

Patient Informed Consent Awareness form in Public Hospitals of Punjab, Pakistan

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ABSTRACT

In Pakistan hospitals, it is generally observed that informed consent is not obtained, or they are not provided with enough explanations about the forthcoming processes and their future consequences by the healthcare teams. The purposes of this study was to explore patient's perception of informed-consent in hospitals of Punjab. It was an exploratory study. A total of 120 patients (84male, 36 female) were included in this study. The patients were selected from public hospitals of Punjab after taking informed consent. A pre- designed and pre-structured validated questionnaire was used for data collection from patients who went through surgical/medical procedures. The data was analyzed through SPSS version 20. Results: In this study, 70% male and 30% female participants with different age groups have participated. Frequency analysis of each question was done to check the response against each statement. The results of independent sample t-test show that there is insignificant difference between male and female groups regarding the understanding level, scope, values and function toward patient informed consent. There is lack of awareness about legal implications of signing or not signing of the informed consent among Patients in Punjab. It is concluded that most of the clinical settings in Pakistan are unaware of importance to obtain informed consent when practicing the workplace environment. It should be emphasized that there would be a need to develop an educational program towards inform consent and further reassessed in order to achieve patient autonomy. The studies should be carried out in other provinces of Pakistan to check that all the workplace environment are following informed consent practices in the workplace.

Keywords

Informed Consent, Public Hospitals, Patients, Health Care.

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Introduction

The term "consent" varies in many countries and cultures; for instance, it varies based on the different regulations cultures, and contexts. Elements of informed consent, state that the patient receiving the treatment must be informed in detail. This consent has been specified by various national and international guidance and regulations. (Afolabi, 2015) Informed consent has been characterized as a self-governing authorization by people of a clinical Intervention. (Svoboda, Van Howe, & Dwyer, 2000) Informed consent (IC) is a process by which a doctor interacts with a patient, enabling to settle a knowledgeable decision with respect to the treatment of their infection. Informed consent comprises not just of the form that patients should read and sign, it additionally includes oral communication that assists doctors with making

up a stronger relationship with the patient. (Makoul, 2003) Informed consent is related to patient's safety it opens an exchange between the patient and supplier so the patient can pose inquiries, realizes what's in store during and after method, and can in any event theoretically help to turn away clinical errors. (Jones, McCullough, & Richman, 2005) Human Autonomy is the major ethical rule that grounds the informed consent measures. (Maclean, 2009) The informed consent process starts with information and ends with consent. There must be a mutually acknowledged and defined medical problem or concern that needs addressing for the two parties to begin developing this new professional obligation. Once there is agreement between the two individuals on the problem, then the risks, benefits, and alternatives of treatment are discussed. (Jones, McCullough, & Richman, 2007) In medical practice, Informed Consent should ideally involve

a conversation between a doctor or healthcare worker (HCW) and the patient, initiated by the healthcare professional. This conversation must involve complete transparency, engagement by both parties, continuity and may require evidence that it occurred, such as eyewitnesses or a signed consent form. (Moeketsi & Chima, 2015).

A signed form is the evidence that their conversation led to a mutual understanding. However, the implementation of the informed consent process differs among countries because informing the patient and requiring the consent are still not regarded as a legal obligation of the physician. (Nys & Schotsmans, 2000) 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. (Paterick, Carson, Allen, & Paterick, 2008) In UK, the Law Commission recommended that, "an individual ought not to be guilty of an offense, notwithstanding that the person makes injury another, of whatever level of seriousness, if such injury is caused throughout appropriate treatment or care managed with the informed consent of that other individual". (Minei, Arafia, Kaipu, & Minei, 2020) In many countries informed consent for medical procedures is a standard methodology for giving the patients data on demonstrative and treatment techniques, dangers, entanglements, and elective treatment alternatives in non-crisis cases subsequently significantly improving the correspondence among doctor and patient. (Paterick, et al., 2008) Looking for informed consent is a proper demonstration in which a patient's signature is attained, with doctors accepting that a significant commitment has been satisfied whether or not the patient has been given satisfactory data about the clinical mediation that is going to happen. (Turillazzi & Neri, 2015) Trust is a basic factor in this relationship. Great bedside way, specialized competency and relational abilities are the doctor's practices most emphatically connected with understanding trust. (Thom, 2001) The UNESCO International Bioethics Committee (IBC) report on informed consent contends that, 'self-governance suggests obligation'. That the ability to choose for one's self

involves fact and acknowledgment of the outcomes of one's activities, which can have extensive results particularly in issues of wellbeing. (Committee, 2009) Educated informed consent includes both inferred and communicated informed consent. Communicated informed consent is additionally partitioned into verbal and composed informed consent. It is basic for a person to be completely familiar with pertinent realities, which is fundamental to the idea of educated intentional informed consent. (Beauchamp & Childress, 2001) It comes from the mindfulness that the outcomes and reason with respect to their choices will coordinate the patient towards the most helpful and successful treatment. Consequently, it is a totally lawful and moral strategy which means to improve the health of a patient and regard the freedom and self-sufficiency of the patient (Alagesan, Vaswani, Vaswani, & Kulkarni, 2015) In Pakistan medical care is being given through open area just as through private area. The overall experts are considered as the spine for the medical services conveyance framework in our nation. In the clinical calling, an overall professional (GP) is a clinical specialist who in spite of the fact that doesn't qualify/spend significant time in a specific field yet he thinks about the overall soundness of the network by treating intense and ongoing sicknesses and by giving preventive consideration and wellbeing training to patients. As to experts' insight about bioethics, it is clear that in spite of the fact that they feel that patients reserve a privilege to information about their infection status however a high extent of general specialists don't think of it as important to clarify the subtleties of the treatment encouraged to patients. (Bhurgri & Qidwai, 2004) In Pakistan hospitals, it is generally observed that informed consent is not obtained, or they are not provided with enough explanations about the forthcoming processes and their future consequences by the healthcare teams.

Literature Review

In developing countries, the informed consent's principle is frequently neglected during patient care. In majority of the case of Kuwait, public and private hospitals possess their own informed

consent's forms and they are often in written form. Though, majority of the patients obtain less amount of information via these forms. There is often low patient knowledge of their rights to informed consent. (Bhurgri & Qidwai, 2004) According to the past qualitative research, significant number of physicians is of the view that it is not necessary to provide proper information. (Jafarey & Farooqui, 2005) . The Unites States of America (USA), also assessed the quality of participants' informed consent in cancer clinical trials. It was found out that patients, who possess no education of college and those who speak languages other than English, secured low rating knowledge of the trials. Respondents who discussed about the consent with a nurse in attendance secured a higher score in knowledge. (O'Connor, Rowan, Lynch, & Heavin, 2017) In South Africa, concluded similar results. They assessed, in Cape Town, the quality regarding patients' understanding of the informed consent for participating in vaccine trial. The majority of 192 subjects interviewed, secured greater than 75% for understanding and recalling of informed consent. It was found that majority of the participants knew about the risks. More than 50% were aware of the fact that their participation is voluntarily. (Parmar, Rathod, Rathod, & Parikh, 2016) In an examination led by Farahat W, et al. in Khyber Pukhtunkhwa asked about the apparent significance and weaknesses of informed consent in dentistry. The examination announced that among the sort of informed consent; consent verbal agree was discovered to be the most preferred strategy for acquiring informed consent represented 84.4% of members that are as per our outcomes. This could likely be because of the absence of time and unreasonable patient burden which constrains the dental specialist to favor verbal over composed type of informed consent. (Farhat, Qiam, Shah, Khan, & Khan, 2013) According to the study done in Aga Khan University hospital's community health centre in Karachi, Pakistan, concluded shocking findings. Just 20% of the participants had the knowledge regarding the informed consent's process and all of them had degree of graduation. This study was linked with those studies which were conducted on consent in clinical trials. Most of them reported that level of education was correlated with the

understanding of informed consent. (Alazmi, 2018) In Pakistani context, this is why the right to an informed consent had been given up by some of the patients and letting the doctors choose what was desirable and right decision for them as they used to perceive doctors as their brothers. (Aderibigbe & Chima, 2019) The process of informed consent was not implemented properly as healthcare workers were responsible for this. According to the study in Lahore, Pakistan, they examined the situation of commitment to the practice of privacy, confidentiality, and informed consent in both private and public hospitals. (Humayun et al., 2008).

Methods

Proper understanding of design of research influences the research quality that determines the data was collected. There are three kinds of designs of research which are followed in every study, which are, qualitative, quantitative and mixed method of investigation. This research depends on data collection which is quantitative because information is collected by designing a questionnaire for satisfying research's requirements. The current study is exploratory in the nature and data was collected from respondents. Questionnaires were distributed to the patient hospitalized in surgery departments. In this study, a questionnaire was handed out to patient who had just undergone surgery and who were counseled before their elective surgery and signed their consent forms. Furthermore, the selection of population is done with respect to comparable properties which are possessed by the individuals as determined in the criteria of given research. This study's population comprises of patients 18 years old and above admitted to the surgery departments in the selected hospitals. Sample size for study participants was calculated by a web based freely accessible sample size calculator, Raosoft. Based on the formula for sample size calculation and margin of error from Raosoft. Sample is defined as the portion of the population which provides actual and truthful knowledge of the planned problem of research.

To estimate the effectiveness of the gathered knowledge, there are two widely utilized methods

of sampling, which are non-probability as well as probability sampling. These two methods are considered important because of exclusive properties and criteria of application. The first classification caters the probability of choosing all the respondents and they are given an equal chance for sharing quality and reliable knowledge. The method is termed as random sampling technique also as selection is done randomly. The sampling of non-probability does not give estimation of the number of selected respondents. While selecting the required samples, the technique gives specific problems. With this consideration, the following study has adopted sampling of simple random sampling that helps in examining the provided factors. For this research, a total of 120 respondents are chosen.

In this study, a questionnaire was handed out to patient who had just undergone surgery and who were counseled before their elective surgery and signed their consent forms. The questionnaire was derived from published studies dealing with the same topic as well (Saadoun Faris Al Azm 2018). It took 15-20- minute to be filled. To increase the response rate repeated visits were sometimes necessary to collect completed questionnaire from the patients. The questionnaire consisted of four sections. The first section collected information on participants' demographic (age, gender, nationality, educational status and marital status). Second section included six statements addressing patient's understanding of the legal implications of signing the consent form. The third section included four statements regarding patient's views on the scope of the consent form. The fourth section included ten questions based on 3-likert type scale questions about patient's agreement with statements on the value and function of the consent form. Each question was varied in response from disagree, neutral and agree.

Data is examined based on logical assumptions. Quantitative data includes data's descriptive analysis and if the data is collected via quantitative approach so quantitative analysis is adopted. As quantitative approach adopted by this study so statistical analysis (IBM SPSS version 21.0) assesses and evaluates the data. Description of qualitative variables was performed by comparing frequency tables and quantitative

variables by calculation of mean ± standard deviation. Qualitative variables were assessed using Chi square test. Statistical analysis was done using SPSS version 21. Confidence interval was 95% and P value <0.05 was regarded as significant.

Data Analysis

This part of the research consists of analysis of the results of the study. SPSS has been used to incorporate and analysis of the data, collected by the patients of public hospitals in the Punjab, Pakistan.

The objective of the study is to investigate the patient's perception towards informed consent in public hospitals of Punjab. Out of the total patients surveyed, 120 were included for analysis. The demographic characteristics of hospitalized patients in public hospitals of Punjab are presented in the following table 01.

The following table shows the demographic characteristics of patients in public hospitals of Punjab.

Table 1. Characteristics of the selected hospitalized selected patients in public hospitals in Punjab

	Hospital Type (Public)	
Characteristics	N= 120	
Gender	No.	%
Male	84	70
Female	36	30
Age (years)		
<20 years	12	10.0
21-30 years	43	35.8
31-40 years	38	31.7
41-50 years	24	20.0
> 50 years	3	2.5
Mean ± SD <0.001*		
Marital Status		
Single	55	45.8
Married	60	50.0

Separated	2	1.7
Divorced	1	.8
Widowed	2	1.7
Education		
Literate	113	94.2

Illiterate	7	5.8
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P-value of chi square test *Significant at <0.05 level.

Patients understanding of the legal implications of signing the consent form are shown in table 02.

Table 2. Patients understanding of the legal implications of signing the consent form

Statements	Hospital (Public) n= 120	Agree Frequency (%)	Disagree Frequency (%)	Don't Know Frequency (%)	P value
Signing the consent form is a legal requirement.		23(19.2%)	44(36.7%)	53(44.2%)	<0.001*
Signing the consent form removes your right to compensation.		18(15%)	56(46.7%)	46(38.3%)	<0.001*
You have the right to change your mind after signing the consent form.		12(10%)	58(48.3%)	50(41.7%)	<0.001*
If you are not able to sign the consent form, the operation cannot take place, even if this means you could die.		73(60.8%)	21(17.5%)	26(21.7%)	<0.001*
If you refuse to sign the consent form the operation cannot take place even if this means you could die.		71(59.2%)	17(14.2%)	32(26.7%)	<0.001*
If you can't sign the consent form, your next of kin can sign on your behalf.		31(25.8%)	25(20.8%)	64(53.3%)	<0.001*

Responses are expressed as percentages of patients who agreed about the statement P value of One Sample t-test, * Significant at <0.05 level.

The following table shows the patients' views on the scope of the consent form.

Table 3. Patient's views on the scope of the consent form

Statements	Hospital (Public) n= 120	Agree Frequency (%)	Disagree Frequency (%)	Don't Know Frequency (%)	P value
All exactly are present in the consent form.		28(23.3%)	63(52.5%)	29(24.2%)	<0.001*
The doctor may do something different from what is one the form if he/she thinks it best for me.		73(60.8%)	26(21.7%)	21(17.5%)	<0.001*
The doctor cannot do anything different from what was on the form unless it is life-saving.		25(20.8%)	56(46.7%)	39(32.5%)	<0.001*

I fully understood what was going to happen.		23(19.2%)	55(45.8%)	42(35%)	<0.001*
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Responses are expressed as percentages of patients who agreed about the statement P value of Chi-square test, * Significant at <0.05 level.

The following table shows the patients' views of the value and function of consent form.

Table 4. Patients' views of the value and function of consent form

Statements	Hospital (Public) n= 120	Agree Frequency (%)	Disagree Frequency (%)	Don't Know Frequency (%)	P value
The consent form is important to me.		77(64.2%)	26(21.7%)	17(14.2%)	<0.001*
The consent form made it clear what was going to happen.		8(6.7%)	67(55.8%)	45(37.5%)	<0.001*
The consent form made aware of the risks of the operation.		5(4.2%)	79(65.8%)	36(30%)	<0.001*
The consent form made my wishes known.		21(17.5%)	46(38.3%)	53(44.2%)	<0.001*
The consent form prevents mix ups during the operation.		20(16.7%)	65(54.2%)	35(29.2%)	<0.001*
The consent form was just another piece of paper.		59(49.2%)	40(33.3%)	21(17.5%)	<0.001*
I just signed the consent form so I could have the operation.		73(60.8%)	26(21.7%)	21(17.5%)	<0.001*
Signing the consent form was mainly to protect the hospital.		61(50.8%)	33(27.5%)	26(21.7%)	<0.001*
The consent form gave the doctors control over what happened.		52(43.3%)	57(47.5%)	11(9.2%)	<0.001*
Signing the consent form was a waste of time.		49(40.8%)	42(35.0%)	29(24.2%)	<0.001*

Responses are expressed as percentages of patients who agreed about the statement P value of Chi-square test, * Significant at <0.05 level.

Independent Samples T-Test

The research study was conducting to measure the gender difference of patient informed consent awareness form in public hospitals of Punjab. To confirm the differences between the mean values two (2) groups; male and female, independent sample t-test was used. For analysis of independent sample t-test, the variables were computed on the basis of questionnaire. Patients

understanding of the legal implications of signing the consent form was computed as 'understanding' on the basis of six items, Patient's views on the scope of the consent form was computed as 'scope' on the basis of four items and Patients' views of the value and function of consent form was computed as 'values and function' on the basis of ten items. The below mentioned below tables show the p value of both groups. If the p is value less than .05 i.e., .000, it

means that there is significant difference between the groups were existed.

Comparison of Understanding

H1: There is significance difference between understanding toward patient informed consent of male and female groups.

Table 5. Comparison of male and female groups regarding understanding

N = 120							
Groups	Variable	Mean	SD	T	df	P	
Male	Understanding	2.059	.37	-.010	118	.992	
Female		2.060	.28				

Table no. 5 shows the comparison of (2) groups; male and female group. The mean value of male is 2.059 (SD, 0.37) and the mean value of female is 2.060 (SD, 0.28). Mean values of both groups' shows that there is no difference between male and female understanding. In the column under the t value label, the insignificance value of t-test is given (<1.96). The male and female group for understanding had $p > .05$, it is $p = .992$. This value is indicating that there is insignificant difference

between male and female group regarding the understanding level. So, the research hypothesis is rejected.

Comparison of Scope

H2: There is significance difference between scope toward patient informed consent of male and female groups.

Table 6. Comparison of male and female groups regarding scope

N = 120							
Groups	Variable	Mean	SD	T	df	P	
Male	Scope	1.973	.46	.392	118	.696	
Female		1.938	.45				

Table no. 6 shows the comparison of (2) groups; male and female group. The mean value of male is 1.973 (SD, 0.46) and the mean value of female is 1.938 (SD, 0.45). Mean values of both groups' shows that there is no difference between male and female scope. In the column under the t value label, the insignificance value of t-test is given (<1.96). The male and female group for scope had $p > .05$, it is $p = .696$. This value is indicating that

there is insignificant difference between male and female group regarding the scope level. So, the research hypothesis is rejected.

Comparison of Value and Function

H3: There is significance difference between value and function toward patient informed consent of male and female groups.

Table 7. Comparison of male and female groups regarding value and function

N = 120							
Groups	Variable	Mean	SD	T	df	P	
Male	Value and Function	1.890	.22	-.027	118	.979	
Female		1.891	.21				

Table no. 7 shows the comparison of (2) groups; male and female group. The mean value of male is 1.890 (SD, 0.22) and the mean value of female is 1.891 (SD, 0.21). Mean values of both groups' shows that there is no difference between male and female value and function. In the column

under the t value label, the insignificance value of t-test is given (<1.96). The male and female group for scope had $p > .05$, it is $p = .979$. This value is indicating that there is insignificant difference between male and female group regarding the

value and function level. So, the research hypothesis is rejected.

Discussions

Despite the fact that patients need to know their lawful rights in clinic beneficiary attention to legitimate and moral issues identified with the informed consent process is frequently limit. In spite of the fact that patients need to know their lawful rights in emergency clinic there are countless patients are ignorant of, or misconstrue their moral rights. When contrasted with this examination 41.7 members have offered the response that they don't think about it. Conflicting with other examination, our discoveries add to confirm demonstrating that in any event, when the informed consent process fulfills regulatory and legitimate necessities, patients' requirements may not be met, and a few patients may even agree to a medical procedure they don't need. (Bhurgri & Qidwai, 2004) Numerous patients appear to have restricted attention to the lawful ramifications of marking or not marking informed consent structures, and they don't perceive composed informed consent as fundamentally serving their inclinations. Current informed consent strategies appear to be lacking as a methods for the declaration of self-governing decision, and their moral standing and believability can be raised doubt about. (Akkad et al., 2006) The findings of this study were that the participants have agreed the statement of "Signing the consent form is a legal requirement". In steady, concentrates likewise uncovered that most patients accepted that the informed consent structure was an authoritative archive and they needed to sign it, albeit most perceived that they could adjust their perspective. The President's Commission had comparative discoveries with 83.0% of patients thinking about that their mark on an informed consent structure set up consent to treatment. They considered the agree structure to be an official record. (Bioethics, 2016) The presence of legitimate and moral questions in informed consent measure in the ebb and flow research doesn't mean the obliviousness of the entire useful assistance of medical care suppliers. The point is the exhibition of a successful analysis, a push to address the reluctant systems and give a cardinal base to introducing more satisfactory and wanted

structure to care more for the patients. (Davoudi, Nayeri, Zokaei, & Fazeli, 2017)

Consequently, it is vital that the measure of getting data which is needed to be comparable with the degree of members' schooling and give the individuals at the period of scarcity since it appears to be that the members' assumptions change contingent upon their degree of instruction. (Jovic-Vranes, Bjegovic-Mikanovic, Marinkovic, & Kocev, 2011) Accordingly, it is basic to receive fitting measures so that educated informed consent becomes educated decisions. Kumanka and et al study demonstrated that among 2026 overviewed patients just 19% had enough wellbeing education. This investigation likewise showed to a significant issue; having expansion to influencing the fulfillment of clinical consideration they get. (Komenaka et al., 2014) In the current investigation, 55.8% patients accepted that by marking the informed consent structure, they didn't completely comprehended what planned to occur. Our investigation indicated that 43.3% patients in the public emergency clinics accepted that by marking the informed consent structure, this gives the specialists power over what occurred. Studies from Japan and Kashmir reflect comparable perspectives wherein patients are happy to acknowledge what doctors decide for them, while doctors are happy with their part of a chief. (Miyashita et al., 2006) In an examination by Yousaf et al, (2007) 65% doctors in Kashmir and 35% doctors in Malaysia said they would tune in to the family's solicitation to retain data from the patient. (Yousuf, Fauzi, How, Rasool, & Rehana, 2007) Satisfactory data arrangement has wide advantages of clinical informed consent structure for patients. These incorporate expanded fulfillment, diminished passionate trouble, and decreased utilization of absence of pain underlining the significance of successful measures to improve understanding instruction. (Kinnersley et al., 2013) As contrasted with this examination There were 60.8% members were concur with, specialist may accomplish something else based on what is one the structure in the event that he/she thinks it best for me.

As compared with this study 64.2% patients reported that the consent form is important to them, and 55.8% disagree with statement consent form made it clear what was going to happen. Studies demonstrated that a few patients getting

elective surgeries don't get sufficient data, the data isn't completely justifiable or the data patients get isn't customized to their specific necessities (Schattner, Bronstein, & Jellin, 2006). In this study 49.2% patients imagined that the informed consent structure was simply one more bit of paper. When eliciting in shaped informed consent, clinicians will in general zero in on conveying the particular specialized dangers identifying with the arranged methodology. (Barkun et al., 2009) Patients are frequently left to find their postoperative course in the days following their method as opposed to at the hour of thinking about whether to continue with the activity. (Fraval, Chandrananth, Chong, Tran, & Coventry, 2015) Moreover, huge patient weight at public medical clinics frequently makes it unimaginable for the specialists to follow the full convention of educated informed consent and, even specialists who favor rehearses like educated informed consent, regularly surrender these practices since they accept that the vast majority of their patients are uninformed and would not have the option to choose what is best for them. It is likewise evident however, that regularly the patients would prefer not to take any choice and need the specialist to choose each and everything for them. The aftereffects of this examination should be considered with regards to constraints. A poll based overview was utilized for information assortment as opposed to perception of the administrations in the wards to assess their quality. All things considered, we accept that it is useful to archive the usage of patients' privileges in open medical clinics.

Conclusion

This study concludes that there is an enormous discrepancy between the informed consent that supposed by patients in the hospitals. The change in perception of patients and their limited knowledge of the authorized implications of signing or not signing consent form indicates that consenting in its current form is not informed and should be reconsidered in order to achieve patient self-sufficiency. This study tried to find the relationship between informed consent practices, and its relationship with decision-making. The results obtained show that most of the settings in Punjab are not following informed consent

practices for decision-making, which is significantly bringing their value down. The results of study are anticipated to support the hospitals towards simplified and make informed consent easy to understand for the patients. Furthermore, the results will be importance to develop educational program towards informed consent. There is a significant demand for obtaining informed consent when making decisions, but hospitals in Pakistan are not following this practice in their hospitals. Based on the results obtained, it can be concluded that most of the clinics in Pakistan are unaware of importance to obtain informed consent when practicing the workplace environment. The results of independent sample t-test show that there is insignificant difference between male and female groups regarding the understanding level, scope, values and function toward patient informed consent. There is lack of awareness about legal implications of signing or not signing of the informed consent among Patients in Punjab. It should be emphasize that there would be need to develop an educational program towards informed consent and further reassessed in order to achieve patient autonomy.

Limitations and Future Studies

This study carries many limitations, which include the following:

- The study was only carried out in Punjab.
- The study was limited to 120 respondents only.
- The investigation was only based on checking informed consent practices when many other variables of decision-making could have been taken.

In terms of future directions, scholars should carry out research for following relationships:

- How informed consent environment should be inducted in workplace by adopting a strategic planning approach should be investigated.
- The studies should be carried out in other provinces of Pakistan to check that all the workplace environment are following informed consent practices in the workplace.

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