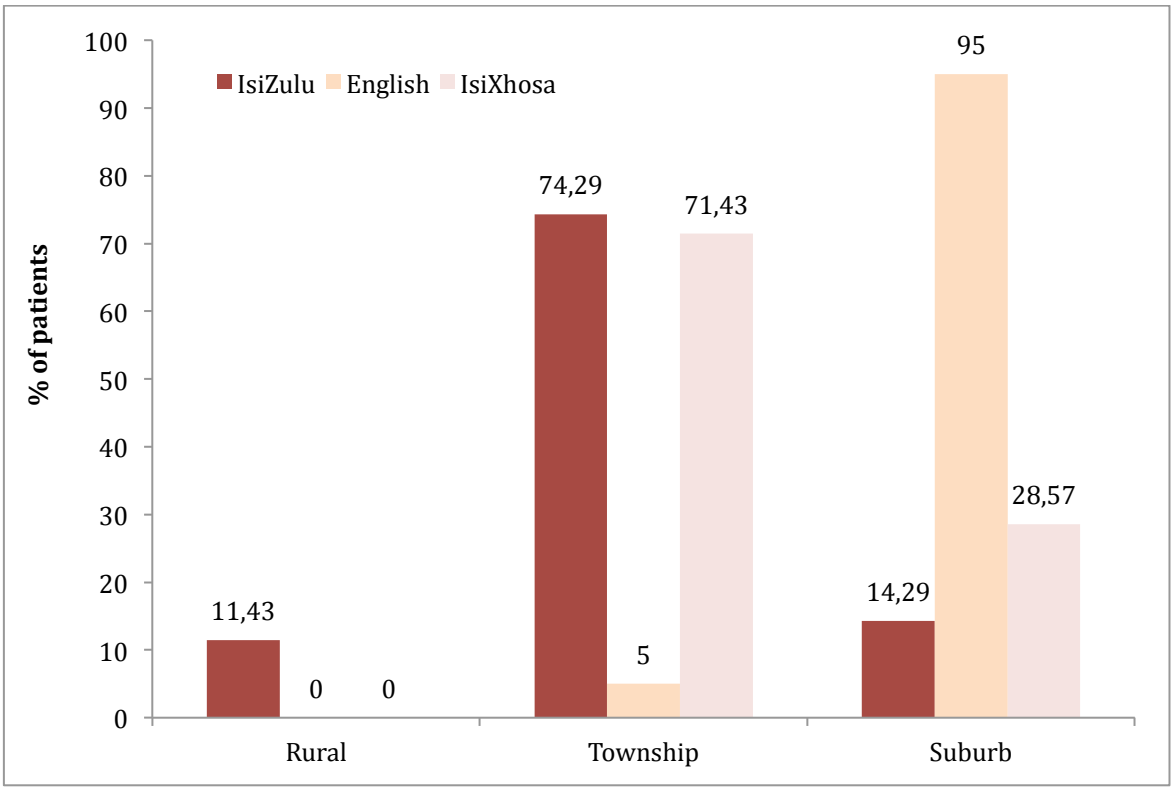


Figure 3.10. Association between home language (top 3 languages only) and residential area

There was a significant, moderate, association between education and residential area type (p=0.0017; Cramer's V=0.33), see figure 3.11. The patients from the rural areas tended to be less educated than those from the townships who in turn tended to be less educated than those from the suburbs.

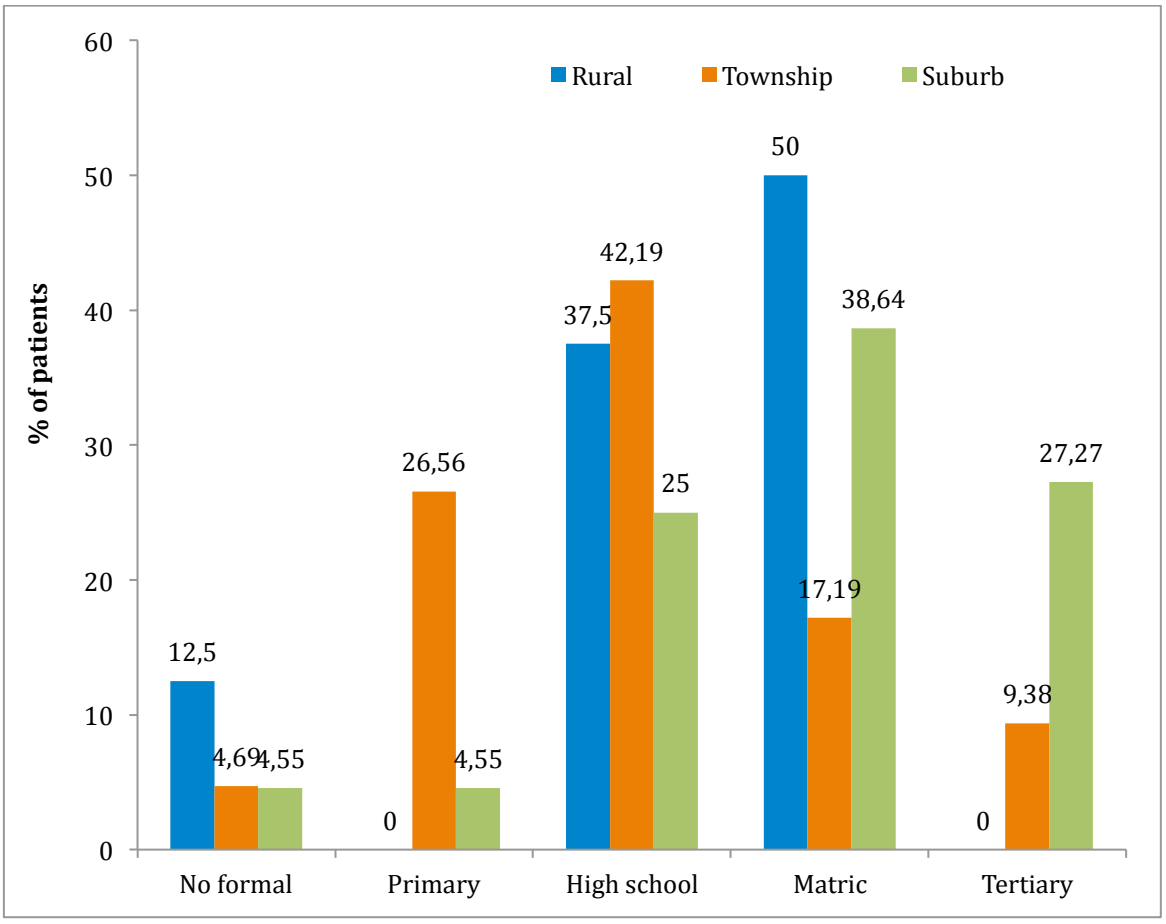


Figure 3.11. Association between education and residential area type

3.3. Administration of the consent form

According to the patients, a doctor administered the consent for the CT scan in 98% of cases (there was one recording of 'NA' and one of 'Other' – according to the consent form, this was a doctor).

According to the consent forms, a doctor had indeed administered the consent for the CT scan in 95% of cases, with a radiographer having administered consent in 2 cases (1.7%) and a nurse in 1 case (0.9%) – these were apparently mistaken for doctors by the patients. There were 3 cases of 'NA' according to the consent forms. The cross-tabulation comparing survey and consent form data is shown in table 3.2. Given that the vast majority of patients consented by a doctor, these items were not analysed further.

Table 3.2. Administration of the consent form

Consent according to patient	Consent according to form				
	Doctor	Nurse	Radio-grapher	NA	Total
Doctor	110	1	2	2	115
Other	1	-	-	-	1
NA	-	-	-	1	1
Total	111	1	2	3	117

3.4. Language of consent in relation to patient's proficiency

61% of the patients were consented in either their home language (directly or via an interpreter) or in a language that they understood. There was no significant difference between hospitals w.r.t this profile (p=0.17), as shown in figure 3.12.

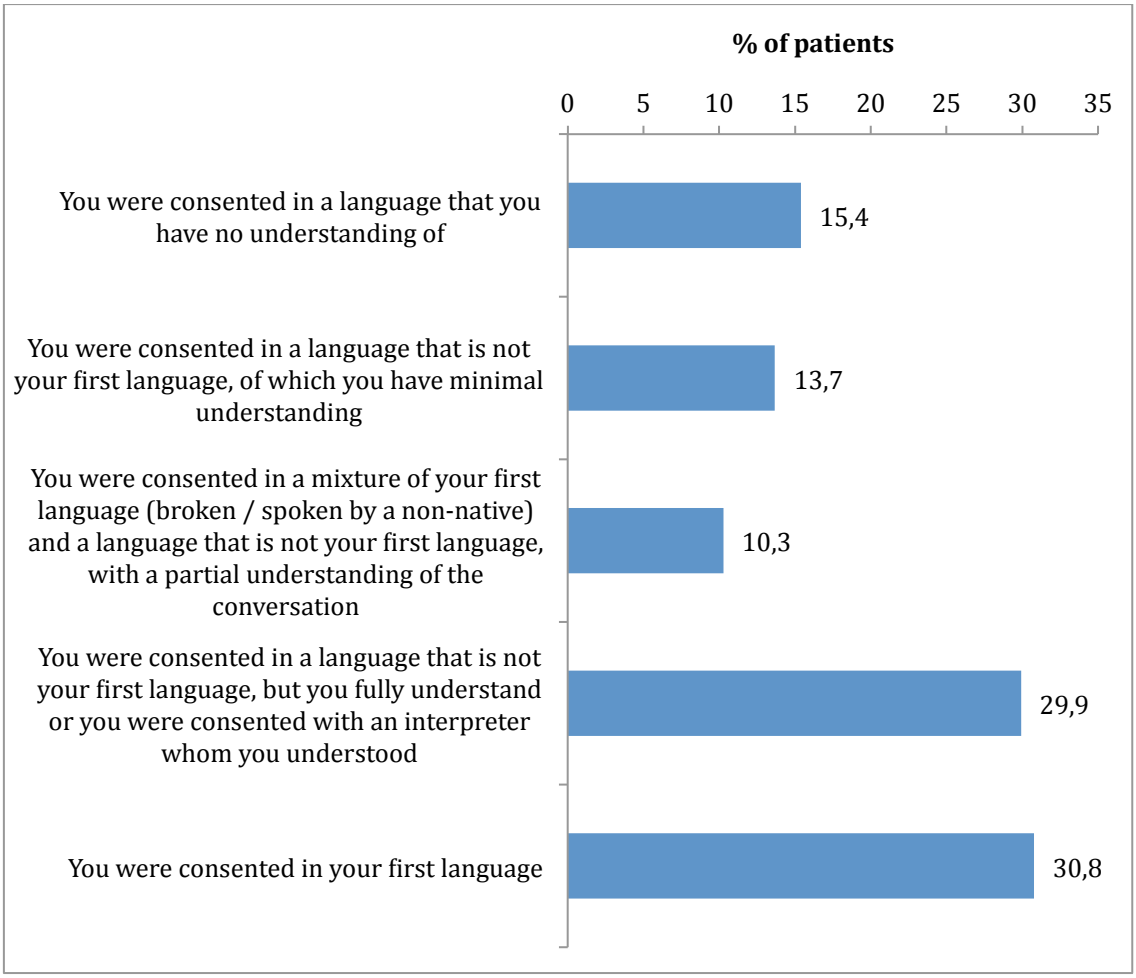


Figure 3.12. Language of consent in relation to the patient's proficiency

For further analysis, the language of consenting was grouped into two categories: understood (last two categories in figure 3.12) and not understood (first three categories in figure 3.12). There was also no significant difference between hospitals (p=0.088) with regard to these categories.

There was a significant, moderate, association between whether the language of consent was understood or not understood and the home language of the patients (p=0.0013; phi coefficient=0.43), as shown in figure 3.13. English-speaking patients predominantly understood the consenting language, while substantial proportions of those who had other home languages did not understand the consenting language. The proportions for the relatively uncommon languages should not be over-interpreted, as the patient frequencies were very low.

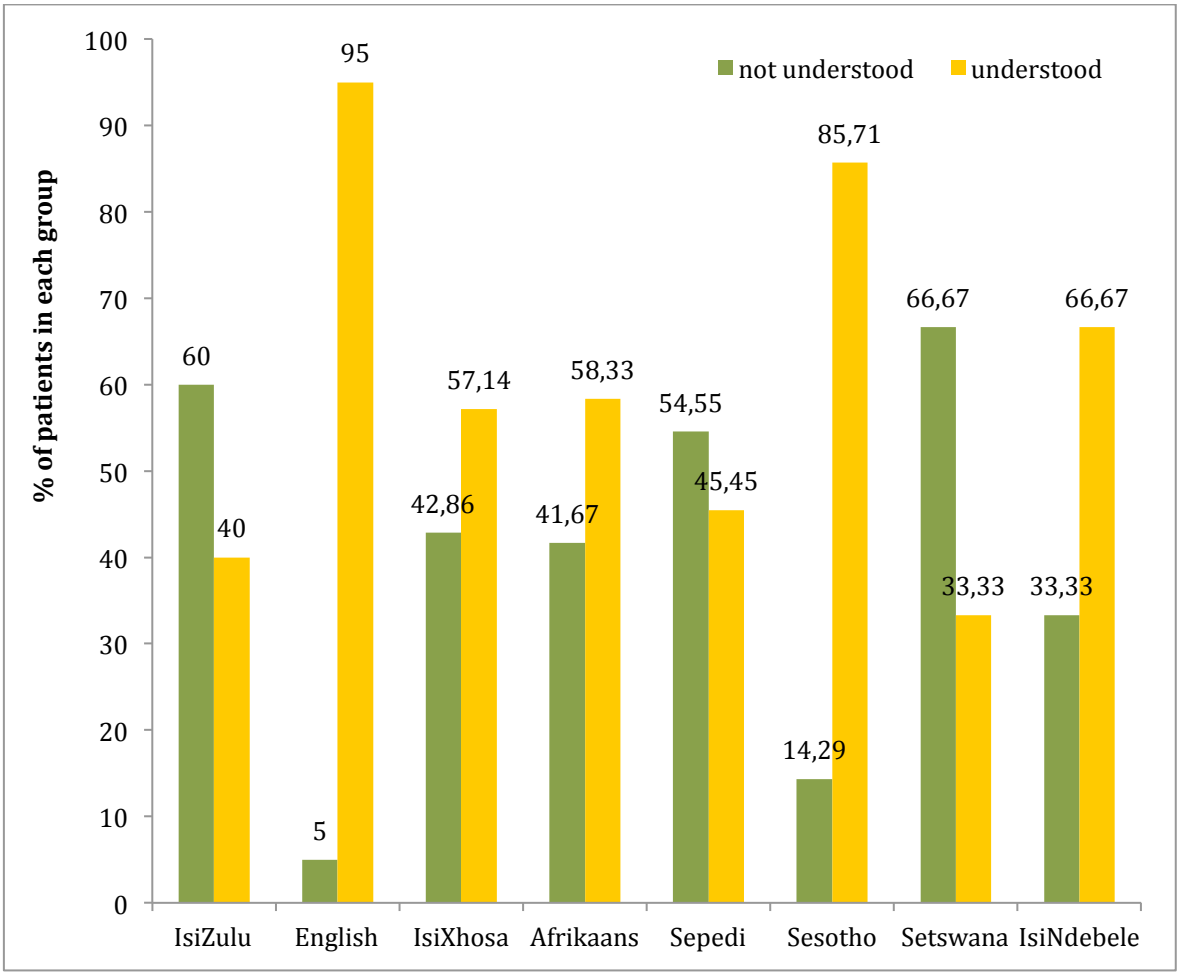


Figure 3.13. Association between whether the language of consent was understood or not understood and the home language of the respondent

There was a significant, moderate, association between the language of consenting (understood / not understood) and cultural background (p=0.0012; phi coefficient=0.34), as shown in figure 3.14: The majority of White and Asian / Indian patients understood the consenting language, while substantial proportions of Black and Coloured patients did not. This relates back to the home language differences since we know that cultural background and home language are strongly confounded.

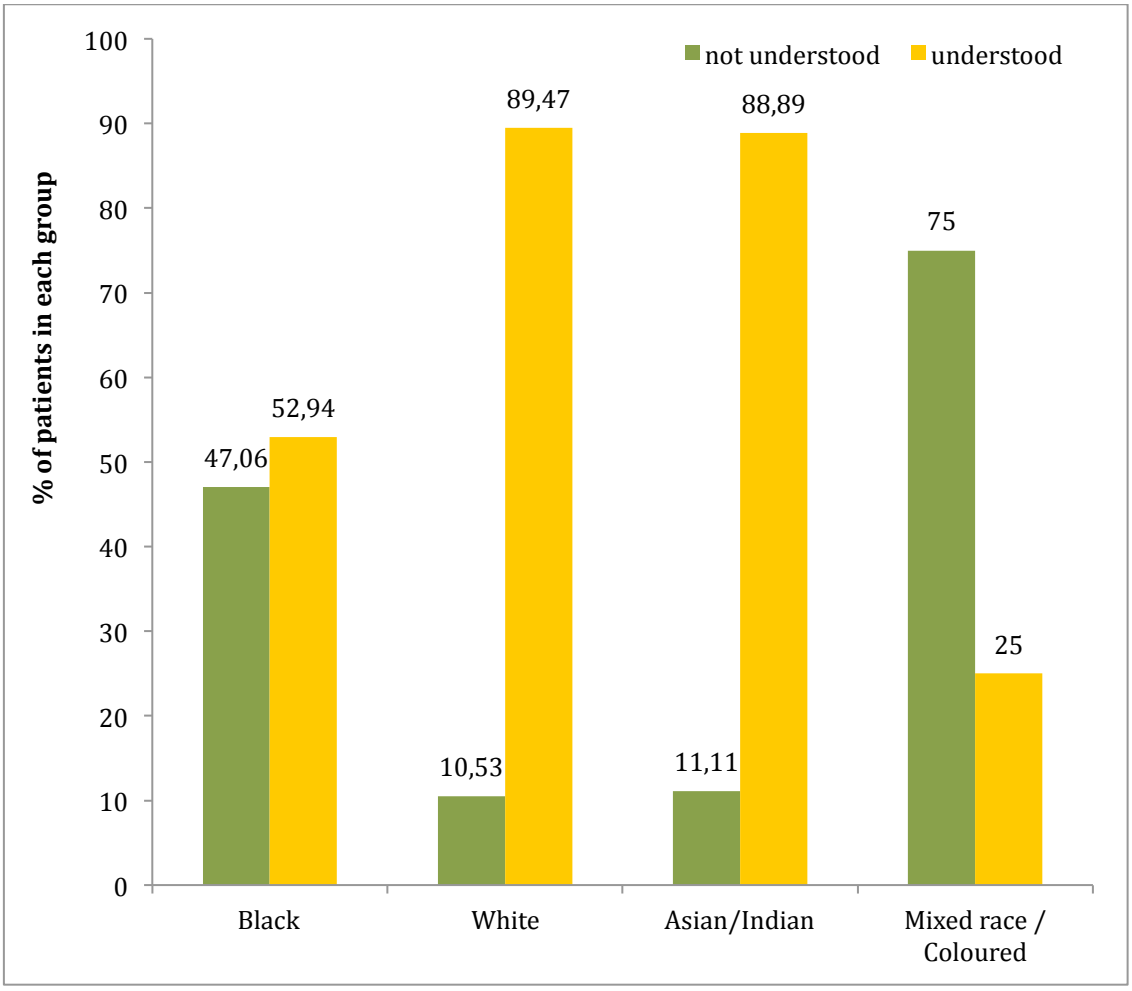


Figure 3.14. Association between the language of consenting (understood / not understood) and racial group

There was a significant, moderate, association between the language of consenting (understood / not understood) and education ($p<0.0001$; phi coefficient=0.41), as shown in figure 3.15. The proportion of patients who understood the consenting language increased with the level of education.

There was no significant association between the language of consenting (understood / not understood) and gender ($p=0.13$) or age category ($p=0.72$).

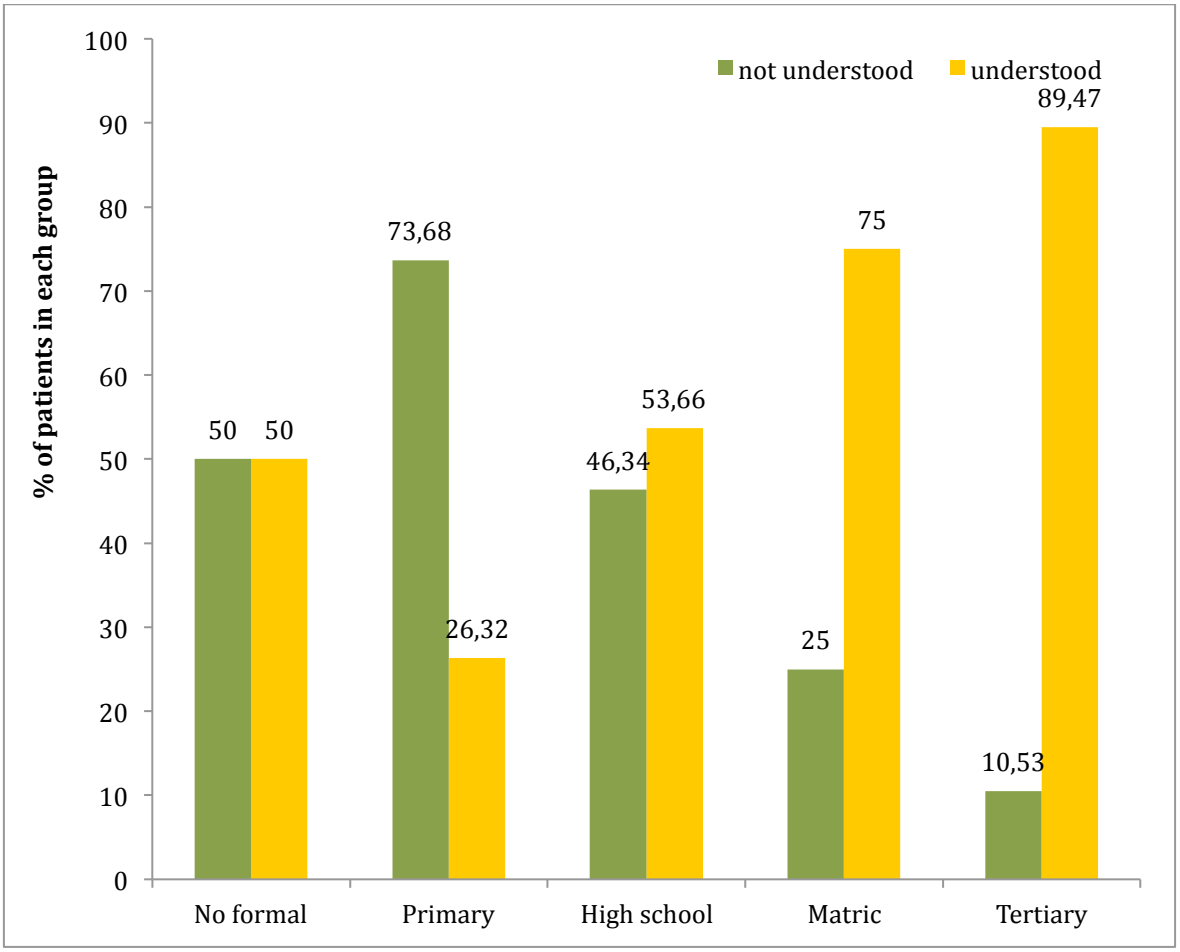


Figure 3.15. Association between the language of consenting (understood / not understood) and education

3.5. Level of understanding of contents of consent

The figure 3.16 shows the percentage of patients who indicated full understanding for each knowledge / information component. The error bars show the 95% confidence interval for the proportion. The highest level of understanding was around the body part to be investigated (74% of patients had full understanding). This level of understanding was significantly higher than that of all the other knowledge / information items

Marginally fewer than 50% of patients had a full understanding of the reason for their CT scan, while fewer than 40% of patients had a full understanding of the finer details – the necessity of oral medication or an injection as well as the risks and benefits of the procedure. These results are summarised in figure 3.16.

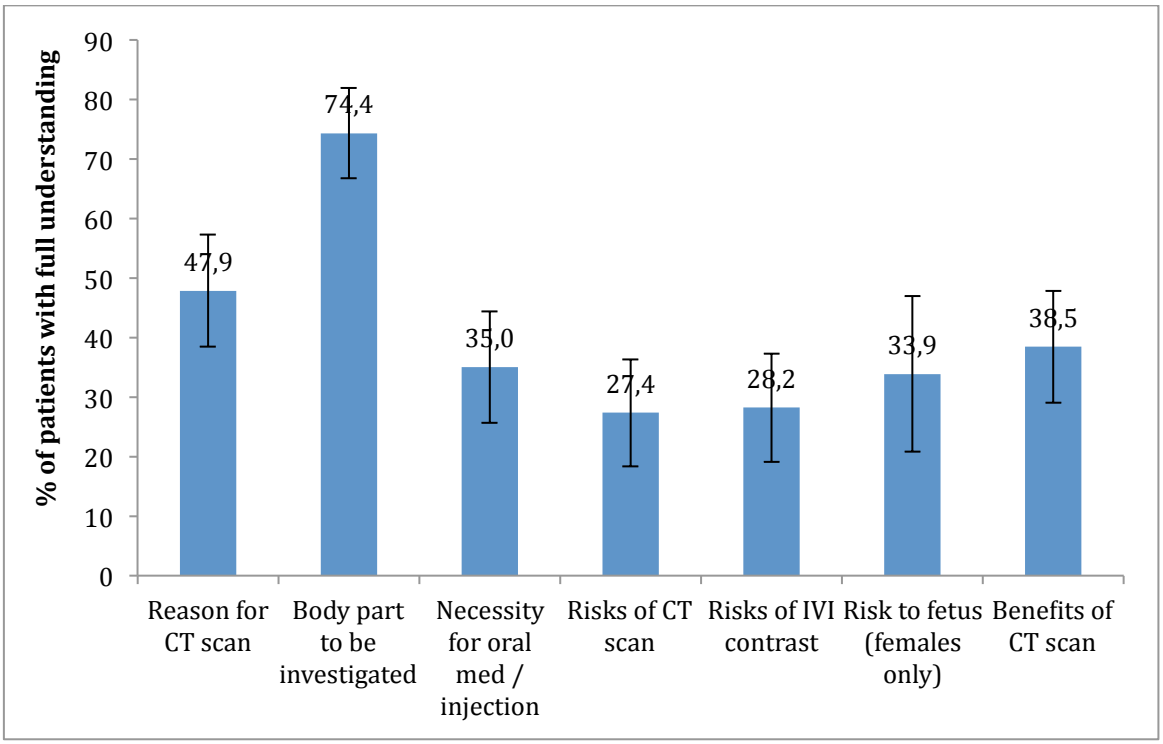


Figure 3.16. Percentage of patients who indicated full understanding

The level of understanding for each of these items was significantly associated with the language of consenting e.g. there was a significant, strong, association between the language of consenting (understood / not understood) and the level of understanding of the reason the patient was at the CT department ($p<0.0001$; Cramer's $V=0.63$), as shown in figure 3.17. Amongst those who had a full understanding of the reason for the CT scan there was a much higher proportion of patients who had understood the language of consent, than amongst those who had no understanding of the reason for the CT scan. The same relationship was true for the other knowledge / information items. The results are summarised in table 3.3.

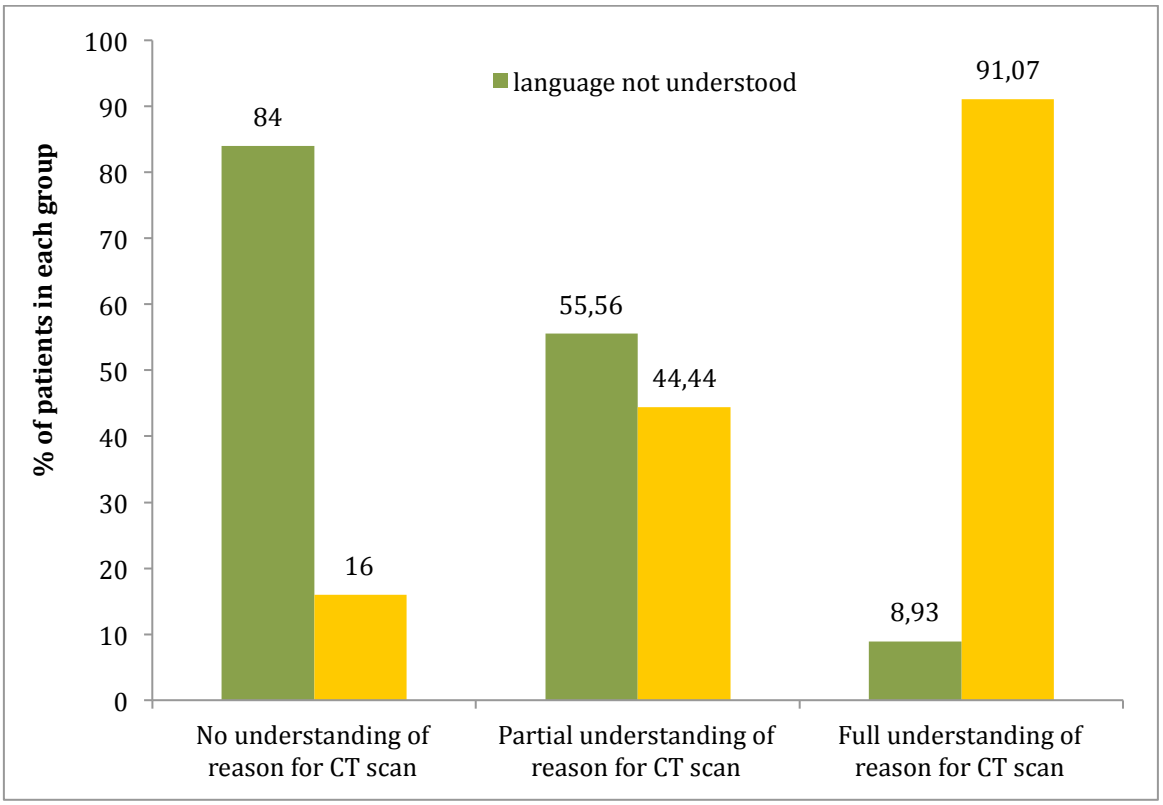


Figure 3.17. Association between the level of understanding with the language of consenting

Table 3.3. Association between level of understanding for each item with the language of consenting.

Item	P-value	Cramer's V	Strength of association
Reason for CT scan	< 0.0001	0.63	strong
Body part to be investigated	< 0.0001	0.46	moderate
Necessity for oral med / injection	< 0.0001	0.41	moderate
Risks of CT scan	0.0082	0.29	weak
Risks of IVI contrast	0.0008	0.35	moderate
Risk to fetus (females only)	0.017	0.36	moderate
Benefits of CT scan	< 0.0001	0.48	moderate

There were significant differences between hospitals with regard to some, but not all, of the items. Figure 3.18 demonstrates, for each hospital group, the percentage of patients with full understanding. Those items for which there was a significant difference between hospital groups are marked with an asterisk.

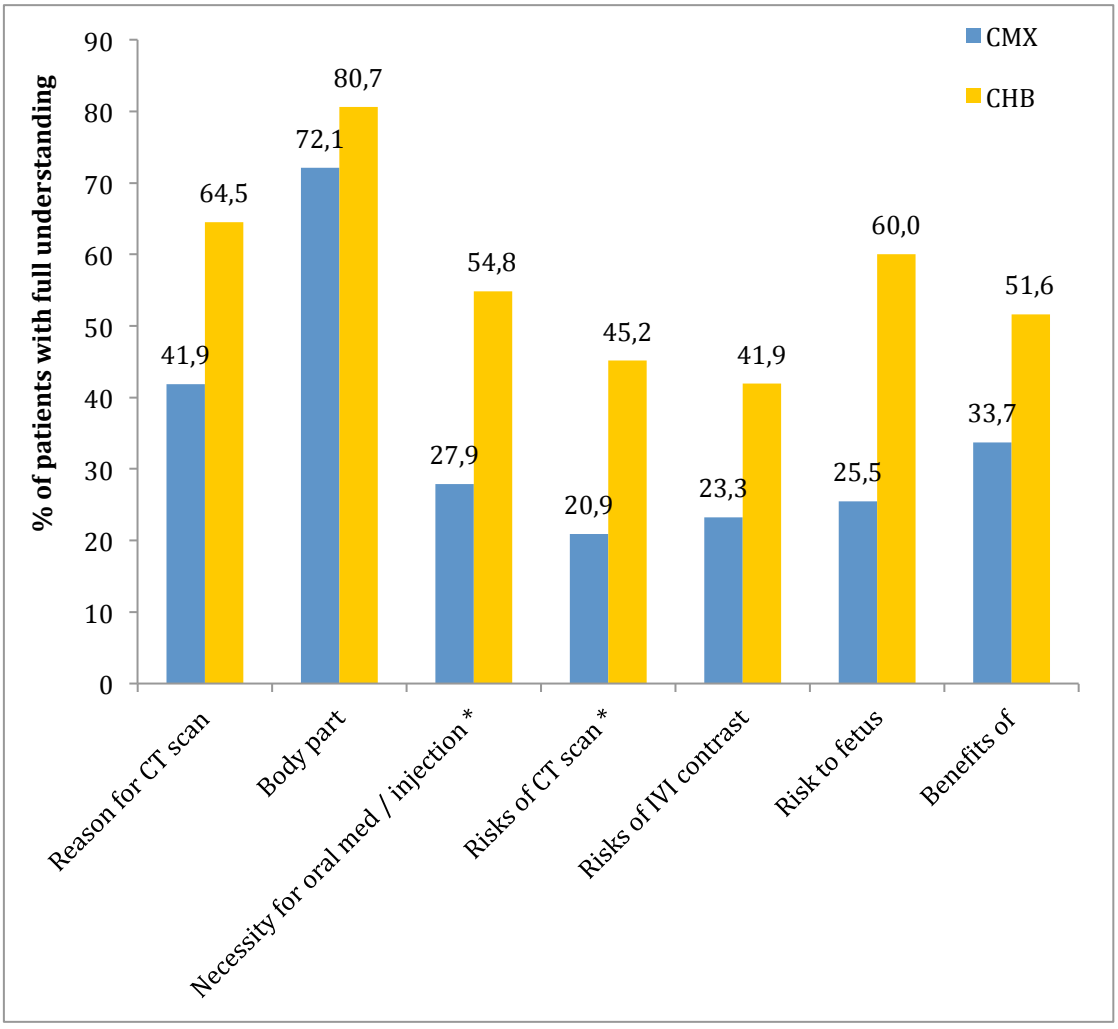


Figure 3.18. Comparing the differences between hospitals per item.

*Those items for which there was a significant difference between hospital groups are marked with an asterisk.

The proportion of patients with full understanding was higher in the CHB group for understanding of the body part to be investigated, the necessity for oral medication or injection, the risks of the CT scan and the risk to the foetus. Indications are that the CHB group also did better on the remaining items, but due to the small size of this group, the comparisons were not significant.

3.6. Level of information / alternatives given during consenting

Figure 3.19 shows, for each component of information and alternatives, the percentage of patients who indicated that the item in question had occurred. The error bars show the 95% confidence interval for the proportion. 50% of patients felt that they had been given enough information and had had an opportunity to ask questions. Only 33% had been offered an alternative to the CT scan; of those offered an alternative to CT scan, 87% had then had the risks and benefits of the alternative explained to them.

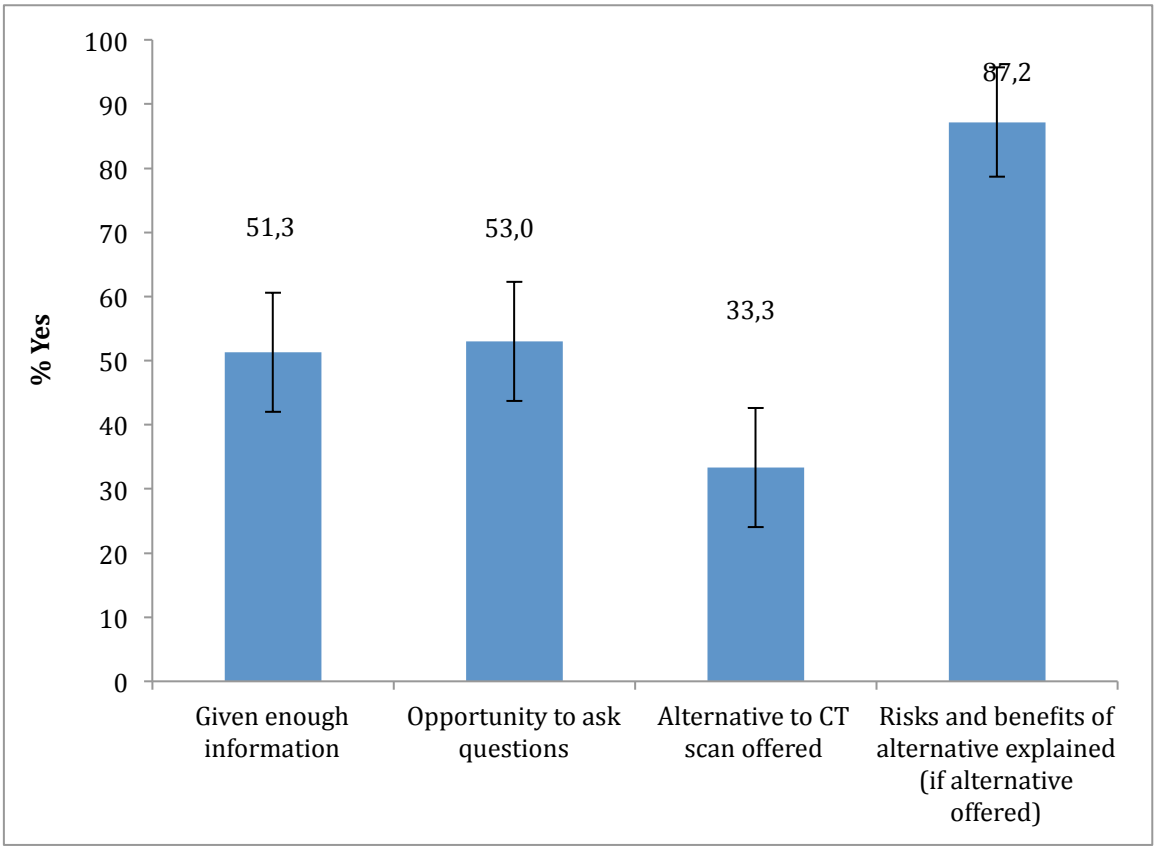


Figure 3.19. Level of information / alternative given during consenting

The level of understanding for each of these items was significantly associated with the language of consenting. An example is given for 'enough information given':

There was a significant, moderate, association between the language of consenting (understood / not understood) and whether or not the patient felt enough information about the CT scan had been given ($p<0.0001$; Cramer's $V=0.48$), see figure 3.20. Amongst those who felt that enough information had been given there were a much higher proportion of patients who had understood the language of consent, than amongst those who felt that not enough information had been given. The same relationship was true for the other items (with the exception of the last item – most likely due to small sample size); the results are tabulated in table 3.4. There were no significant differences between hospitals on any of these items.

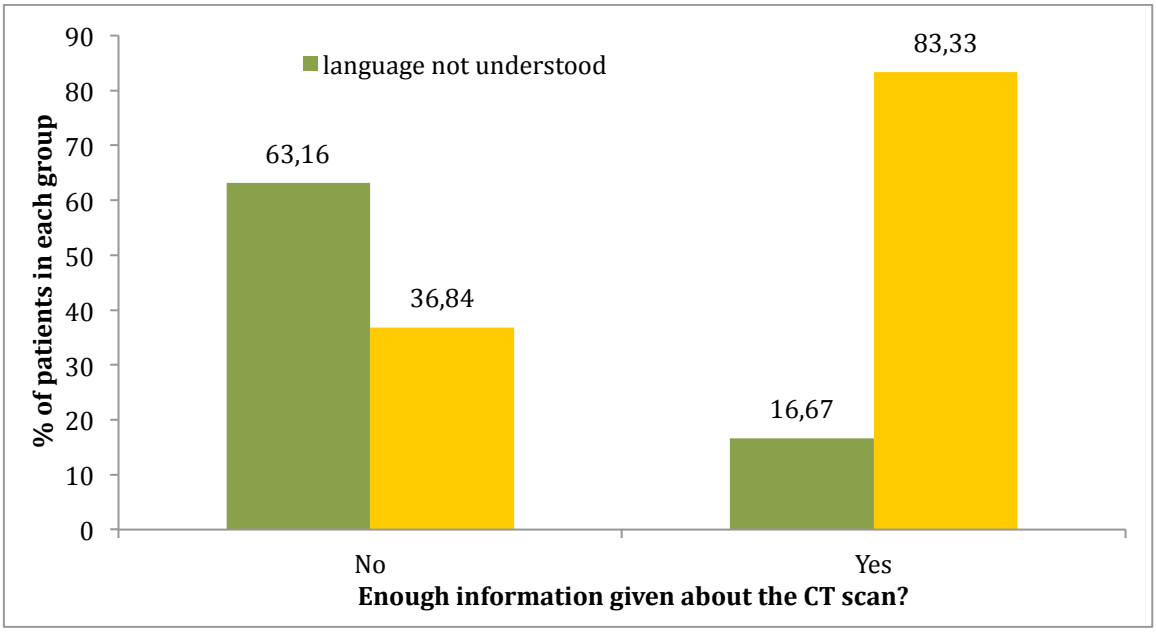


Figure 3.20. Association between the language of consenting (understood / not understood) and whether or not the patient felt enough information about the CT scan had been given

Table 3.4. Association between level of understanding for each of these items with the language of consenting

Item	P-value	Cramer's V	Strength of association
Given enough information	< 0.0001	0.48	moderate
Opportunity to ask questions	< 0.0001	0.36	moderate
Alternative to CT scan offered	0.016	0.24	weak
Risks and benefits of alternative explained (if alternative offered)	0.070		

3.7. Overall adequacy of consent score

The overall mean adequacy of consent score was 50.6±5.5%. The distribution in scores is shown in figure 3.21 with wide variation

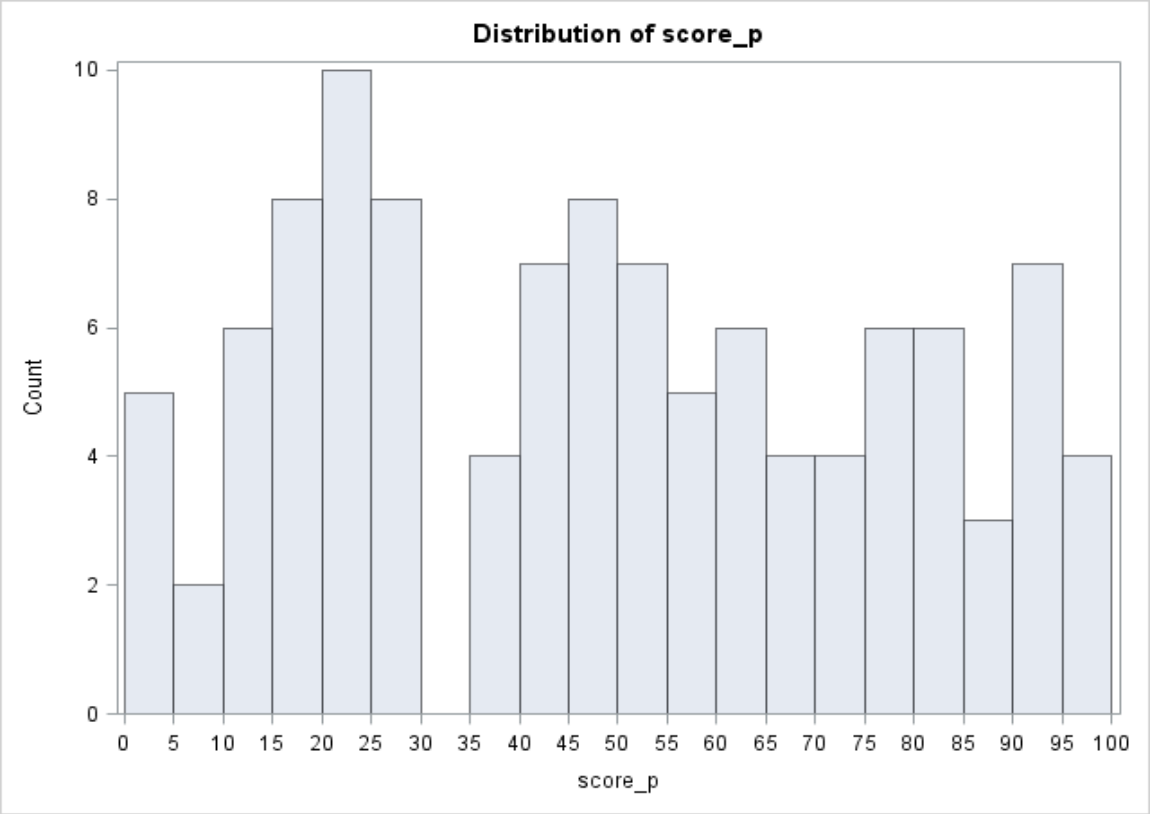


Figure 3.21. Overall distribution in adequacy of consent score

There was no significant difference in the mean adequacy of consent score with regards to gender (p=0.24) or age category (p=0.83).

There was a significant difference in the mean adequacy of consent score with regards to cultural background ($p<0.0001$) as demonstrated in figure 3.22. Post-hoc tests showed that the mean score for white patients (77±13%) was significantly higher than that for black patients (44±6%). The effect size was large (Cohen's $d=1.22$). The error bars in figure 3.22, as well as the values after the ± above, denote 95% confidence intervals for the mean.

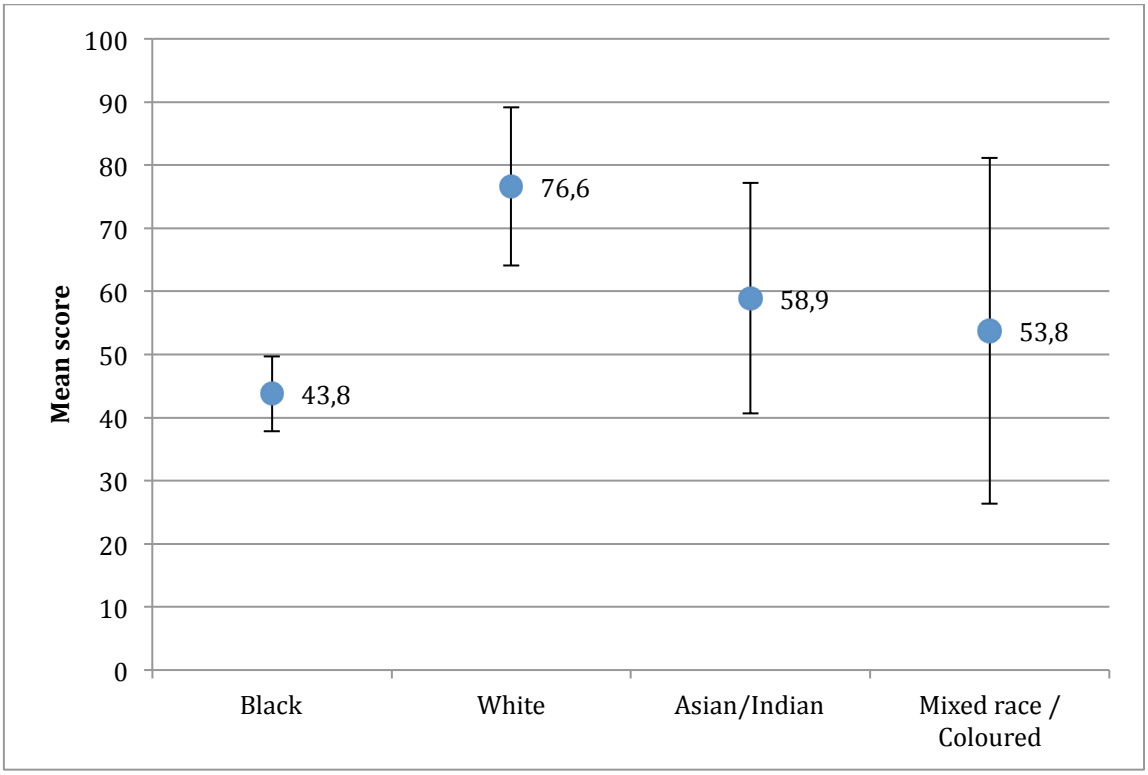


Figure 3.22. Differences in the mean adequacy of consent score with regard to racial group

There was a significant difference in the adequacy of consent score with regards to home language (p=0.0073), as shown in figure 3.23. Post-hoc tests showed that the mean score for English-speaking patients (71±13%) was significantly higher than that for IsiZulu-speaking (40±10%) and Sepedi-speaking (37±17%) patients. The effect sizes were large (Cohen's d = 1.02 and 1.27 respectively).

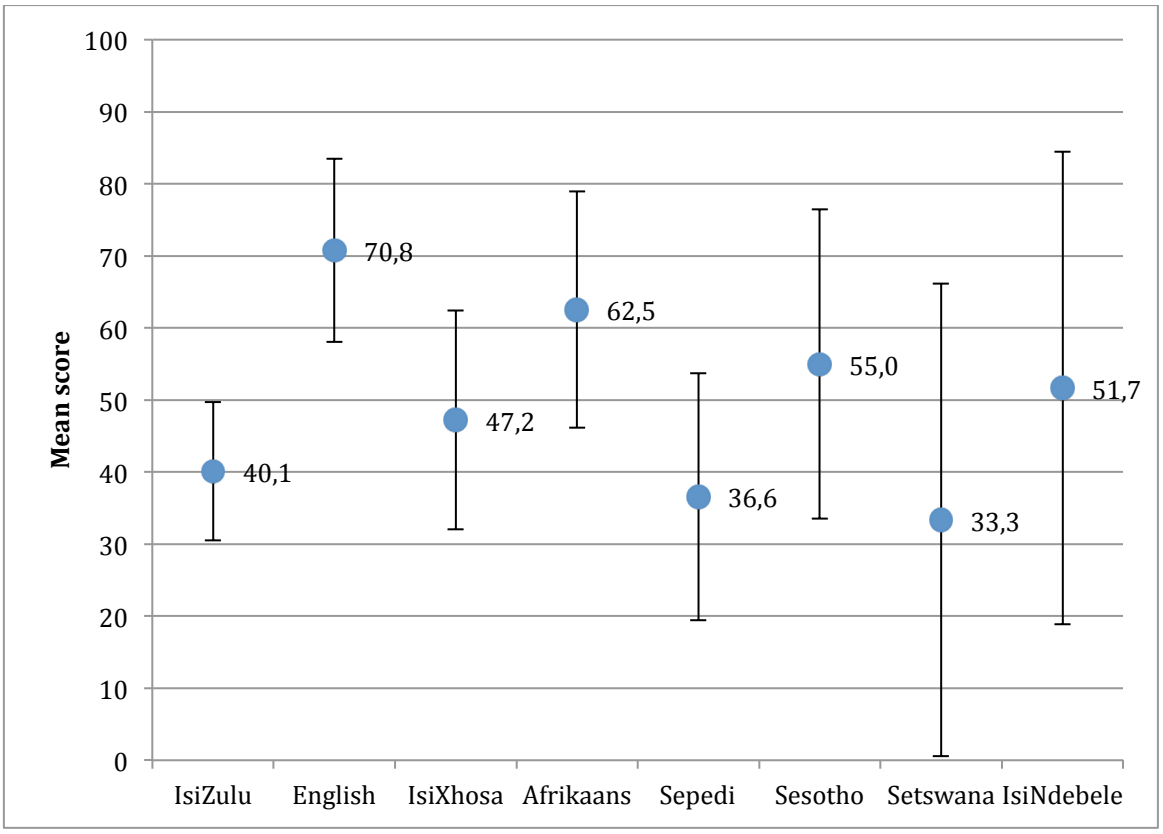


Figure 3.23. Differences in the adequacy of consent score with regards to home language

There was a significant difference in the adequacy of consent score with regards to residential area type ($p<0.0001$), as shown in figure 3.24. Post-hoc tests showed that the mean score for patients from the suburbs (67±8%) was significantly higher than that for patients from either the townships (42±7%) or the rural areas (33±19%). The effect sizes were large (Cohen's d = 0.87 and 1.25 respectively).

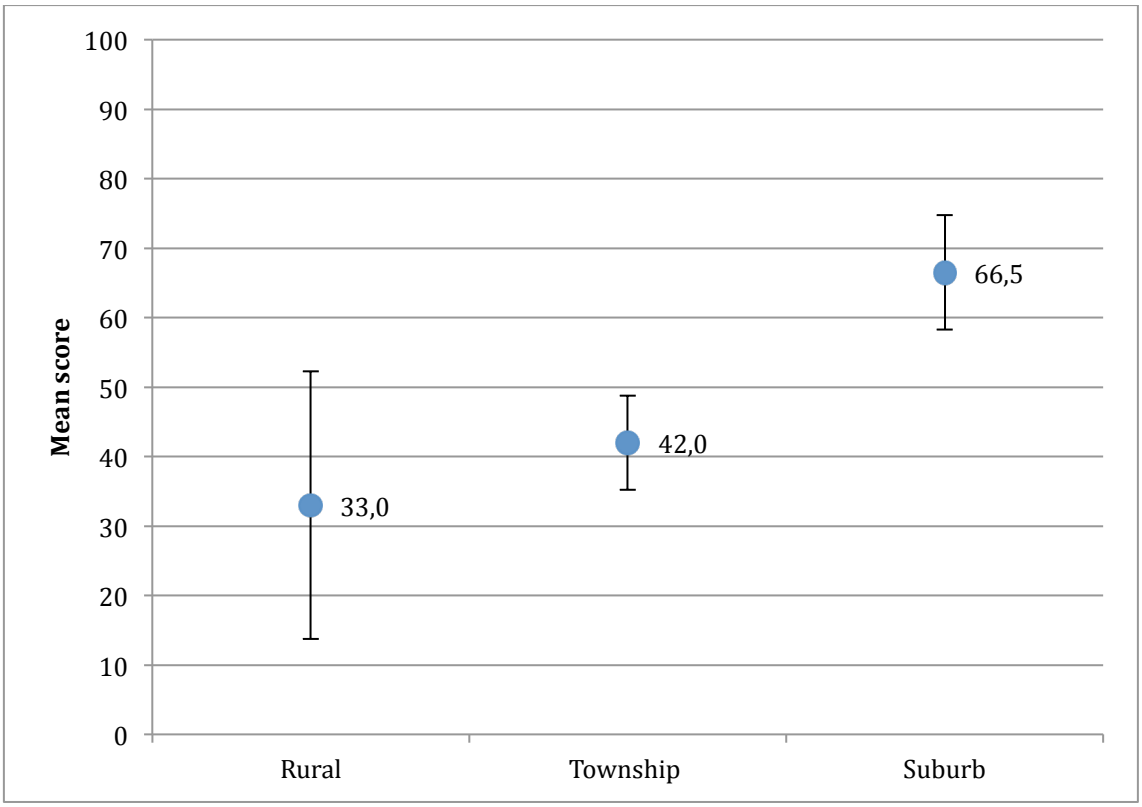


Figure 3.24. Differences in the adequacy of consent score with regards to residential area type

There was a significant difference in the adequacy of consent score with regards to level of education ($p<0.0001$), as shown in figure 3.25. Post-hoc tests showed that the mean score for patients with tertiary education (72±12%) was significantly higher than that for patients with high school or less education. The effect sizes were all large. The mean score for those with matric (62±9%) was significantly higher than those with primary or no formal education. The effect sizes were moderate to small.

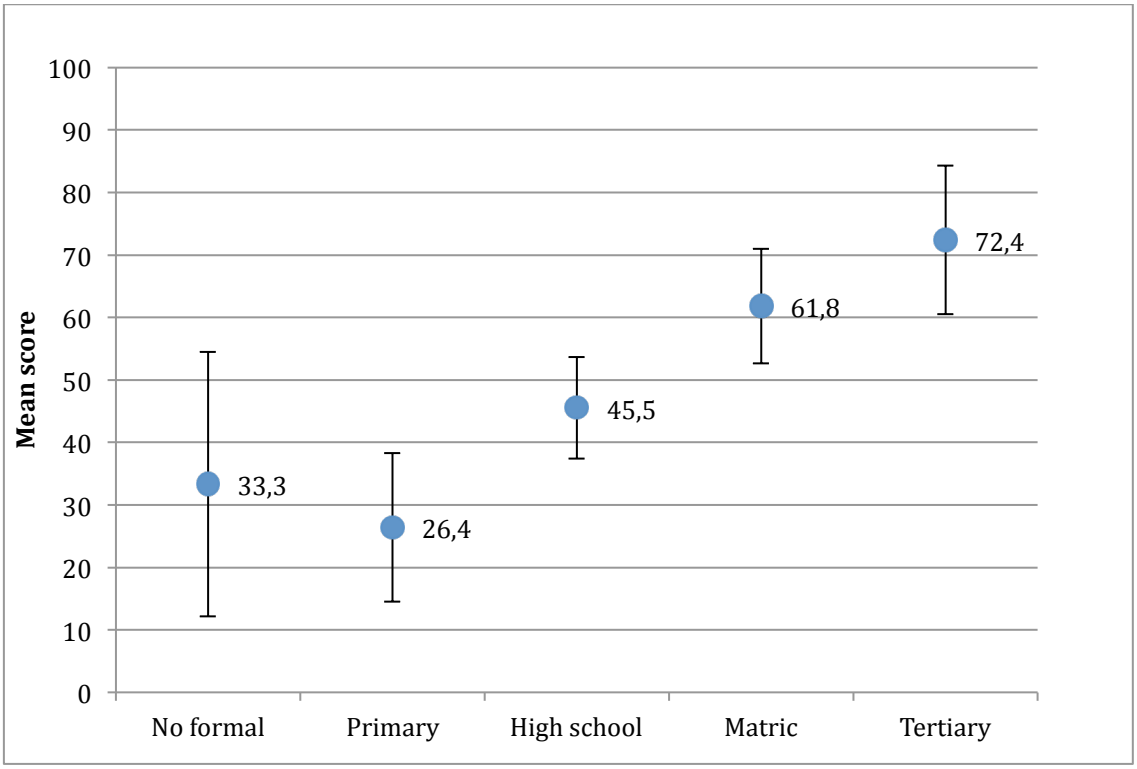


Figure 3.25. Differences in the adequacy of consent score with regards to level of education

There was a significant difference in the adequacy of consent score with regard to hospital (p=0.035), see figure 3.26. The mean score for patients from CHB (60±12%) was significantly higher than that for patients from CMX (47±6%). The effect size was small (Cohen's d=0.44).

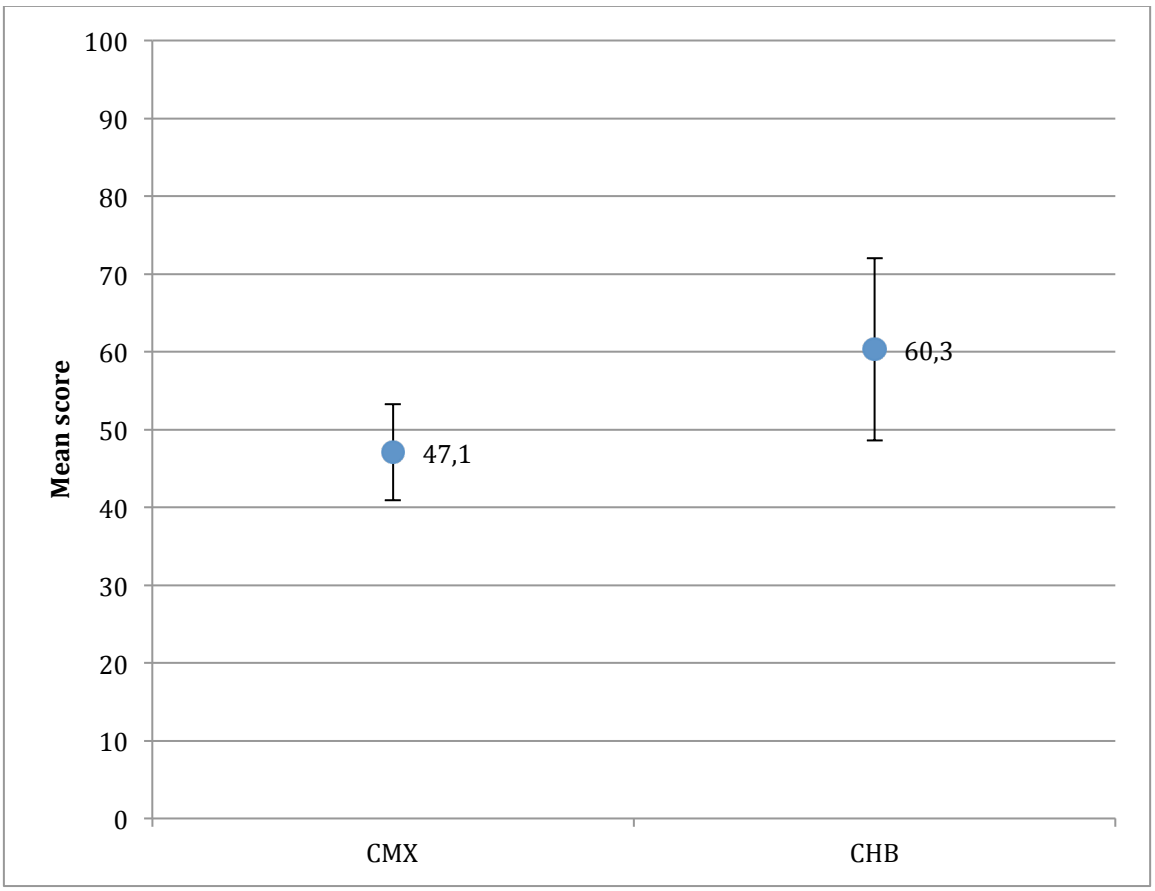


Figure 3.26. Differences in the adequacy of consent score with regards to hospital

3.8. Overall satisfaction with the information provided and how it was delivered

Only 40% of the patients indicated that they were fully satisfied with the information provided and how it was delivered, with 34% and 26% indicating moderate satisfaction and no satisfaction respectively. There was no significant difference between the two hospital groups (p=0.12).

This response linked very strongly to the adequacy of consent score (p<0.0001), as illustrated in figure 3.27. There were significant differences between the mean scores of each satisfaction category.

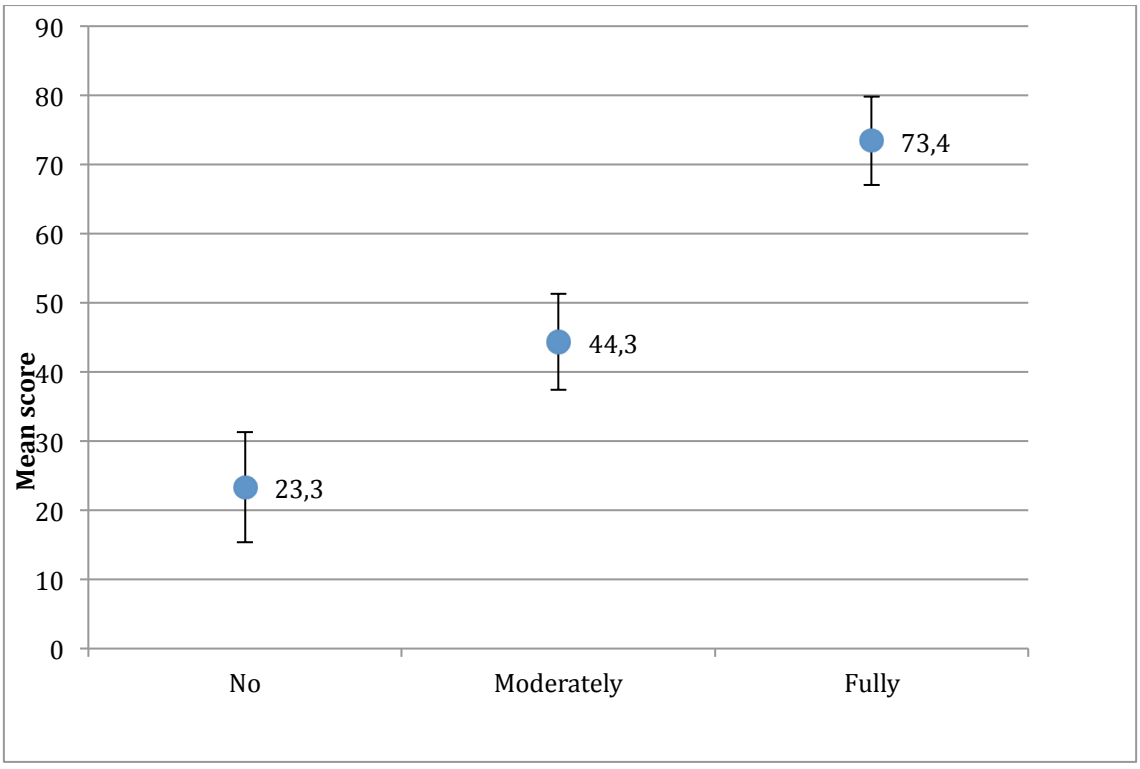


Figure 3.27 Association between the overall satisfaction with the information provided and adequacy of consent score

3.9. Females / pregnancy

Only 31% of the total of 62 female patients in the study had been asked if they were pregnant. There was no significant difference between the hospital groups (p=0.12). A higher proportion (48%) of female patients did claim to know that the CT scan would pose a mild / significant risk to an unborn foetus. There was no significant association between these two items (p=0.082), but the sample size was small (n=62).

One female patient indicated that she might be / is pregnant. This patient was, in fact, not asked if she was pregnant!

3.10. Request for information

93% of patients indicated that they wanted to be given information about the risks and benefits associated with CT scans and IV contrast. There was no significant difference between hospital groups (p=0.44) or with any of the demographic variables.

4. Discussion

4.1. Results in context

In the three month period of data collection, we surveyed 117 patients, 86 (74%) from Charlotte Maxeke Johannesburg Academic Hospital (CMX), and 31 (26%) from Chris Hani Baragwanath Academic Hospital (CHB). The demographics of our sample were a good representation of the population, comparable with the findings of the South African census of 2011 (18) (summarised in table 4.1.1, appendix D). We found that a significant proportion of our sample had some form of formal education with 27.4% of our sample having completed grade 12 and 35% with some high school education, which is comparable to 28.4 and 33.8% respectively for the general South African population. Surprisingly a very small segment of our sample had no formal education at 5.1%. This was not markedly different from the findings of the census recording 8.6% for the general South African population. As we had anticipated, younger patients (18-40 years) tended to be more educated compared to older patients (41+ years). More white patients had formal education and of these a high percentage had completed matric or a tertiary qualification compared to the other races, which reflects the previously privileged group in our country.

We found that black patients hailed from all types of residential categories (suburbs, rural areas and townships), compared to white patients' who were exclusively from the suburbs. Patients who indicated English as their first language predominantly came from suburbs whereas the IsiXhosa and IsiZulu speaking patients were predominantly from the townships with only a small portion from the suburbs. It is important to note, that the

patients from the rural areas were also the least educated, followed by patients from the townships, while patients from the suburbs were the most educated. It should be kept in mind, that occupants of townships and rural areas are predominantly black. In brief, our findings demonstrated a moderate association between racial group, home language, residential area type and education. There was also some association between education and age.

In the overwhelming majority of the patients we interviewed, the consenting procedure was predominantly conducted by doctors but only 61% of the patients were consulted in either their home language (directly or via an interpreter) or in a language they understood. The remaining 39% had minimal or no understanding of the consulting language, probably because the majority of doctors either speak English as a first language or because the consenting documentation is widely available in English.

We found that there was an association between the patients' home language and whether the language of consent was understood or not understood. The English-speaking patients predominantly understood the consenting language, whereas a significant proportion of the patients who did not indicate English as their home language did not understand the consenting language. This also therefore speaks to the association between the language of consenting and cultural background. A significant proportion of the black and predominantly Afrikaans-speaking coloured patients did not understand the consenting language, with the majority of white and Asian / Indian understanding the consenting language. The proportion of patients who understood the consenting

language increased with an increasing level of education, presumably as a result of increased proficiency in English.

Language differences, different racial groups and low health literacy in patients are barriers to effective communication, which is critical for rendering safe, good quality health care to our patients (16). The correlation between the patient's level of education and their ability to retain and recall information is well documented. Patients with a higher education level generally have a better grasp in the information and are better participants in the decision-making regarding their care (7).

We found that less than 50% of the patients had a full understanding of why they needed a CT scan, while less than 40% of patients had a full understanding of the finer details. The highest level of understanding was around the body part to be investigated (74% of patients had full understanding). This level of understanding was significantly higher than that of all the other items on the questionnaire presumably because this aspect is most closely related to the patient's illness and their reason for presenting to hospital.

Yet again we found that the level of understanding for each of these items was significantly associated with the language of consenting. Amongst those who had a full understanding of the reason for the CT scan there was a much higher proportion of patients who had understood the language of consent, than amongst those who had no understanding of the reason for the CT scan.

We noted significant differences between hospitals on some, but not all, of the items. The proportion of patients with full understanding was higher in the CHB group for understanding of the body part to be investigated, the necessity for oral medication or injection, the risks of the CT scan and the risk to the foetus. Indications are that the CHB group also did better on the remaining items, but due to the small size of this group, the comparisons were not significant. This was an unexpected finding as we had anticipated that people who attend CMX would be more educated and more likely to speak English compared to those who attend CHB. It is well documented in medical literature that patients do not retain much information from the consenting procedure, but this has been related to how well the information has been delivered to start with (2, 10, 15).

We found that only 51.3% of patients felt that the information they were given was adequate and had an opportunity to ask questions during the consenting procedure. The language of consenting, level of education, medical literacy and the paternalistic style of medicine could be seen as factors in this regard. Patients are often afraid to question the doctor or possibly do not have the language skills to do this. The latter appears to be a significant barrier in our population. Only 33% had been offered an alternative to the CT scan. Of these patients, 87% had the risks and benefits of the alternative explained to them.

South Africa being a developing country is under-resourced and some might view it unrealistic at times to even consider alternative modalities such as MRI if a diagnosis can be made on CT, which is more widely available. Ultrasound is however often a useful consideration for a patient considering the risks of radiation. For consent to be informed

the information shared with patient must include but not limited to the nature of the proposed procedure, benefits of the proposed procedure, risks associated with the proposed procedure, alternatives to the procedure and the risks and the benefits associated with the alternative (3, 5-8).

Our findings demonstrate without doubt that the level of understanding for each of the items we investigated, was significantly associated with the language of consenting. Amongst patients who felt that enough information had been given, a much higher proportion of them had understood the language of consent, than amongst those who felt that not enough information had been given. During the consenting procedure the patient must be able to use his/ her understanding of the provided information to formulate a knowledgeable decision (4). Our findings then beg the question whether the information was delivered but simply not understood by the patients due to a language barrier or whether the information was pitched at a technical level so that it was difficult for patients to understand.

We did not find significant differences between hospitals on any of these items. This is interesting, considering that the CHB patients reported a somewhat higher level of understanding. Their appraisal of the overall amount of information given, opportunity to ask questions and alternatives offered, did not differ from that of the CMX patients. This clearly demonstrates that these two institutions have a similar practice in the consenting of patients. This particular practice may be inherited from the heads of units and senior consultants and then passed down to registrars and interns much like other medical knowledge in the training institutions. Medical officers, interns and medical students alike

have historically not been taught specific courses in consenting practices in South Africa. Other possibilities may be the lack of time and patience due to high patient volumes, and heavy workload resulting in doctors dedicating less time to the details of this important consideration of patient's rights and the medico-legal implications.

We used an arbitrary score for calculating 'adequacy of consent score' using all the parameters collected, equally. We found that the overall mean adequacy of consent score was fairly low (50.6±5.5%). Even though previous reports indicate that younger patients are likely to understand or take more from the consenting procedure than their older counterparts, this has been postulated to be related to the high chance that the younger patients tend to be more educated (9). Our results did not show that gender and age category had a significant difference in the mean adequacy of consent score. We did find a significant difference in the mean adequacy of consent score when we looked at racial grouping, home language, residential type and level of education. White patients scored significantly higher than black patients, with English speaking patients scoring significantly higher than IsiZulu and Sepedi speaking patients. Patients from the suburbs fared significantly better than those from townships and suburbs and finally the patients with tertiary education scored significantly higher than those with lower levels of education.

Even though we showed no significant demographic differences between the two hospitals studied, the patients from CHB scored significantly higher than those from CMX, and the difference in adequacy of consent score may well relate to a difference in consenting practice between these two hospitals or a different profile of the staff performing the consenting procedure [their cultural group, language skills, time taken for

consent or in-house practice may be different]. This is currently under investigation through a different study from our research group.

Less than a third (31%) of the female patients were asked if they were pregnant during the consenting procedure. This trend was noted for both hospitals. Interestingly, though, almost half (48%) of female patients did claim to know that the CT scan would pose a mild / significant risk to an unborn foetus.

An overwhelming 93% of patients indicated that they wanted to be given information about the risks and benefits associated with CT scans and IV contrast. This confirms that patients want to be part of the decision-making regarding their management and is in keeping with recent reports that improved patients level of understanding reduces anxiety in contrast to older papers which reported the opposite to be true (12).

The literature is clear on the patients desire be to informed and educated about medical issues affecting them so as to empower them to make informed decisions regarding their management (12). We are cognisant of the fact that patients preference differ with regard to how much information is provided to them, yet, cultural, societal and family preferences considered, it is our ethical obligation to inform and empower patients so that they become partners in their management (9).

Paternalistic medical practise is still prevalent in our society where patients are willing to accept whatever the doctor decides to be 'in their best interest' (4). The extent to which patients can recall or retain information passed to them has been a subject of much

investigation, with the predominant finding being that very little information is retained or recalled (2, 10, 15). Patients' age, level of education, language differences and the consenting practice itself play a role in this regard

The broader implications of this limited study of consenting for radiology should be considered seriously. Our research has focused on consenting for CT, which has the highest radiation burden and a small mathematical risk to the patient but no direct immediate effect. The same consent form however is in use, by the same doctors who refer to radiology, for the same patient population, for surgical and other interventional procedures that have more frequent and more significant risks, including death. The implications of our findings are therefore far more serious and more widely applicable within the greater medical practice and should be taken extremely seriously.

4.2. Limitations of the current study

Limitations of our study include a relatively small sample size, unequal sample sizes between CMX and CHB. Including only two institutions also creates some bias as these are both attached to the same medical school and do not reflect practice at district and regional hospital level.

5. Conclusion and Recommendations

The findings of this research suggest a major divide between doctors and their patients relating to language differences. These findings highlight a need for doctors to have some training in indigenous languages either as an entry criterion from high school or during the medical course at our medical schools as a compulsory subject.

Furthermore, a national campaign to increase awareness regarding informed consent for medical procedures may increase patient awareness and is our responsibility as medical practitioners. This could be part of a combined initiative by the medical society, the radiological society and the governing body.

The consenting procedure needs to be formalised and incorporated into medical school curricula countrywide. Formal translations need to be in place so that patients can at least read the document and understand it before signing it.
Better training of translators may assist as an interim measure

Broader issues such as social upliftment to increase literacy levels of the population should be highlighted through important examples such as these where people's wellbeing is affected directly.

There is a need for a study to assess the doctors consenting practice and this is already underway by our research unit, at the same hospitals

Appendix A: Ethics Clearance Certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Thandaza Shayingca

CLEARANCE CERTIFICATE	**M121015**
PROJECT	Adequacy of Consenting Patients for Computed Tomography (CT) Scans in a Developing Country: A survey of Two Academic Hospitals in Johannesburg, South Africa
INVESTIGATORS	Dr Thandaza Shayingca.
DEPARTMENT	Clinical Medicine/Diagnostic Radiology
DATE CONSIDERED	26/10/2012
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 26/10/2012 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Prof S Andronikou

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Appendix B: Data collection sheet

Questionnaire / Data Collection Sheet - adequacy of CT consenting procedures

Study number: _____(1-300)

Hospital:

Charlotte M [ ] Chris H [ ]

Population group:

Racial group:

Black [ ] Mixed race / coloured[ ] White [ ] Asian/Indian [ ]

Home language

……..

Gender

Male [ ] Female [ ]

Age:

16-29 [ ] 30-44 [ ] 45-59 [ ] 60 and older [ ]

Habitat / Place of residence: ***How would you best describe the place that you reside?***

Rural [ ] Township [ ] Suburbs [ ]

Level of education: ***What is your maximum level of education achieved?***

No formal education [0]

Primary school education grade 1- grade 7 [1]

High school education but did not matriculate [2]

Matriculated but no tertiary education [3]

Completed tertiary education [4]

Who administered / facilitated the consent for the CT scan according to the patient

Not applicable [0]

Doctor [1]

Nurse [2]

Radiographer [3]

Unknown [4]

Other (specify)…….

Language of consenting in relation to patients proficiency:

Which of the following best describes the language used for consenting in relation to the languages you speak?

You were consented in a language that you have no understanding of [0]

You were consented in a language that is not your first language, of which you have minimal understanding [1]

You were consented in a mixture of your first language (broken / spoken by a non native) and a language that is not your first language, with a partial understanding of the conversation [2]

You were consented in a language that is not your first language, but you fully understand **or** you were consented with an interpreter whom you understood [3]

You were consented in your first language [4]

(other – elaborate _____) [ ]

Level of understanding of reason that patient is at the CT scan department [maximum 2 points]

How do you best describe your understanding of the reason for your CT scan referral?

You are **not sure** why you were requested to present to CT scan) / you have **no understanding** of why you were referred for CT) [0]

You partially understand (definition: understands that they will undergo a test but not clear on the details of it being an imaging test) [1]

You fully understand (definition: understands that they are presenting for an imaging test involving radiation/ X-ray requiring them to go into a machine) [2]

Level of understanding of body part to be investigated: [maximum 2 points]

How do you best describe your understanding of the body part needing scanning?

You are not sure which body part(s) are to be scanned / no understanding [0]

You partially understand (Definition: aware of general body area to be scanned) [1]

You understand exactly the part to be scanned (Definition specifies part) [2]

Knowledge of whether there may be oral medication or an injection necessary:

[maximum 2 points]

Do you know if you will have to take any medication for the procedure?

You are not sure / don't know you will need any medication for CT [0]

You understand that you may need *medication for CT* [1]

You know that *oral medication or* an injection is an integral part of CT [2]

Level of understanding of risks of CT scan:

Which sentence best describes your understanding CT?

You have no knowledge of any risks / you are not sure if there are any risks [0]

You partially understand (Definition: knows there is harm from CT but doesn't know what) [1]

You fully understand (Definition: radiation from CT scan can potentially increase risk of cancer later on in life) [2]

Level of understanding of risks of IVI contrast: [maximum 2 points]

Which sentence best describes your understanding of IVI contrast risk?

You have no knowledge of any risks / you are not sure if there are any risks [0]

You partially understand IVI contrast can be harmful but don't know how [1]

You fully understand that IVI contrast has defined risks (Definition: allergic reactions (potentially fatal) and kidney damage) [2]

Risk to foetus:

How do you best describe your perception of risk of CT to an unborn child of a pregnant mother?

CT has no risk to an unborn foetus [0]

CT has mild risks to an unborn foetus [1]

CT puts a foetus at significant risk [2]

Level of understanding of the benefits of doing CT:

How do you understand the benefits of using CT as a diagnostic tool?

You have no understanding whether CT has benefit compared to other tests

No [0] Yes [1]

You suspect that CT has some advantages (more than X-ray or ultrasound)

No [0] Yes [1]

You know CT is a very advanced diagnostic tool for making a diagnosis

No [0] Yes [1]

Do you feel you were given enough information about the CT scan?

No [0] Yes [1]

Were you given an opportunity to ask questions during the consenting procedure?

No [0] Yes [1]

Were you offered an alternative to CT scan?

No [0] Yes [1]

If you answered yes to the above question, were the risks and benefits of the alternative explained to you?

No [0] Yes [1]

Overall were you happy with the information provided and how it was delivered?

No [0] Moderately [1] Fully [2]

For females only - *Were you asked if you were pregnant?*

No [0] Yes [1]

For females only - *Is there any possibility that you could be pregnant?*

No [0] Yes [1]

Do you want to be given information about the risks associated with CT scans and IV contrast?

No [0] Yes [1]

Appendix C: Consent form

Consent to participate in a research study

Adequacy of consenting patients for computed tomography (CT) scans in a developing country: A survey of two academic hospitals in Johannesburg, South Africa

My name is Dr Shayingca from the University of the Witwatersrand; I am conducting a research study as part of masters (M Med) degree in Diagnostic Radiology. In this study we are looking to test how well informed the participants are about the procedure when they are referred for a CT scan. This information will help us understand if the current system of informing patients about the CT scan is adequate or if it needs to be changed. With this information we will be in a better position to recommend to members of the management team on ways which to improve the system if need be. This will in turn improve patient understanding and the quality of health care afforded to patients.

We invite you to participate in our research study. Before you agree to participate it is important that you understand that participation to this research study is voluntary. You can opt out of the study at anytime and this action will not put at any disadvantage or affect your treatment in anyway. The responses to the interview will have no bearing on the test that you are presenting for. I will collect the information from the interview in an anonymous fashion. There are no risks associated with participating in this study, however your participation will help to offer better care to patients presenting to our institution. This study is approved by the University of the Witwatersrand ethics committee and adheres to the standards set out by the declaration of Helsinki.

Your signature below will be kept separately from the information collection sheet and indicates that you agree to participate in this study.

Hospital number of participant ……

Signature of participant……Date……..

Appendix D: Demographics

Table D.1. Demographics: Our sample compared to census South Africa 2011

		Our Study (%)	Census SA 2011 (%)
Gender	Females	53	51.3
	Males	47	48.7
Cultural background	Black	72.7	79.2
	Coloured	3.4	8.9
	White	16.2	8.9
	Indian/Asian	7.7	2.5
Language	IsiZulu	29.9	22.7
	IsiXhosa	12.0	16.0
	Afrikaans	10.3	13.5
	English	17.1	9.6
Education	No formal schooling	5.1	8.6
	Primary school	16.2	12.2
	High school	35.0	33.8
	Grade 12	27.4	28.4
	Tertiary education	16.2	12.1

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