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Physicians' Perspectives of Informed Consent for Medical Procedures: A Qualitative Interview Study

Alfred P. Minei[1], Rachelyn Ann S. Araña[2], Sam O. Kaipu[1] and Jerry M. Minei[3]

1. School of Law, University of Papua New Guinea, Waigani, PO Box 126, National Capital District, Papua New Guinea

2. Institute of Statistics, College of Arts and Sciences, University of the Philippines Los Baños, Laguna 4031, Philippines

3. Townsville Hospital, Townsville, PO Box 670, Townsville Queensland 4810, Australia

Abstract: This work is based on an on-going research on medical informed consent in Papua New Guinea (PNG) with 19 doctors from hospitals, health care centers and private medical establishments in the National Capital District and Central Province who voluntarily participated in the study. The authors conducted an examination of doctors' understanding of informed consent for medical procedures through a qualitative interview study and we describe our findings. We saw a need to involved patients in decision-making about their care, ethical imperative and concerns about litigation and their complaints highlighted the issue of informed consent. In order for the patients to make an informed decision about medical procedure, the doctors involved in the proposed treatment should conduct the informed consent discussion. The discussion should include the treatment, the risks and benefits of treatment, and alternative therapies with associated risks and benefits. We studied doctors' perspectives of gaining informed consent for routine medical procedures. We used qualitative study methods using structured interviews selected by purposive sampling. The data collected were entered into a data base and were analyzed thematically. The discussion is based on review of legal decisions, commentaries and our personal experience in studying medical malpractice cases. We have utilized case reports and several informative writings that have appeared in the world literature, as well as selections from vast amounts of material available in USA, UK, Australia, India and PNG. The current informed consent processes do not appear to be ideal for many doctors in PNG. In particular, there are inhibiting factors that affect patients from making medical informed decisions, doctors find time not enough to run discussions on informed consent, Department of Health does not have a standard informed consent form, patients complain about no consent form, and they have not signed consent forms. These are but some issues that affect patients when trying to make informed decisions. We say that informed consent process flows from the relationship between doctor and patient, however when this does not occur, serious legal and ethical consequences may result. This report is not intended to be specific advice on any private legal matter.

Key words: Health care professionals, qualitative study, consent form, medical procedure, litigation.

1. Introduction

This paper examines informed consent in medical practice. We have explored the notion of consent and determined its underlying theory and important attributes. We argue that consent should be seen as a permissive state of mind that waives the right to bodily integrity. Once communicated to the actor the permission takes effect by justifying the intervention and legitimizing the virtuous exercise of the doctor's power. The process is usually formally documented by the reading and signing of a "consent form" by both the patient and the doctor who is proposing the treatment. A medical consent form is a common form used in healthcare facilities by health care professionals to obtain medical consent for a certain treatment or medical procedure.

In the US Supreme Court Rehnquist C J [1] averred with regard to an individual's autonomy and bodily integrity that no right is held more sacred or is more carefully guarded by the common law than the right of every individual to the possession and control of his own person, free from all restraint or interference of another, quoting the judgement in the case of Union Pacific Railway v Botsford [2] with approval where

Corresponding author: Alfred P. Minei, PhD candidate, research fields: law and medicine.

the court said that "No right of every individual to the possession and control of his own person, free from all restraint or interference of others unless by clear unquestionable authority of law". In that case Gray J was citing Cooley J who averred that the "right to one's person may be said to be a right of complete immunity; to be let alone". Therefore, it is an established ethical and legal principle that a medical doctor or other healthcare workers who provide medical treatment or perform a surgical procedure or a dental procedure on a patient without his or her consent is prima facie guilty of either a tort (or a delict) [3] or a crime [4]. The crime would be tantamount to an assault or trespass to the person, and the tort or delict would be based on negligence due to failure to follow established professional rules enforced by law [4]. The physicians need to understand informed medical consent from an ethical foundation, as codified by statutory law in many states, and from a generalized common-law perspective requiring medical practice consistent with the standard of care [5]. In UK, the Law Commission [6] proposed that, "a person should not be guilty of an offence, notwithstanding that he or she causes injury to another, of whatever degree of seriousness, if such injury is caused during the course of proper treatment or care administered with the consent of that other person". The Law Commission goes further to define "medical treatment" as: medical treatment or care administered by or under the direction of a duly qualified medical practitioner. This includes not only surgical and dental treatment or care, but also procedures taken for the purposes of diagnosis, prevention of disease, the prevention of pregnancy or ancillary to treatment [7].

The goal of informed consent prior to treatment has always been the same, to focus on the health of the individual patient. One of the issues in dealing with informed consent is that the scope of the patient's consent may be limited. This was addressed in the early case of Schloendorff v New York [8]. In that case the patient agreed to undergo an examination. The reason for the examination was to diagnose a lump suspected of being a tumor. After the surgery patient suffered gangrene and other illnesses as a result of the procedure. She contended that she did not give authorization for the removal of the growth but rather had only consented to an examination and diagnosis. She sued her physician for battery. The court ruled in her favor that she was not informed of the risks and alternatives involved in the treatment prior to taking any action other than what was authorized. Timothy and co-workers [5] explain that ethically physicians engaged in patient-physician relationships involving medical informed consent have a moral responsibility to identify the best treatment for each patient on the basis of available medical evidence and to discuss with patients the hoped-for benefits and the potential risks. Disclosure of the potential for adverse effects to the patient is a primary element of informed consent. In Natanson v Kline [9] the plaintiff visited a radiation oncologist for follow-up treatment of a mastectomy. The treating physician ordered the administration of radiation to the affected area. The ensuing treatment destroyed skin, muscle, and bone surrounding the plaintiff's chest. The plaintiff sued on the basis that she had not been informed of the potential for the adverse effect. Essentially, to establish a true informed consent, a physician is now required to disclose all risks that might affect a patient's treatment decisions. In Canterbury [10], the decision outlined key pieces of information that a physician must disclose [11]:

(1) Condition being treated;

(2) Nature and character of the proposed treatment or surgical procedure;

(3) Anticipated results;

(4) Recognized serious possible risks, complications, and anticipated benefits involved in the treatment or surgical procedure, as well as the recognized possible alternative forms of treatment, including non-treatment.

In this paper "medical treatment" will be applied as a generic terminology covering all forms of medical examination, assessment, diagnosis, and all procedures whether surgical, medical or psychiatric, dental or nursing, which involve any physical touching or penetration of the patient's body, however trivial [4, 12]. It includes information about the patient and provides details about the medical procedure being performed. A medical consent form is generally completed, and consent is officially granted when the person giving consent signs the form. A copy is generally given to both parties. Medical consent means that a physician or other medical care providers must inform a patient of any and all potential benefits, risks, and alternatives involved in a medical procedure. In other words, patients have the right to make an informed decision about their medical care based on all of the available medical information. Medical consent form requires specific details and varies state by state.

There are challenges that usually occur when obtaining informed consent in medical settings. In India, the physician is held in very high esteem, and patients typically proceed with treatment regimens as recommended by the practitioners without asking about the possible effects of the procedure [13]. A similar circumstance occurs in Japan, where patients rarely ask questions about their treatment or treatment options [14]. The effect of this high level of trust between a patient and a physician may pose ethical issues that both parties might not readily know. Ethical issue of consent has generated the most debate globally regarding healthcare needs. The consent procedures seem inadequate as a means for the expression of autonomous choice and the ethical standing can be called into question. Lack of informed consent can reinforce a claim of medical malpractice where the case is otherwise weak. Demonstration of a real conducted informed consent process not only protects the physician from exposure to liability but also increases the patient's autonomy in decision concerning health and encourages compliance with treatment.

In PNG, misunderstandings concerning the medical procedure led to patients withdrawing from participation in a maternal and child health clinic. In this case, a mother refused to attend the family planning clinic and refused her child for immunization because she was shouted at by an angry nurse for her lack of understanding to participate in the clinic. The medical procedure which may be essentially important to the individual health of the child is refused by the mother participant. This case highlights the issue concerning refusal of essential healthcare program and raises the question of why refusal occurred, and would the situation have been different if informed consent was obtained [15]. It also implies that a responsibility exists in the healthcare professional that ought to explain fully and meaningfully what the health program is about and the participants' involvement. To appreciate, in particular the importance of consent process, it is ethically necessary to account and correct for the misunderstandings in the entire consent process, which starts when the mother enters the clinic place till she approves of her child to receive immunization. However, the healthcare worker did not commence the process to obtain the patients informed consent to medical procedures when the mother refused to participate in the family planning and immunization for her child [15]. In this case, the legal rights of the participant had not been waived and the healthcare professional may not be subject to liabilities in negligence. The doctrine of informed consent adds a remedy for patients with injuries that result from undisclosed risks, even though they consented to treatment and are unable to show negligent diagnosis or treatment. On record, PNG has no informed consent case that had passed through its judiciary.

The concept of informed consent to medical treatment is a fundamental precept in law. It recognizes autonomy and the right to personal inviolability. One factor relevant to lack of a regulatory mechanism and enforcement is the inaction of the law enforcement bodies including the state and courts. Another factor which may be related is the varied socio-cultural aspect of lives of people, the way indigenous people live, interacts with one and another within their community and with other people. It is believed that traditional customs are essential to consider in developing tailored approaches to informed consent process. In another situation, for example, in PNG, the Department of Health has still yet to develop standard consent forms and this has left free public hospitals, healthcare centers and private medical clinics to develop their own consent documentation.

In UK, the General Medical Council, British Medical Association and the Department of Health have provided advice on what information should be shared with patients prior to their consenting to surgery. Information should indicate why surgery is required, the perceived benefits and risks, and all options of available treatment, including the option not to receive active treatment [16-18]. The government has updated their standard consent forms with the understanding that the forms would be easier to use and provide greater assurance that clinicians are meeting required standards for informed consent. Doctors should engage patients in discussions regarding suggested treatment options, giving them an opportunity to reach an informed decision based upon the information they have received. This means that during the process patients should be provided with all the relevant information, understand the information given, being given enough time to consider it, and not be acting under duress.

Consent is generally seen to confirm the contractual agreement between the physician and the patient, but this assumption has been challenged. Legal and medical practitioners, as well as other social science researchers and others, argue that the complexity of the language used on consent forms, the explanation required and the usually short time to explain the form to obtain consent, all render the consent forms are somewhat meaningless. Informed consent recognizes a patient's right to be informed about a procedure, treatment, surgery, or other medical procedure before deciding whether or not to proceed with the procedure. Informed consent is designed to protect patients, who have the right to refuse any treatment they do not desire. The validity of the consent is not dependent on the form in which it is given. There is no requirement in law that consent should be in writing, except when it is specified, for example, as in the conduct of biomedical research [19]. Many countries, including PNG, have recommended the use of consent forms as a matter of good practice where interventions such as surgery are planned and conducted.

The US Federal Regulations and the International Ethical Guidelines including CIOMS Guidelines [20] and the Helsinki Declaration [21] all consider this good practice in research settings. A case [22] in US considered the limits of the consent form. In that case Proplewell J stated: "For my part I regard the consent form immediately before operation as pure window dressing in this case and simply designed to avoid the suggestion that a physician has not been told. I do not regard the failure to have specialized consent form at the time to be any indication of negligence". In another like case Bristow J said: "Getting the patient to sign a proforma expressing consent... would be no defense to an action based on trespass, if no explanation had in fact not been given (and) consent obtained in 'form only' is no consent at all" [23]. Lord Donaldson M. R. in RE T explained with regard to consent forms authorizing or refusing blood transfusion as follows: "They will be wholly ineffective... if the patient is incapable of understanding them, they are not explained to him and there is no good evidence, apart from the patient's signature that he had that understanding and fully appreciated the significance of signing it" [24].

Therefore, for the patients consent to be a valid legal defense against trespass or negligence, the consent must be expressed, implied, oral or written, or part oral-part written, for as long as the conditions described under valid consent have been fulfilled. Actually, the consent agreement between the doctor and the patient creates a special relationship which goes beyond a usual arm length contract [25]. The healthcare practitioner can not withdraw from that patient's consented treatment while the patient still retains that right; even after signing consent form the patient can still withdraw at any time from the proposed treatment [26]. The doctor directly involved in the proposed treatment must ensure that a valid informed consent has been obtained before commencing the procedure. Delegating the task of seeking consent to another person has been challenged. Junior medical staffs who often obtain informed consent for surgical procedures may lack understanding of the procedures for which they have little or no experience [27] and this leads to poor discussion of the risks [28].

Information sharing is important to the informed consent process. To do this well, doctors must first assess the patient's information needs. Doctors may struggle with underestimating, or overestimating, the amount of information they give. What patients want from their physicians is much more than just facts or the freedom to make their own decisions. They want a partner, teacher, and friend who understand their values and will help guide them through their illness [29]. When patients remark, "Well, you are the doctor", they are really asking you to help them get through whatever it is they are facing. As their physician, you can offer a great deal of relief in this situation simply by replying. "I understand why this is so frightening and confusing. I have dealt with this condition numerous times, and, given what I know about you, this is the course of action I would recommend. It is the same treatment I would recommend if you were my mother." Physicians should aim to understand the patient's values and choose the best health-related values that can be realized. The physician not only indicates what the patient can do, but knowing the patient and wishing what is best, the physician can and should indicate what the patient should do [29]. Unfortunately, with limited time, physicians must be careful not to unwittingly impose their own values on patients who may be overwhelmed by their medical conditions or uncertain of their own views, making them too easily accept of this imposition, which would fall in line with being paternalistic. Organizational issues also appear to complicate the consent process. The British Medical Association recommends that consent should be gained at least on the day before the medical procedure [17]; however, in many situations the consent process is often completed just hours before the patient undergoes the procedure or surgery. Thus, in the informed consent process, knowing your patient's emotional state and, in particular their fears, will go a long way in enabling you to tweak your approach when necessary and ensuring a better overall physician-patient relationship.

Previous studies exploring the consent process had focused on doctors [28] and patients' perspectives [15, 30] and concluded that current processes are often inadequate as patients often have limited understanding of the process, are frightened or disempowered by the process, or feel that they have either not understood or not been told relevant information about their treatment. Rahman and co-workers [31] reviewed consent documents and found doctors' variability in covering complications. There has not been much exploration of the consent process from the doctors' perspectives and even the search of the literature confirmed that not much has been done using the qualitative interview studies that focus on doctors' perspectives of informed consent for medical procedures. This study was particularly concerned with the doctors' perspectives of informed consent process, that is, how doctors in PNG communicate risk, barriers doctors face in gaining informed consent for medical procedures, and how the current informed consent process can be improved.

2. Methods

2.1 Participants, Ethical Approval and Procedures

This research study was conducted with approval from the Post Graduate & Research Committee of the University of PNG, ethical approval was endorsed by the National Medical Research and Ethics Council, and authorization to conduct the study came from Provincial Health Authority in both the National Capital District and Central Province. Qualitative methods were chosen to collect relevant data from doctors and recruitment was by purposive sampling whereby doctors selected themselves by accepting the consent form to voluntarily participate in the study. Doctors were mainly working in the National Capital District in various health care facilities, including hospital, public care centers, and private medical centers. Few doctors who participated worked for both public hospital and private care centers. The doctors represented a range of experiences from general practice and specialist; they worked in general practice, surgery, internal medicine, pediatrics, obstetrics and gynecology, pathology, and radiology. A sample frame of 30 doctors was to be surveyed however only 19 stayed in the study and completed the questionnaire study interview. We administered the questionnaire forms and interviewed the doctors. Prior to the interview we explained the study plan, the aims and objectives of the surveys, questionnaires, and informed consent, and then distributed the consent forms to the subjects who were willing to participate in the study. Doctors understood their roles in the study and the reasons for conducting it. Participants also received survey or research information about the conduct of the study. Following the meeting/interview with the participants, we collected the consent forms and advised for the expected interview date and time. At the end of each survey the questionnaires were checked and saved away in cabinet safe at the Law School office. During free periods, we checked, examined, cleaned the questionnaires and then entered the data into the lap-top computer. The questions that were answered were analyzed and described forming the results in this study.

We conducted a brief literature review on the process of informed consent which revealed a lack of studies on the doctors' perspectives of the consent process. Even fewer studies [15, 28, 30] already conducted had expressed views about how the consent process was undertaken. This study was part of a bigger study and the interview schedule was piloted on 20 persons (n = 5 doctors). The participants were staffs of the School of Medicine and Health Sciences of University of PNG and the University Clinic. The data from this pilot interview were incorporated into the final analysis. Validations and the comments from the participants were then incorporated into the final questionnaires after the initial design and compilation. The development of subsequent questions was iterative; questions were adapted accordingly as new insights emerged during the pilot stage, which allowed formulation of the finalized interview schedule.

2.2 Data Collection

This study was conducted at the healthcare facility sites in private rooms or doctors' rooms between February and April 2018. The interviews lasted for about 60-90 minutes. Interview questionnaires were structured ensuring that pertinent topics were covered, while allowing flexibility to pursue doctors' experiences and opinions into greater depth. All interviews were audio-recorded and brief notes were also made. Data were reviewed after 10 interviews had been conducted at which point data saturation was evident and no new themes were emerging from the newly collected data. At interview 19, data were reviewed for evidence of saturation, and it was decided that interview can be concluded.

2.3 Data Rigor and Credibility

Data rigor was achieved through several features in the study design [32]. The verbatim transcription from audio-recordings accurately captured the words of the informants ensuring data trustworthiness. We collected and transcribed all of the data. Our involvement in the research from the conception stage made him the most knowledgeable person about what could best address the study aims. In this study we worked with the statistician who has wide experience in dealing with qualitative and quantitative data research and analysis. Doctors were specialist medical doctors in surgery, obstetrics, pediatrics, medicine, and general practice. Few doctors were trained both in PNG and Australia who have proven professional records in medical practice and served many years in the health care services. Few doctors taught and trained many young medical doctors in PNG. In this study they participated voluntarily. This study also relies on representations made by highly skilled and experienced doctor informants. All the informants in the study are abreast of the health care services system in PNG and their comments made at the interview study and Focus Group Discussion (FGD) meetings were valuable.

Coding was conducted in a systematic manner and in respect of any changes in codes and code definitions we ensured their justifications and causes, and all other analytic decisions were documented, contributing to the transparency in the interpretive process. During text analysis, reliability checks were conducted by RA, in fact coding process was performed twice, each time starting with the raw data and then comparing and documenting the findings. We ensured that the results were anchored in sound evidence.

2.4 Data Analysis

The analysis focused on fleshing out, to the greatest extent possible, the concept of consent. Our exploration included particular attention to the elements of consent, namely, capacity/competence, voluntariness, and information disclosure; however, they were open to new insights about what informed consent might be and other new insights about the accepted elements of consent. This was bound by the particular situation in PNG, in terms of medical treatment and the way people live and how it affected their lives. When the interviews were transcribed verbatim, the texts were uploaded into an electronic database. Each individual transcript was read and re-read to become engaged as far as possible with the data. This study was interested in whether and how participants might have talked about the kinds of concepts that are usually thought to contribute to the notion of consent, and in particular to the legal and ethical elements of consent, how these concepts might differ in the accounts of the different groups, whether there is something specific about the medical treatment that might alter or affect these elements.

The socio-demographic and economic profiles of doctors were summarized using percentages and frequencies for qualitative characteristics such as sex, marital status, and education. Meanwhile numerical descriptive measures such as the mean and standard deviation were computed for quantitative characteristics such as age and number of years in service for medical professionals. To determine the awareness, attitude, and practices of the doctor-participants towards informed consent, questions pertaining to those aspects were tabulated in terms of percentages and frequencies. The results from the FGDs were coded according to themes and were incorporated in the discussion of each aspect. The non-verbal cues, such as body language and silences observed in the FGDs, were also reported in the discussion. The FGDs were done to understand how informed consent is being discussed by doctors. The verbatim responses were captured in the FGDs. Thus, the video recordings of the meetings corroborated the interviews. The interviews were audio-recorded at the health care facility and university conference room. Data were reviewed after 10 interviews had been conducted at which point data saturation was evident and no new themes were emerging from newly collected data [33].

All interviews were audio-recorded, transcribed verbatim and anonymized. We took brief field notes. Transcripts were analyzed using thematic analysis; a common method of qualitative data analysis used in health research for exploring questions about salient issues [34]. The analysis involves examination and comparison of participants' responses, to create a classification of themes that recur across the data set [34]. The analysis was conducted alongside the data collection to ensure that notable topics that emerged during the interviews could be incorporated and clarified in future interviews. We had regular meetings to confer about emerging themes and codes. We agreed to the final coding framework and developed it. For the management of the data set, we used qualitative data analysis. In this study, a Multiple Correspondence Analysis (MCA) [35] was used in order to identify demographics associated with the patterns of responses among participants.

2.5 Laws in Informed Consent

A desktop review of all health care laws, government policies and related documents was examined and was summarized while noting that there is no specific law on informed consent in PNG. This study relied on the PNG Constitutional Law. The possible gaps of the law and the actual conduct of informed consent were compared. Issues arising from the participants in terms of getting consent of patients were presented and triangulated with the themes created from the FGDs.

All quantitative analysis, encoding, and coding were done using MS Excel and visualizations were done using R software [36].

3. Results

3.1 Study Participants

Doctors who voluntarily took part in the study were from the healthcare facilities, mainly in the National Capital District. A total of 19 doctors actually completed the interview study. There were an equivalent number of males and females who responded, with 52.63% of them being male doctors. About 80% of doctors were married. The youngest doctor-participant was 27 years old and the oldest 56 years with 42 years old on the average. In terms of working experience, they have been practicing for an average of 17 years, with 6 years and 34 years the shortest and longest working experience (Table 1).

The usual information that the doctor gives to his or her patients is presented in Table 2. Majority of the doctors give information on the diagnosis and procedure for treating the illness of the patients and also the likely complications and possible options. Some of them even inform their patients on possible changes in the treatment if ever the first procedure does not work.

In terms of ensuring that the patient understands the information, doctor-respondents usually reiterate (88.89%) what they have said to patients. There are doctors that encourage patients to ask questions to them to ensure that they have understood the information given (11.11%). Although nineteen doctors participated, only 6 continued to take part in the FGD interview. A finalized FGD schedule was developed (Table 3).

The meeting was held with the doctor-informants to understand how informed consent is being discussed by medical practitioners (Table 4). On an average most of the participants are educated and there were more male than female doctor-respondents who participated in the FGD meetings and interviews.

Interviews were audio-recorded, transcribed verbatim and anonymized. Transcripts were analyzed using thematic analysis, that is, the themes and subthemes were extracted from the interviews and the results are presented in fewer than four thematic groups as follows: consent form, laws about informed consent, custom and culture, and doctor's responsibility (Table 5). Each theme is exemplified with data extracted from interview transcripts, alongside a participant identifier, to reflect main points of interest.

Table 1 Quantitative characteristics of the doctor respondents.

Characteristics	Mean	Std. Dev.	Min	Max
Age (in years)	42.11	9.04	27	56
Number of years in service	17.00	8.33	6	34
Number of years working in the current hospital	10.81	8.76	0.33	32
Number of female patients in a week	20.72	20.14	5	80

Table 2 Information usually given by doctors to patients.

Information	Percentage of doctors
The diagnosis and indication of operation	94.74
The procedure	94.74
Likely complications	89.47
Alternative treatment options	84.21
Preventive medicine	5.26
Changes in treatment	5.26

Table 3 Finalized FGD schedule.

Number	Question
1	How many patients do you encounter in a day? From these patients how many of them are female?
2	Cite any right(s) you have as a doctor when a patient seeks medical treatment from you.
3	How does informed consent apply to your professional duties?
4	To what extent do you feel is necessary to inform a patient about a procedure?
5	Could you explain a situation where a patient ever backed out of a procedure because s/he did not understand?
6	How do you deal with them?
7	Could you explain a situation where a patient ever rejected a procedure, you had to perform on them due to some sort of cultural, religious, or other relevant concern? How do you deal with them?
8	Have you ever had a patient attempt to waive their rights to choose their care? What do you do?
9	Suppose a patient can not afford the treatment you recommend, but the alternatives are nowhere near as effective. What do you do?
10	Describe if possible, the culture around informed consent in the medical community. Is there a culture around how patient of at-risk communities is treated?
11	How do you go about explaining a diagnosis or procedure to a female patient of cultural difference? What sort of resources do you use or share in order to inform them?
12	Do you have any suggestions on how informed consent to medical treatment should be given?

Table 4 Doctors' characteristics.

Participant	Specialty	Total
Doctors	Internal medicine	1
	Surgeon	1
	Pediatrician	1
	Obstetrician	1
	Pathologist	1
	General practitioner	1

Table 5 Themes and subthemes describing views and experiences of the informed consent process for medical treatment.

Themes	Subthemes
(1) Consent form	General form when seeking consent, doctors, healthcare workers, and patients have no clear understanding of consent form.
(2) Laws about informed consent	No awareness on laws related to informed consent.
(3) Custom and culture	Custom and culture are crucial factors in giving consent.
(4) Doctor's responsibility	Doctors acknowledge that there is a need for improvement in patient handling.

3.2 Consent Form

This verbatim response was captured at the FGD meeting with the doctor respondents.

"Dr. said … I am aware of consent form. I see at the other hospital and had used the form at Port Moresby General Hospital. However, I have not seen or used the form lately." The participants generally said there is no standard informed consent form and various health care facilities make of their own consent form. Whilst the doctors' respondents understood the concept of informed consent, they expressed concerns that other health care workers did not understand the concept of consent. "Another Dr. …, I would like to see a uniform consent form to be used throughout all health institutions in PNG so the doctors should develop a habit of …"

It was felt that there should be more awareness for the health care workers on the concept of informed consent. This is to give both the health care workers enough time to consider it and help with patients and to give patients better opportunities to ask questions and understand as well the notion of consent. "Other Dr. … Most consent is taken verbally and written on the patient records, including mine as well, on the patient's records."

Some doctors do ask for consent among their patients, but it is usually taken verbally, the doctor writes or scribbles on the patient's record and keeps the records. The health care professional must take on the responsibility of ensuring the patients are provided with relevant information and fully understand the process to obtain informed consent. "Few doctor respondents said if a consent form was to be signed, it would be at the operating theatre, the form is signed just before the procedure commences. Consent forms are for patients who consent for elective procedures leaving them with less time to consider discussing information with patients. Doctors are usually the ones who conduct the discussion for informed consent. Nurses and other health care workers do not conduct informed consent discussion. Doctors said females prefer female doctors and female nurses to discuss their medical conditions including informed consent discussion."

Doctor respondents said that many of their patients were non-literate and can not give consent through signing. However, consent forms were not being used in the clinics. Respondents said a patient gives verbal consent and it appears that doctors scribble this information on their clinical records. "Most doctor-respondents agreed that there is no model general consent form created by the Department of Health in PNG."

3.3 Laws about Informed Consent

The results from the survey responses resonated with outcomes of FGD as:

A Dr. said … "I am not aware of a law or provisions which provide for the protection of both patients and health care professionals in PNG. I am aware of the medical doctor's code of practice which I rely on… when I am performing my work. He said there is none and so public hospitals and private medical health centers are doing these themselves". Dr. C said I think the Department of Health might be working on something now." Obtaining consent involves informing the patient or individual about his or her rights, the purpose of the procedure, the procedures to be undergone, and the potential risks and benefits of participation. The individual taking the procedure must participate willingly. Submission to treatment justifiably implies an understanding of the procedure, and willingness to undergo it. Another Dr. said … "resorting to law was confined to the most egregious cases in which healthcare professionals visibly harmed the patients by doing something that the patients clearly did not desire or foresee, for example the removal of a kidney and not the appendix where source of the complaint lays. There must be awareness conducted at the health care facilities on laws on informed consent for doctors, health care workers, patients and public".

Table 6 Perceptions of doctor respondents toward legal aspects of informed consent.

Perceptions towards legal aspects of informed consent	Percentage of doctors		
	Disagree	Not sure	Agree
Informed consent is must for any procedure	11.11	0.00	88.89
Signing consent form is just a formality	27.78	16.67	55.56
Informed consent is protective shield for doctors/healers	0.00	5.56	94.44
Informed consent is legally necessary	0.00	0.00	100.00
Consent form is meant to protect patients' rights	0.00	5.56	94.44
Signing consent form eliminates patients' right to compensation	33.33	22.22	44.44
Patient can refuse procedure after signing consent	5.56	16.67	77.78
Signed consent form proves that patient understood nature and consequences of procedure	0.00	0.00	100.00
Patients' relatives can sign consent form on behalf of patient	22.22	5.56	72.22
Without signing in consent form, operation/procedure is illegal	5.56	0.00	94.44

Table 7 Salient features of individual rights, responsibilities and medical doctors code of ethics in PNG.

Individual (or patients) rights	Patient responsibility	Medical doctor code of ethics
I deserve respectful care from my doctor	I will maintain healthy lifestyle and take responsibility for my own health	I like to see the doctor's code of ethics
I would like to be heard to my satisfaction	I will be respectful to other individuals including my doctors	I will see my doctors, healthcare workers
I would like to get complete information about my medical problems	I will be honest and disclose my information about my family and me	I will encourage friends
I would like to be educated, so I can provide informed consent	I will do my best to assist with my doctors and health care workers	I will cooperate and facilitate to get medical records as required
I would like my privacy to be respected	If I am not happy, I will inform my doctor	I must be told anything and everything about my medical conditions
I want confidentiality to be maintained	I will cooperate and do my part. I will participate intelligently	I like to be prescribed my treatment; I want to be informed of other treatment options, side effects of treatment
My doctor is to write my prescriptions legibly and explain to me my dosage	I will understand what I am taking and why	I will inform and cooperate
I like to know the laws, rules and regulations	I will know what to do and what to expect	I will not proceed until I am satisfied that I understood the benefits and risks of each treatment and I must agree
I would like information on whom administration to contact in case of emergency	I will settle my bills on time	I will cooperate with the hospital
I would like all my medical records	I will have realistic expectations from my doctors	I will be a patient and display this character

In terms of doctors' perception towards legal aspects of informed consent, majority (88.89%) of them agree that informed consent is a must for any procedure (Table 6).

All the doctors in this study also view that informed consent is legally necessary and signed consent form proves that patient understood the nature and consequences of procedure. Around 33.33% of doctors see that signing consent form eliminates patients' right to compensation. In terms of handling patients, 72.22% of the doctors have encountered refusal to be treated from patients and thus obligating patients' family relatives to sign consent form on behalf of the patient.

This study places the importance on the challenges encountered in the process of obtaining informed consent prior to medical treatment in medical settings where indigenous people strictly adhere to their culture, particularly local customs which they strongly believe and practice in their communities and affects women particularly female patients. This study conducts an examination of laws in PNG and assesses the protection of the laws, if indeed any, that is afforded to the patients. In PNG if patient rights are violated, the only recourse is to approach the consumer courts. Prominent features of patients' rights, responsibilities and code of ethics [28] are given in Table 7 (adopted and amended).

3.4 Custom and Culture

This verbatim response was captured at the FGD meeting with the doctors:

"A Dr. acknowledges … that there is a need for improvement in dealing with patient particularly from the rural areas. Doctor said for this to happen, Department of Health should seriously look into the relationship between doctor-patient and attend to issues that affect them. Doctor said there should be more research into informed consent; doctor said health awareness on informed consent was necessary to educate doctors, patients and the public."

"All doctors agree that… there is no law that provides for informed consent. Doctors said if a patient feels like withdrawing herself or himself from the medical treatment or procedure there is a form which patient and doctor fills a withdrawal to consent form provided by the health care establishment before the patient leaves the health facility. Doctor said this form lies between the institution, doctor and patient. Doctor said few health care facilities have developed their own forms."

Simply consenting to treatment is not enough. A patient must give informed consent and this means that before a doctor can treat or touch a patient, the patient must be given some basic information about what the doctor proposes to do [37]. Informed consent has been called the most important legal doctrine in patient's rights [38]. A Dr. said …"law(s) varies and court decisions vary according to informed consent world-all-over however the trend is clearly towards more disclosure of information rather than less. He said there is more to be done in PNG now as many patients are becoming educated and understood their rights. He further stated that one issue that affects doctor-patient relationship in PNG is the indigenous traditional customs where many patients hang on and abide". Another doctor said research should be conducted to look into the peoples' customs and culture in the context of medical informed consent."

3.5 Doctor's Responsibility

The results from the survey responses resonated with outcomes of FGD as:

The purpose of informed consent was explained at the meeting. "A Dr. acknowledges that there is a need for improvement in dealing with patient. Doctor said for this to happen, Department of Health should seriously look into relationship between doctor-patient. Doctor said there should be more research into the area of study to educate doctors, patients and the public."

"Dr. said administrative issues in the hospitals appear to interfere with the clinical work thus in turn affect the consent process. He said consent in surgery should be taken a day before the procedure, but he noted the consent process is often taken hours before the patient is taken to the theatre. He said patients can withdraw or refuse the procedure at any time. He further said doctors are too busy and time is the most serious issue he struggles with."

"Another Dr. asked if there is law(s) in PNG that protects patients' rights. He said he is not aware of any laws in PNG that specifically provide for medical informed consent. He asked if there has been any case gone through the courts in PNG." If a patient sues a doctor, or a medical group or a hospital and alleges lack of informed consent, the defendant(s) will be able to present the written consent form or the documentation of the discussion in court as evidence that medical consent was in fact secured. Medical consent form does not equate to medical consent. Rather it represents evidence that the medical consent process occurred. The consent form should contain an accurate description of the proposed procedure, the risks and benefits of the procedure to be undertaken. "A doctor acknowledges that more health awareness should be conducted at the hospital, outpatient and during nurse outreach into outstation to address the issue of informed consent among the doctors, patients and public."

The notion of consent is founded on the basis of human dignity, liberty, and respect for both an individual's autonomy and self-determination. In practice, the legal and ethical terms are of assumptions underpinning the necessary elements of consent, including capacity/competence, voluntariness and information disclosure. The importance of this study is that doctor respondents made meaning of these aspects in the context of their own practice and experience (Table 8). It also involves more than just satisfying these elements, it involves authorization where a person authorizes (or agrees to) a particular course of action.

The medical interview is a major medium of the health care. It is a major interface between care-provider and care-seeker. In this study it implies that the patient agrees to a medical treatment or to undergo a procedure. To assess the knowledge of doctor-respondents about informed consent, several questions were asked using the survey questionnaire and were validated through the focus group discussions. Majority of doctors (78.95%) said that informed consent should be applied in all procedures to be done with the patient. Doctors that answered informed consent should only be applied to critical cases (10.53%).

In terms of the content of consent form, more than 84.21% agreed that patient's education, recording of the consent (84.21%), and patient's and doctor's signatories should be in the form (89.47%). Only

Table 8 Knowledge on informed consent of doctor-respondents.

Knowledge	Percentage of doctors
When informed consent is applied	
All procedures	78.95
Elective ones	10.53
Critical cases only	10.53
Content of consent form	
Evaluation of competence	38.89
Patient education	84.21
Recording of consent	84.21
Patient's signature	89.47
Doctors' signature	89.47
Witness	11.12
Stamp/date	11.12
Age of those who can give valid informed consent	
All ages	36.84
Patients aged above 17	42.11
Depending on clinical judgement of maturity	10.53
Above 18 and depends on level of education	5.26
Special consideration on people with disability	5.26
Which time to obtain informed consent	
On the admission counter	38.89
In the ward/clinic	94.44
In the operation room	44.44
The night before the procedure	77.78

about 38.89% of the doctors cared to include their evaluation of competence in the form. In terms of age of patients who can give valid informed consent, it can be observed that there are varying responses given by the doctors. Most of them (42.11%) said patients aged above 17 years are the ones who can give valid consent. In terms of who should give the informed consent, all doctors agreed that it should come from the patient. However, there were notes coming from the doctors that for minors, parents should be involved in this decision. Also, they added that if the patient can not provide consent because of unconsciousness or not in the right state of mind, or husband, father, or family relatives can decide for them. And in terms of which time to get the informed consent, more than 94.44% of them answered, in the ward or clinic. Some doctors answered in the operating room especially if these are emergency cases. Some suggested it to be at the admission counter for straightforward cases. Doctor-respondents were also asked about the necessity of getting informed consent from patients. Out of the nineteen doctor-respondents, only one doctor did not agree to this statement. It also involves more than just satisfying these elements, it involves authorization where a person authorizes (or agrees to) a particular course of action.

"A female Dr. explained that the relationship between the doctor-patient is important one. She said the information between the parties is shared and trust exists between the parties. She has enjoyed working with her patients. She said many patients feel disempowered by the consent process and do not fully understand either the process or the information provided to them. She agrees with the other doctors that they are working in time-pressured environments." Trust is a defining element in any interpersonal relationship that has been recognized as important between the doctor and patient.

4. Discussion

This is a qualitative questionnaire study of 19 doctors; working across different specialties reveals that informed consent is a concern among clinicians. The responsibilities of obtaining consent for medical procedures fall on the doctors and often they find no time to discuss informed consent with the patients and thus many doctors expressed regrets that they had not undertaken informed consent discussions. Doctors noted that working in time-pressured environment affects the quality and amount of information they impart to patients which is consistent with findings in others studies [39, 40]. This study shows that doctors do not obtain consent perhaps not many are confident in their ability to conduct the process for informed consent and feel pressure to obtain consent for procedures with which they are unfamiliar. This has been observed as well in previous studies of doctors and other health care workers while obtaining consent for medical procedure [15, 41].

Informed consent has its base in ethical theory, from a moral point of view and in the healthcare context. Informed consent is concerned with autonomous choices of patients. There are healthcare laws in PNG but there is no specific legislation for informed consent. In other words, there is no legal case where informed consent is a subject of judicial proceedings in PNG. The discussion with the doctor respondents has been beneficial in this study regarding informed consent. It was explained that informed consent is present and as such it is manifest in the PNG Constitution, Section 49. While its presence is minimally recognized in the healthcare laws and in court practices, it provides at the national level internal regulation for protection of the rights of patients' autonomy and autonomous choice in the context of how such choice impacts on any subsequent preventable injury to a patient.

There are aspects of our findings that resonate with previous studies exploring doctors' perspectives of informed consent [28, 39, 40]. The doctors in this study observed that informed consent's influence can be felt amongst patients, healthcare professionals and individuals. In the FGD interview, doctors said that patients complained that doctors do not have enough time to discuss informed consent this lack thus affects the quality and amount of information that should be imparted to the patients. Informed consent plays a role in defining the rights of patients and individuals and has increasing relevance for areas of formal law such as criminal law and evidence law. It has a connection with other health care laws globally, and together with other informal and non-state law it has power to shape and influence the vast majority of human behavior.

This study observed that doctors understood what informed consent is to medical procedures. It also observed that doctors seemed to lack knowledge on the legalities of informed consent; it is further assumed that doctors felt lack of connection with the patients. In clinical practice and in law, there is frequently most emphasis on disclosure of information. The practical reason behind this stance is that it is presumed that people making decisions need information, want information, and will use information in coming to a reasoned decision. We say so forcefully, information "… liberates people from the servitude to others that ignorance creates". Doctors are obliged, both legally and morally, to tell patients the truth about their illness, their prognosis, the proffered treatment, the alternatives if any, and likely adverse effects that may follow treatment. Doctors therefore, are expected to be technically competent, virtuous, committed to their patients' welfare and to honor a fiduciary duty to their patients. In PNG, Minei and co-workers [15] said that culture also plays a key role in the understanding of how consent is gained, consistent with previous findings in India and Japan [13, 14].

In this study a copy of a consent form which has been used elsewhere was shown to the doctors. This form showed the following: potential advantages and disadvantages of no treatment, alternative treatment strategies and their risks and benefits, the potential for a successful outcome, the estimated recuperation time, and the estimated time required to return to normal activity. The form also contained the name of the physician involved and clauses dealing with photography, disposition, and use of removed tissues, organs, and body parts. The form also reads: patients are allowed to strike out any part of the consent form with which they do not agree or to which they do not consent and a patient who does not understand the details of the treatment or a procedure can discuss with the doctor so they can reach a mutual understanding. In regard the consent form itself, the responses captured verbatim at the FGD meeting show doctors agreed that there should be more patient education, more informed consent discussion, and patient and doctors to sign the consent form [15]. The doctor-respondents further said that they use patients' clinical records to record discussions with patients. The purpose of informed consent recorded on the consent form and in the informed consent notes in the patient's clinical record, is to have evidence of the exact terms of the medical consent in case of future disagreement.

A finding of this study is that there is overwhelming support for consent being seen as a process overtime and possibly over several consultations rather than a one-off event [41]. The study found among the doctors that consent of the patient usually takes place just few hours before the procedure is undertaken. Patients must be informed that consent is freely given and can be freely withdrawn at any time, whether it was given orally or in writing does not affect the patient's ability to change or withdraw the consent. Likewise, patients can refuse any or all treatment [42]. The decision to refuse treatment should contain a release of medical responsibility and any associated liability for the hospital, nurses, and employees, including the physicians connected in any way to the patient. Doctors in this study said certain patients threatened by serious illness do not make decisions in isolation, or do so independently. Patients frequently talked about how their decisions would impact the lives of their intimate circle of people, noting that it was necessarily the patient who had the most to lose, a child may lose her mother, young children may grow up without their father, and a spouse may have to continue life without his or her soul mate, and so on. This concern for the impact that our decisions have upon others and this recognition that their interests may factor in our decisions can be understood both socially and philosophically in that it suggests that autonomy is located socially and not simply within the breast of an individual. The respect for patient autonomy in clinical practice is of great moral importance in our society. We say that almost every discussion about consent begins with a statement about the importance of autonomy or about the need of respect for autonomy. Given this, it is perhaps surprising that as yet, there remains no universally accepted interpretation of what autonomy actually means. However, many commentators [13-15, 40, 41] say, in very general terms, it means having the freedom to choose, particularly to choose one's own moral position or more basically to have the capacity for intentional reasoned action.

A finding in this study revealed as well that doctors rely more on their code of conduct. This response was captured verbatim at the FGD meeting with the doctors. One doctor said that without the informed consent law he will abide by the doctors' code of conduct. The health care code of practice is described in the professional code of good practice in PNG. There are no professional rules apart from the doctors and nurses' code of ethics which comply with the requirements of the National Health Administration Act (1977). The code of practice provides an assurance to patients that medical care practitioners seek to avoid or refrain from coercion and deception. The statement of good practice shuts down certain avenues of exculpation where a health care provider might seek to excuse or justify his or her deceptive or coercive actions by, for example, pointing out that such actions are not expressly forbidden, or that, surely, it is his responsibility to exercise professional judgement as to how much his patients need to know. What is striking about the accounts of decision-making experiences for medical procedures of the patients is that attempts to educate through health awareness to improve the knowledge of the public to appreciate and value health care services, are failing.

One area where questions still arise with regards to health care decisions by the doctors is with regards to peoples of differing customs and languages. It is imperative to understand the circumstances in which the patients live, the socio-economic standing of the community, and the indigenous culture [43]. Cultural issues such as customs, language and other social factors impact on health care of the communities. Some groups would involve people in the decision-making process to reach a medical decision, and other groups may dislike certain medical procedures. Certain groups of people have different views on what should be disclosed of the patient's condition. Informed consent process is believed to be affected in areas where indigenous customs occur and has influence on the lives of the people [15, 44, 45]. In other words, specifically, are the legal and ethical constructs of consent achievable in the medical settings with patients adhering to their customary norms, and their opinions?

The doctors in this study agreed and said education of patients is an important issue and a step to realize the values of their own care and well-being. This fact has been insufficiently appreciated and has led to misunderstanding and confusion, further compounded by shortage of medical personnel and resources and that health services seem to promise more than they deliver. We say that the thrust of informed consent is to make the patient an active and informed participant in the decisions which must be made. Failure to obtain informed consent to medical treatment renders the medical care professionals liable for lack of informed consent which constitutes malpractice.

5. Conclusion

To explore the doctors' perspectives of gaining informed consent for medical procedures this study explored the prevailing circumstances of the doctors and examined how the medical decisions could be affected. There is need to involve patients more in decisions about their health care, the ethical imperative and concerns about litigation and complaints have highlighted the issue of informed consent and how it is obtained. The current consent processes do not appear to be ideal for many doctors, in particular when dealing with patients who refuse to cooperate due to their traditional customs, beliefs, and opinions, and doctors and other health care workers require more support to undertake this task. This might include written information, ward-based and outpatient communication skills and training on how to obtain consent. In this study we recognize the logistical issues specifically lack of time will be difficult to address but medical directorate could work together with the hospital administration to reorganize the clinician workflows to avoid last-minute consenting of patients. Finally, we say that the institution of healthcare must be organized to facilitate the practice of this obligation.

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Conflict of Interests

Authors declare that they have no competing interests.

Authors Contributions

AM: Conception and design, acquisition of data, analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript for important intellectual content, administrative, or material support, and supervision.

RA: Conception and design, analysis and interpretation of data, drafting of the manuscript and critical revision of the manuscript for important intellectual content, and supervision.

SK: Critical revision of the manuscript for important intellectual content, administrative, and technical support.

JM: Critical revision of the manuscript for important intellectual content and technical support.

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