Adherence to a national consensus statement on informed consent: medical students' experience of obtaining informed consent from patients for sensitive examinations

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ABSTRACT

AIM: To determine whether the guidance from the New Zealand medical programmes' national consensus statement on obtaining informed consent from patients for sensitive examinations are being met, and to explore medical students' experience of obtaining consent.

METHOD: A self-reported, online, anonymous questionnaire was developed. Data were collected in the period just after graduation from final year medical students at The University of Auckland in 2019.

RESULTS: The response rate was 35% (93/265). Most students reported that they were "not always compliant" with the national consensus statement for obtaining informed consent for almost all sensitive examinations. The main exception was for the female pelvic examination (not in labour) under anaesthesia, where most students reported being "always compliant". We identified factors related to students, supervisors, institution, and the learning context as reasons for lack of compliance.

CONCLUSION: Adherence to the national consensus statement on obtaining informed consent for sensitive examinations is unsatisfactory. The medical programme needs to review the reasons for lapses in implementing the policy in practice, to ensure a safe learning environment for patients and our students.

"Volenti non fit iniuria: no injury is done where the subject is willing"[1]

Informed consent is one of the most discussed themes in medical ethics.[1] The ethical justification for the practice of seeking informed consent is based on autonomy and patients' basic rights to control their body.[2] Extra care is required regarding the need for informed consent for student involvement in teaching and learning activities, especially for sensitive examinations (breast, rectal, genital, and pelvic examinations).

One of the challenges specific to teaching and learning sensitive examinations involves the conflict between ethical and educational needs.[3] Balancing the educational needs of students to learn sensitive examinations on real patients and the vulnerability of these patients raises an ethical dilemma.[4] Moreover, ethical values change over time.[3] Performing unconsented sensitive examinations, particularly under anaesthesia, is now considered unethical and indefensible.[2]

To address this challenge, many institutions have created guidelines around sensitive examinations to help determine when and how students and their supervisors should seek consent from patients.[5–9] In addition, many institutions provide graded opportunities to learn these skills, including the use of anatomical models, simulation, and live participants trained and consented for such examinations, for example Gynaecology Training Associates (GTAs).[10–12]

In New Zealand, Bagg et al[13] published a consensus statement prepared by the Faculty of Medical and Health Sciences of The University of Auckland and the University of Otago Medical School, Chief Medical Officers of District Health Boards, New Zealand Medical Students' Association and the Medical Council of New Zealand, with guidance for medical students and supervisors on informed consent. The document states that for sensitive examinations performed on competent conscious patients, consent should be explicit. This may be verbal consent; however, ideally, it

should be documented in the patient's notes. In contrast, for sensitive examinations performed under anaesthesia, formal written consent should be obtained in advance and signed by the patient. The consensus statement also states that, "without such consent a student cannot undertake such activity".[13]

In the late 1980s, Cohen et al reported more than 60% of medical students do not think it is important to get consent when given the opportunity of performing invasive procedures, such as lumbar puncture or paracentesis.[14] A landmark study in 2003 found that, in one English medical school, 24% of sensitive examinations performed by medical students on anaesthetised patients had no consent.[3] More recently, in the New Zealand context, although the requirements for sensitive examinations are clearly set out in terms of informed consent, it appears that they are not always being followed. A qualitative analysis of ethics assignments demonstrated that a number of medical students at our institution were still performing sensitive examinations without informed consent.[15]

We sought to: (i) determine whether the guidance from the national consensus statement[13] on obtaining informed consent for sensitive examinations were being met by medical students, and (ii) if not, what are the reasons for non-compliance. We also sought to perform a qualitative exploration of medical students' experience of obtaining informed consent from patients for sensitive examinations.

Method

Participants

All final year medical students at The University of Auckland who were graduating in 2019 were invited to participate in the study. The students received the invitation on a registered University email address via the institutional learning management system. The emails included a participant information sheet and a link to an anonymous online questionnaire. The emails were sent to the students in October 2019, at the point of graduation. Students had up to two weeks to complete the survey. Each student was assigned a unique Participant Identity Number (PIN).

Setting

The medical programme at The University of Auckland starts at Year 2 (after a general health science year or completion of another degree). Students have specific sensitive examination learning opportunities in simulated and controlled settings in Years 2–5. Students have the potential for supervised learning opportunities in sensitive examinations on real patients in Years 4–6.

Survey

We created an anonymous, online, self-reported survey using Qualtrics (Qualtrics, Provo, UT, USA) as the platform. The survey was divided into eight sections. The first section asked about the students' age, gender and ethnicity. The next six sections collected data on the following six sensitive examinations: male rectal, female rectal, female breast, male genital, pelvic (not in labour) and pelvic (in labour). The last section related to the national consensus statement guidelines on sensitive examinations and explored challenges students faced with regards to performing sensitive examinations in general.

For each type of sensitive examination, students were asked if informed consent was obtained (by the student, supervisor, or both) and documented in the patient's notes. We also asked if students performed the sensitive examination on anaesthetised patients, and if so, whether formal written consent had been obtained in advance. All sections contained a free-text field for students' comments.

Data analysis

Quantitative data were analysed using descriptive and comparative statistics (Chi-squared test or Fisher's exact test, when applicable) for binary or categorical data and Kruskal–Wallis test for continuous data such as age. To compare the mean ages between the sample and the student population, we used a One-Sample t-Test. P-values <0.05 were considered significant. Data analyses were performed using IBM SPSS Statistics version 26 (SPSS Inc, United States).

Qualitative data, in the form of free-text comments for each examination, were subjected to thematic analysis, a method for identifying, analysing and reporting patterns (themes) within data.[16] Themes were identified in a deductive or "top-down" way (ie driven by a specific research question) at a semantic or explicit level. Furthermore, the thematic analysis was conducted within a realist/essentialist paradigm. Data were analysed independently by two authors (HB and CC). The illustrative quotes are reported verbatim.

Ethical approval

This study was approved by The University of Auckland Human Participants Ethics Committee (reference number 023818) for a period of three years.

Results

A total of 93 out of 265 final year medical students responded to the survey; a response rate of 35.1%. The mean age of participants was 25.3 years (standard deviation 3.1). We found no significant difference between mean age of the participants and the population (all final year medical students; 25.5 years; One-Sample t-Test p=0.579). We also found no difference in the gender distribution between sample and population (145 female students [54.7%], 120 male students [45.3%]; Chi-squared p=0.239). We were not able to directly compare ethnic distributions due to differences in the format of the data between sample and population. The gender and ethnicity of the participants are shown in Table 1.

Compliance with the national consensus statement

When asked whether consent was obtained and documented in the clinical notes (in conscious patients), and whether formal written consent was obtained in advance (for anaesthetised patients), students' responses were reported using a Likert scale: "never", "rarely", "occasionally/sometimes", "almost every time", "every time" and "don't know/can't remember". We grouped the responses in three clusters: (i) "always compliant" (only when "every time" was selected); (ii) "not always compliant" (the first four options); and (iii) "don't know/can't remember".

Student compliance for each examination is shown in Tables 2 and 3. In addition, the proportion of students who performed sensitive examinations under anaesthesia is shown in Table 3.

Reasons for compliance and non-compliance with the national consensus statement

Quantitative data

There were no significant associations between reported compliance and gender of the student in conscious or anaesthetised patients' examinations.

We identified an association between students' answers and age in the female rectal exam for conscious patients' (Kruskal–Wallis, p=0.046), although no pattern was identified for this association. No other associations relating to age were identified.

Table 1: Demographics: gender and ethnicity of participants.

	Number of participants (%)
Gender	
Female	50 (53.8)
Male	42 (45.2)
Gender Diverse	1 (1.1)
Ethnicity	
NZ European	53 (48.6)
Māori	7 (6.4)
Samoan	0 (0.0)
Cook Island Māori	0 (0.0)
Tongan	1 (0.9)
Niuean	3 (2.8)
Chinese	19 (17.4)
Indian	10 (9.2)
Other	16 (14.7)

Table 2: Students' compliance with the consensus statement for conscious patients.

	Male rectal	Female rectal	Femal breast	Male genitalia	Pelvic (not in labour)	Pelvic (in labour)
Always compliant	17.3%	22.0%	16.7%	17.6%	30.6%	32.7%
Not always compliant	72.8%	61.1%	66.6%	69.2%	60.0%	50.0%
Don't know/ can't remember	9.9%	16.9%	16.7%	13.2%	9.4%	17.3%

Table 3: Students' compliance with the consensus statement for anaesthetised patients and percentage of students who performed examinations under anaesthesia.

	Male rectal	Female rectal	Female breast	Male genitalia	Pelvic (not in labour)
Examination performed under anaesthesia	28%	12%	28%	10%	86%
Always compliant	15.4%	36.4%	12.5%	12.5%	84.7%
Not always compliant	65.4%	63.0%	66.7%	56.2%	11.1%
Don't know/ can't remember	19.2%	0.0%	20.8%	31.3%	4.2%

Table 4: Identified factors relating to adherence to the consensus statement.

	Compliance barriers	Compliance facilitators
Student-related	Lack of awareness of policies	Resilience
Supervisor-related	Pressure	Positive role-model
	Indifference	
	Hierarchy	
	Lack of awareness of policies	
Institution-related	Medical school inertia	
Learning context-related	Access to notes	Supportive environment

We also identified an association (Chi-squared p=0.003) between Indian students and being "always compliant" for pelvic examinations (in labour).

For anaesthetised patients, we found an association between Māori students and reporting of being "always compliant" to the national consensus statement for the female rectal examination (Chi-squared p=0.001), and between New Zealand European students and reporting being "not always compliant" in male rectal examinations (Chi-squared p=0.014).

Qualitative data

Themes were identified representing factors that reduce or increase adherence to the national consensus statement (summarised in Table 4).

Factors that reduce adherence

Student-related

Lack of awareness about the specific guidance from the national consensus statement regarding informed consent was a frequently reported by students:

> *"Unaware this [consent] should be documented" (PIN 65; age unreported; male)*

> *"I was also not aware consent should be documented in clinical notes if pt [sic] awake" (PIN 49; age 23 years; female)*

Supervisor-related

Pressure from the supervisor was a common theme in the students' comments. One student stated:

> *"I was forced to perform an unconsented DRE [digital rectal examination] examination in theatre while a patient was under general anaesthetic. I objected to this but was coerced into performing it anyway by the urologist." (PIN 2; 23 years; male)*

Indirect pressure from supervisors towards patients was also noted:

> *"Patient not given an opportunity to think about it without me in the room" (PIN 49; 23 years; female)*

Supervisors were also portrayed in students' comments as being indifferent and sometimes not being supportive with regards to obtaining informed consent from patients, as shown by the following statements:

> *"I explained the University policy, but he [supervisor] wasn't concerned…" (PIN 3; 26 years; female)*

> *"Consultants not always helping to obtain and document consent." (PIN 59; 23 years; male)*

Other times, students reported finding it challenging to stand up to authority.

> *"Due to the hierarchy in 4th year often felt unable/unwilling to question seniors even though I was aware the consent process was not followed." (PIN 49; 23 years; female)*

> *"This was sometimes difficult due to the differing authority levels." (PIN 28; 23 years; male)*

The perceived lack of knowledge of the University's guideline by the supervisor was also noted. For example:

> *"Many of the senior doctors were unaware of the universities policies placing a large amount of the responsibility upon the students." (PIN 28; 23 years; male)*

Institution-related

One student reported feeling abandoned by the institution, even after making formal complaints to it about non-compliance with the consensus statement:

> *"Essentially I felt like the medical school didn't care when I contacted them about being forced to perform a male DRE under general anaesthetic WITHOUT consent… Even quite senior staff were contacted about this and simply were either unsure or unconcerned with this behaviour. I was essentially brushed off." (PIN 2; 23 years; male)*

Learning context-related

One theme revealed by the analysis related to difficulty in accessing patients' notes. This aspect was reported as both a physical inability to easily

access the notes and uncertainty as to whether the supervisor documented consent in the notes. This was illustrated by the following two students:

> *"Verbal informed consent is possible to enforce with minimal disruption. Pt notes are often not at the bedside." (PIN 33; 32 years; female)*

> *"Others were in clinic where the consultant did the notes so I don't know if these were documented or not." (PIN 43; 24 years; male)*

Factors that increase adherence to consensus statement

Student-related

Student resilience was identified as a compliance facilitator. Some students reported needing to oppose a senior doctors' request, even if it meant losing the opportunity of performing the examination. One student affirmed:

> *"Was asked to do DRE on a patient under anaesthesia who had not been consented... I didn't perform the DRE but it was an awful experience." (PIN 3; 26 years; female)*

Supervisor-related

The behaviour of some supervisors as positive role models impacted positively on students' experiences on informed consent for sensitive exams, as stated by the following comment:

> *"In my opinion, it was done particularly well by [de-identified], a general and colorectal surgeon at [de-identified]. When he consents patients at their last clinic appointment before surgery, he always informs them there may be 1. students present, 2. that they may be assisting in the operation and 3. that they may also examine the patient under anaesthetic, then he gains and documents consent (for however much of it they are comfortable with)." (PIN 16; 26 years; female)*

Learning context-related

Some settings in which the sensitive exams teaching occurred were also identified as a supportive environment for obtaining informed consent. The primary care setting was cited as an example:

> *"I think that GP was the best opportunity to practice this, and consent was always gained verbally by my supervisor and then by me again" (PIN 31; 23 years; female)*

Discussion

Our data shows that the national consensus statement developed in New Zealand[13] for guiding informed consent regarding sensitive examinations are not being followed by many of the medical students sampled at The University of Auckland for most sensitive exams, with the exception of the pelvic (not in labour) examination for anaesthetised patients.

Quantitatively, we could not find any meaningful associations between gender or age and compliance/non-compliance to the consensus statement. Although we found associations between some ethnic groups and compliance, they were not consistent throughout the dataset. Qualitatively, we identified that medical students, their supervisors, the learning context, and the institution play an important role in influencing adherence to the consensus statement.

Since Coldicott's report almost 20 years ago, where unconsented rectal and pelvic exams were performed on 5% of conscious and 24% of anaesthetised patients,[3] there is a paucity of papers that have quantified sensitive examinations done with or without informed consent. In a recent qualitative study of senior medical students, Malpas et al[15] identified the same issues of unconsented sensitive examinations. The study showed that a number of medical students at The University of Auckland were performing sensitive examinations without the patient's informed consent, but often driven by directions from others.

Conversely, it is reassuring that we found students abiding by the national consensus statement regarding pelvic (not in labour) exams in anaesthetised women. In contrast, contemporary international studies looking at pelvic examination consent[5,17] have shown many medical students are not obtaining informed consent and that this issue still needs addressing.[18] Our finding is likely due to the presence of a thorough process that is in place to make patients, students and supervisors safe in Obstetrics and Gynaecology (O&G) attachments. For these attachments in Years 5 and 6, medical students receive a document and a briefing that states how consent should be sought for performing a pelvic examination in anaesthetised patients. The supervising clinician

should obtain consent while the student is not present. In consenting, both the patient and the clinician must sign a pre-printed sticker, which was attached to the operative consent form.[19] In the absence of the sticker on the patients' surgical papers, the student is not allowed to conduct the pelvic examination.

Our study failed to associate student's gender, age or ethnicity with a higher or lower compliance rate. We found some important barriers to students' compliance that are consistent with recent papers. Rees and Monrouxe (2011) stated that simply having a guideline is not enough for schools to make sure patients' rights are being respected.[20] At The University of Auckland, as with other institutions, ensuring that medical students know about the guidelines regarding informed consent needs to be improved,[7] as does ensuring that those supervising medical students understand such guidance in the context of sensitive examinations. Although the consent process is raised as part of core learning in Years 2 and 3, this may be forgotten or become a victim of the hidden or informal curriculum. In a large medical programme, widely geographically dispersed, and with large numbers of staff involved in their learning, maintaining compliance with a consensus statement has its challenges. It should be noted that the solution is complex, and any implication that the medical school simply needs to do more is an over-simplification. For example, as with most programmes, those supervising students are mainly clinicians employed in the health system and not by the tertiary institution.

Our findings that some supervisors are not compliant with guidelines are, unfortunately, similar to other studies in the literature.[3,20,21] Reports of students feeling that their grades, reputation or professional future might suffer due to standing up to senior clinicians have been published.[4,22]

We also found some factors that facilitate compliance, such as the supervisor acting as a positive role model, and where the learning context is a positive environment. This could help in setting an appropriate ethical climate for students.[20] When a student sees a senior staff acting respectfully and following guidelines in relation to their patients, this sets an important example that will shape their attitude. In our study, students cited both a surgeon and a general practitioner, as model examples of supervision.

This study has a number of limitations. Firstly, our data is based on a self-reported survey where students had to retrospectively recall their experiences. Secondly, it is not possible to determine if the lack of compliance related to lack of consent, lack of documentation, or both. This makes it difficult to separate out exactly where the problem lies. Thirdly, the response rate of 35.1% is low, although comparable with other online surveys.[23] Given the above limitations, no claims around prevalence can be made. Finally, this is a single institution study and so the results may not be generalisable.

Sensitive examinations are important clinical skills for undergraduate medical students to learn during their training. Using a sample that is representative of the final year medical student cohort, our study is one of the few that looked into the proportion of sensitive examinations performed without the patient's consent, including in the anaesthetised setting.[2] We also identified some important factors that contribute to the adherence to a national consensus statement.

In conclusion, the majority of final year medical students at The University of Auckland who participated in this study reported not always being compliant with the New Zealand national consensus statement for obtaining informed consent regarding sensitive examinations, with the exception of pelvic examinations (not in labour) in anaesthetised patients. We identified factors related to students, supervisors, institution, and the learning context as reasons for this non-compliance. Adherence to national consensus statement on obtaining informed consent is unsatisfactory, for our setting and the sample reported. For our institution, we need to review the implementation of policy in practice to ensure a safe learning environment for patients and our students. For others, this may challenge an audit of compliance and reflection on whether they have a policy, and what might influence the adherence to policy.

COMPETING INTERESTS:
Nil.

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