

## Research Article

# Informed Consent and Shared Decision Making in Women at a Tertiary Care Hospital

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**Abstract: Introduction:** Informed consent is an important aspect of ensuring good medical care and patient autonomy. In a developing country, the experience of women is often overlooked when deciding methods for obtaining consent. This study assesses the practice of taking informed consent in a hospital setting and factors that affect decision-making for treatment methods among gynecology patients Pakistan.

**Materials and Methods:** Women coming to the Hamdard University Hospital gynecology outpatient department or surgery were asked to participate in the study. The questionnaire asked about informed consent, cultural factors, and interaction between the doctor and the patient. The study was conducted for a duration of 5 months. Descriptive statistics were used to analyze the results.

**Results:** 300 women participated in the study. While all women said that doctors asked for consent before examination, 30.7% said they were not aware they could say no to being examined, 23% said the doctors did not explain the benefits or side effects of the medicines prescribed, and 22.7% were not told about alternative treatments. 91.7% said their husbands signed consent forms for them.

**Conclusion:** This study highlights the need to improve the practice of taking informed consent in the country, as it involves educating the patient about the intervention before obtaining consent. It is important that doctors keep in mind the cultural factors that influence decisions when obtaining consent and informing patients about their treatments and management.

**Keywords:** Informed consent, Gynecology, Shared decision-making, Ethics, Autonomy, Surgery.

## INTRODUCTION

Informed consent is the process through which a healthcare provider educates a patient about a treatment or procedure. It involves the discussion of the intervention with the patient, its risks and benefits, as well as the alternatives and an assessment of the patient's understanding. Shared decision-making is the mutual participation of both the doctor and the patient in choosing that treatment or an alternative [1]. Together, informed consent and shared decision-making help doctors provide care centered around the individual patient.

In a developing country like Pakistan, ethics are often overlooked when it comes to healthcare. A study found that informed consent was obtained from only 66.4% of patients, and more than half (56.9%) were not informed about the side effects of their medicines [2]. In other studies, patients reported they did not sign their own consent forms for surgery, or felt they had no choice in signing the forms [3,4]. There is also a lack of awareness of informed consent among patients, which is not surprising considering Pakistan's low literacy rate [5, 6]. Previous studies have been done exploring informed consent in Pakistan. However, they often overlooked the experience of women. Women in Pakistan often have lower levels of education and financial indepen-

dence. Important matters, including those related to healthcare, are decided by family elders rather than the patient themselves.

It is essential to explore the unique challenges Pakistani women face when making decisions about their health and when providing consent, especially in the context of social and cultural factors.

## MATERIALS AND METHODS

This study was conducted at Hamdard University Hospital, Karachi, from June to October 2021. The inclusion criteria were patients presenting to the Gynecology Outpatient Department or Surgery who gave consent. The exclusion criteria were anyone who could not give consent or was in pain or discomfort. A questionnaire was designed after an extensive literature search on PubMed and Google Scholar. There were a total of 21 questions about informed consent, shared decision-making, and communication between doctor and patient. There were 11 questions about informed consent with Yes/No responses. 4 Yes/No items were checked separately to see how many women understood consent and autonomy. To assess decision making, doctor-patient communication was analysed with 6 items: 4 with Yes/No responses and 2 with multiple choices (who signed the consent form, and who do they prefer makes decisions about their health). A

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section focusing on challenges related to cultural or social factors faced by female patients in the gynecology OPD and surgery was included as well. Non-probability sampling was used, and Raosoft Sample Size Calculator was used to calculate the sample size as 300.

**STATISTICAL ANALYSIS**

The data were analysed using the software IBM SPSS Statistics 26. Frequency and percentage were used to compare the data. Demographic data such as age, ethnicity and educational level were analyzed. Factors of interest were whether doctors asked for consent, and whether women were aware of informed consent. Cultural factors were assessed to understand women’s involvement in the decision-making, such as who signed the consent forms and whether anyone influenced them to undergo surgery. Finally, women were asked whom they preferred to make the final choice regarding their health.

**Table 1.** Demographics (N=300).

		FREQUENCY	PERCENTAGE
Age	Between 20-30 years	189	63.0%
	Between 30-40 years	17	5.7%
	Between 40-50 years	58	19.3%
	Older than 50 years	36	12%
Children	1 child or less	111	37%
	2 or more children	189	63%
Education	Did not attend school	50	16.7%
	Class 6	55	18.3%
	Class 10/Matric	66	22%
	Inter/Alevels/High-School	49	16.3%
	University	80	26.7%
Ethnicity	Urdu-Speaking	153	51%
	Sindhi	39	13%
	Punjabi	57	19%
	Pathan	51	17%

**RESULTS**

A total of 300 women participated in the study. All of the women were married, and 91% of them described themselves as being middle class. Only 9% of the participants were working class. The participants were from different educational levels and ethnicity (Table 1). None of them were pregnant at the time of the study, and 94.3% of them were housewives.

All participants reported that doctors asked for consent before examining them. 23% of the women said that doctors did not explain the benefits or side effects of the medicines when prescribing them. 22% of the women were unaware that they could ask to speak to the doctor alone if there was someone in the consulting room. 30.7% were not aware they could refuse to be examined, and only 5.7% had ever refused an examination (Table 2).

**Table 2.** Knowledge about Consent among Women (N=300).

		FREQUENCY	PERCENTAGE
If there is someone other than the doctor in the consulting room, are you aware you can ask to speak to the doctor alone?	Yes	234	78%
	No	66	22%
If there is someone else in the consulting room, have you ever asked to speak to the doctor alone?	Yes	113	37.7%
	No	187	62.3%
Are you aware that you can say no to being examined by a doctor?	Yes	208	69.3%
	No	92	30.7%
Have you ever said no to being examined by a doctor?	Yes	17	5.7%
	No	283	94.3%

None of the women signed consent forms for their surgeries themselves, with 91.7% reporting that their husbands signed them. Half of them said they preferred their families to make the final decision regarding their health (Fig. 1). All of the

women said it was important for the doctors to involve their husbands or family in decisions regarding their health. Frequencies and percentages of the women's responses are given in Table 3.

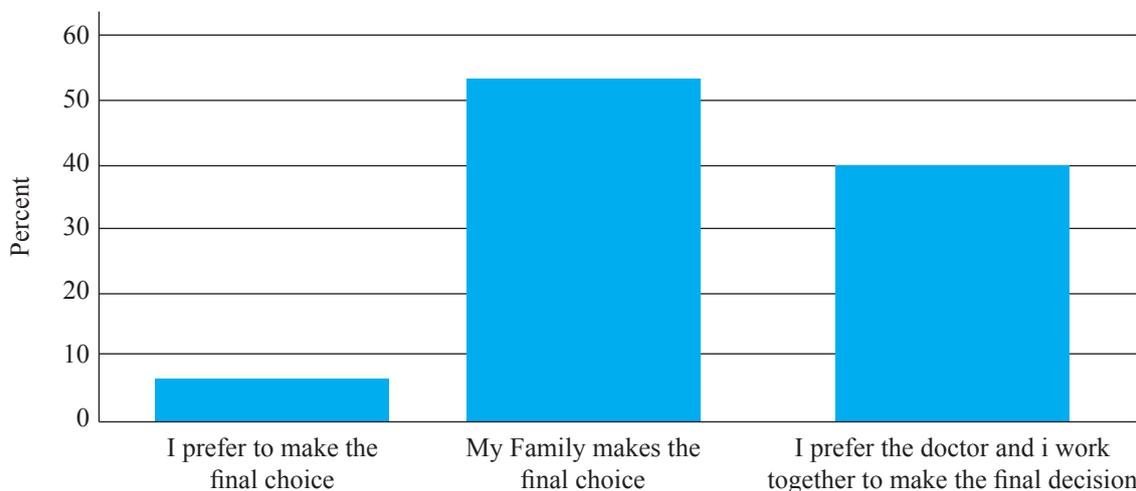


Fig. (1). Who do you Prefer makes the Final Decision about your Health?.

Table 3. Women's Responses as Percentages (N=300).

Did the doctor allow you to ask any questions	Yes	255	85%
	No	45	15%
Did the doctor explain the procedure/surgery's purpose, benefits, and risks of the procedure/surgery to you beforehand?	Yes	239	79.7%
	No	61	20.3%
Did the doctor explain the benefits and potential side effects of the medication to you when he/she prescribed them?	Yes	231	77%
	No	69	23%
Did the doctor explain the reasons for the lab investigations that needed to be done?	Yes	266	88.7%
	No	34	11.3%
Did the doctor explain the results of lab investigations and/or your diagnosis?	Yes	249	83%
	No	51	17%
Did the doctor inform you of different options for treatment, surgery, or medicines?	Yes	232	77.3%
	No	68	22.7%
If you had surgery, do you feel you were given proper instructions for taking care of yourself before and after the surgery (pre and postoperative surgery care)?	Yes	219	73%
	No	81	27%
Did you feel discriminated against due to your ethnicity, culture, dress, or language?	Yes	45	15%
	No	255	85%
Do you feel the doctor spent enough time with you?	Yes	273	91%
	No	27	9%
If you were asked to sign a consent form, who signed it?	Yourself	0	0.0%
	Husband	275	91.7%
	Parent	9	3%
	Other	16	5.3%
Was the consent form available in a language you could read and understand?	Yes	260	86.7%
	No	40	13.3%
Were you influenced by anyone to proceed with the surgery?	Yes, husband	79	26.3%
	No	221	73.7%

## DISCUSSION

Our study reveals that most of the time, the doctors ask for consent before the examination. However, knowing about consent and exercising the right to say no are different in practice. Our study found that 22% of the patients were not aware they could speak to the doctor alone, and more than half had never exercised their right to privacy. 208 out of the 300 women stated they did not know they could refuse an examination by the doctor. However, all participants said they were asked for consent, which states that the method or phrasing used to ask did not explicitly imply that the patients could say no. This is not surprising since doctors in Pakistan often do not receive adequate training on obtaining informed consent, and a majority do not ensure that the patient understands the information being explained to them at the time of obtaining consent [7].

Regarding cultural factors affecting women in Pakistan, we found that majority of the women wanted their families to make the final decision regarding their health. In a patriarchal country such as Pakistan, the elders or the head of the household, most often a male, often make important decisions. Doctors often do not get informed surgical consent from the patients and obtain it instead from the attendants or husbands [7]. But this practice does not ensure that the patient's choice is kept at the forefront. In a study assessing informed consent in research done in Karachi, respondents were asked what should be done if the opinion of a study participant differed from that of the family elders. When the scenario involved a man, 74% said his opinion should prevail, but only 53% said the same about a woman [8]. Even when doctors know the woman can give consent, they still prefer to take the husband's consent for surgery, especially gynecology doctors [9].

In our study, we found that most women did not sign consent forms for their surgeries themselves. Seventy nine women also stated that their husbands influenced them to proceed with the surgery. Consent should always be sought directly from the patient when the patient is competent [9, 10]. In other studies, women stated they felt they had no choice about signing surgical consent forms and would have signed it no matter what [4].

Regarding making decisions, half of the women stated they preferred their family would make the final choice. The statistics from studies done in similar patriarchal societies are the same. The option to choose "my doctors make the final choice" was also given, but it was not chosen by any of the participants. Instead, 44% stated they preferred they work together with their doctor to make the final decision. This shows that some women in Pakistan do prefer a shared decision-making style.

Doctors and healthcare staff need to empower women to take

an active role in making decisions about their health, regardless of their educational level or socioeconomic status. Gynecologists in developing countries like Pakistan are in a unique position to encounter patients from all levels of society, including patients that may be inaccessible to the government healthcare system otherwise. The factors determining women's autonomy in South Asian countries are complex. Low socioeconomic status, low levels of education and early marriage all limit women's agency and ability to seek maternal healthcare [11]. Women living in a joint-family system are often subject to the authority of their mother-in laws [12]. Women's choices might be limited if their husbands or mother-in laws have authority over their healthcare decisions and reproductive autonomy [13, 14]. There should be a protocol for women who are illiterate or cannot communicate with the doctor because of a language barrier, and family members should not always be relied on to translate or give consent. Doctors should be trained to ensure that the women understand the information and should be able to relay to the patient that they have a right to refuse or request alternative treatment. It is necessary that doctors provide information to patients in a language that they understand, and take time to educate them about the risks, side-effects, and benefits before starting a new treatment. Medical translators should be employed by the hospital and available for the outpatient and surgery departments when needed. Senior doctors should ensure that consent form before surgery is signed by the patient themselves unless there is a clearly stated reason otherwise.

Keeping in mind the country's social and cultural barriers, healthcare staff should be aware that female patients do not always have the chance to advocate for themselves, and effort must be taken to ensure patient-centred care. Patients should choose to seek advice from their families but the final decision should rest with the patient themselves [15]. This benefits not only the patient but their children as well. A study found that the shared decision-making style increased women's adherence to cancer screenings [16]. It is also known that women with greater levels of autonomy are able to make decisions about contraception, seek out higher levels of antenatal care, and have a positive effect on children's nutritional status [17-19]. Women's empowerment is also associated with early learning and cognitive development for their child [20].

## LIMITATIONS

The limitation of the study was the non-probability sampling and a lack of comparison with different groups. Larger sample size can also be used to show the effects of education, age and multiparity on women's knowledge and use of informed consent and shared decision making.

## CONCLUSION

Doctors need to improve how they seek consent from patients and inform patients about risks, benefits, and alternative treatment options. An effort should be made to seek consent directly from the patient whenever possible, and social factors should be kept in mind to make patients active participants in their treatment.

## CONFLICT OF INTEREST

Declared none.

## ACKNOWLEDGEMENTS

Declared none.

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34529666; PMCID: PMC8483356. DOI: 10.1371/journal.pmed.1003781

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Received: August 17, 2022

Revised: October 10, 2022

Accepted: October 26, 2022

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