

Awareness Regarding Informed Consent Of Assisted Reproductive Techniques Among Nurse Of Selected Private Fertility Clinics – A Pilot Study

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Abstract- Introduction: *The use of ART is now becoming a popular experience in developing countries. Existing institutional and legal regulations on patient rights imposes duties and responsibilities for all health care personnel on this issue. Awareness regarding informed consent of ART helps to prevent ethical problems that might arise.*

Aim of Study: *The aim of study was to assess awareness regarding informed consent of ART among nurses working in fertility clinics of Chandigarh.*

Material and methods: *A quantitative cross sectional study was conducted among 30 nurses selected through enumerates sampling technique working in selected fertility clinics of Chandigarh. Self-Administered questionnaire was used to collect the data. Data Analysis was done by using SPSS version 15.*

Results: *The findings of demographic data showed that 18 (60%) nurses belong to 21-30 yrs of age and completed GNM diploma. Majority 17(56.67%) had less than 5 yrs experience of working. Most of them 16(53.33%) were married. Majority of staff nurses had average knowledge 17(56.66%) regarding informed consent of ART. 12(8.34%) nurses had below average knowledge followed by only 1(3.34%) staff nurse had good knowledge regarding informed consent of ART. 7(23%) staff nurses had achieved maximum score of understanding about informed consent. 2(6.67%) staff nurses had scored maximum regarding ethical principles and only 1(3.33%) staff nurses had scored maximum regarding role & responsibilities. So above findings revealed that they had very less awareness of definition, purposes, ethical principles and responsibilities of informed consent of ART. There is no significant association of knowledge score with selected demographic variables. It was concluded that there is need to create awareness among staff nurses working in fertility clinics regarding ethical consideration of patient using various educational programs, booklets etc.*

Keywords- Awareness, informed consent, Assisted Reproductive Technology

I. INTRODUCTION

Infertility is a serious medical concern that affects the quality of life and is a problem for 10% to 15% of reproductive age couples (American Society for reproductive medicine). Infertility is 'a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse.'¹

Normally a fertile couple has approximately a 20% chance of conception in each ovulatory cycle. Primary infertile applies to a woman who has never been pregnant; secondary infertility applies to a woman who has at least one prior conception.²

According to National survey of family growth (2011-2013), India faces a high burden of infertility, with an estimated 27 to 30 million couples in the reproductive age suffering from lifetime infertility. Out of this Female factor accounts for 40%-50% of infertility, while male factor, which is on the rise in India, accounts for 30%-40%. 10 million married women aged 15-44yrs are infertile. 11.3% women aged 15-44yrs have ever used infertility services.³ Union territories of Delhi, Lakshadweep, Daman and Diu and Chandigarh registered a low fertility rate below the crucial 2.1.⁴

According to a 2013 World Bank estimate, the drop in fertility started about 10 years ago in India, with a steady 17% decline from the year 2000. Today the incidence is around 10% of all those couples who may be trying to have a baby. However, today the male factor is prevalent in 50% cases. In every 100 couples, 40% males suffer from infertility compared to 50% women. In the remaining 5%, the causes are common in both men and women.⁵

Assisted reproductive technology (ART) is used to treat infertility. Assisted Reproductive Techniques (ART) describes clinical and laboratory techniques used to achieve pregnancy in infertile couples for whom direct corrections of

underlying causes are not feasible. ART procedures use donor eggs, donor sperm, or previously frozen embryos.⁶

New technologies are very helpful for couples. Assisted reproductive technologies include IVF, GIFT, ZIFT, ICSI, egg donation, gestational carrier surrogacy and micromanipulation. Additional ART associated techniques include egg and embryo cryopreservation, testicular sperm extraction, in vitro maturation of oocytes (IVM) and pre implantation genetic diagnosis (PGD).⁷

The ICMR has provided “National guidelines for accreditation, supervision, and regulation of ART Clinics” in India and Assisted Reproductive technologies bill 2013 is currently under review. Legislations serves to draw the attention of doctors and public to serious medical, legal and social issues involved in ART.⁸

Assisted reproductive technology clinics shall ensure that patients, donors of gametes and surrogate mothers are eligible to avail of ART. Duty of the assisted reproductive technology clinic to obtain written consent.⁹

According to ICMR, Informed consent for treatment is an ethical requirement often misunderstood or not fully appreciated by physicians. The purpose of obtaining informed consent is to ensure that patients know what doctors propose to do and freely grant their permission.¹⁰ Today, infertility clients receive the information and emotional support they need. The health care professional best qualified to provide the service is, the female nurse. She is more capable of inventing therapeutically, insensitive and empathic manner. Nurses can provide anticipatory guidance about moral and ethical dilemmas regarding use of ARTs.¹¹

Nurses as healthcare personnel have to deal with various ethical issues of treatment. Awareness regarding informed consent of ART will help the nurses to find out their lacunas which further motivate them to enhance their professional knowledge and skills.

II. OBJECTIVES

- To assess the awareness regarding informed consent of Assisted Reproductive Techniques among nurses of selected Private Fertility Clinics
- To find out the association between awareness regarding informed consent of Assisted Reproductive Techniques among nurses of selected Private fertility Clinics with selected demographic variables

III. MATERIALS AND METHODS

A quantitative descriptive pilot study was conducted among 30 nurses selected through enumerate sampling technique working in selected fertility clinics of Chandigarh.

Self-administered questionnaire was used to collect the data. Validity of tool Content was established by submitting it to experts from the field of Nursing and Gynaecologist Medicine. The reliability co-efficient for the questionnaire was calculated by using split half formula, it was found to be .80. It was consisted of two parts:

Part –A – Selected Demographic variables

Part –B – Assessment of the awareness regarding informed consent of Assisted Reproductive Techniques.

S. No.	Domains of Measurement	Q. No
1.	Understanding of Informed Consent	1-5
2.	Ethical Principles	6-10
3.	Role and responsibilities	11-18

The data analysis was done by using descriptive and inferential statistics by calculating the frequency percentage and ‘chi square’ test using SPSS version 15.

ETHICAL CONSIDERATIONS

1. Administrative permission and ethical clearance with regard to study was obtained from Research Committee of Akal College of Nursing, Eternal University, Baru Sahib (HP).
2. Permission was taken from Heads (HOD) of Clinics for conducting study.
3. Written Informed consent was taken from Nurses.
4. The purpose for carrying out research project was explained to the Nurses and assurance for confidentiality was given.

IV. RESULTS

According to age distribution, the majority of staff nurses 18(60%) were in the age group of 21-30 yrs followed by 7(23.34%) in age group of 31-40 yrs, 4(13.33%) in age group of 51-60 yrs and 01(3.33%) in 41-50 yrs of age group respectively. All 30(100%) staff nurses were females. According to marital status, Out of total sample, 16 (53.33%)

staff nurses were married and 14(46.67%) staff nurses were single.

According to Educational status, majority of staff nurses 18 (60%) had completed GNM followed by 6(20%) B.Sc. Nursing, 06(20%) other diploma holder and none of them had completed MSC Nursing respectively. According to distribution of duration of service, most of them 17(56.67%) had less than 5 yrs experience followed by 7(23.33%) had 6-10 yrs, 3(10%) had 11-15 yrs and 3(10%) had >16 yrs experience respectively.(table 1)

Table-1: Frequency and percentage distribution of sample characteristics of study subjects.

S. NO	DEMOGRAPHIC VARIABLES	(n)	(%)
1)	Age (in yrs)		
	a) 21-30	18	60
	b) 31-40	07	23.34
	c) 41-50	01	3.33
	d) 51-60	04	13.33
2)	Gender		
	a) Male	00	00
	b) Female	30	100
3)	Marital Status		
	a) Single	14	46.67
	b) Married	16	53.33
4)	Educational Status		
	a) GNM	18	60
	b) B.Sc. Nursing	06	20
	c) M.Sc. Nursing	00	00
	d) Any other diploma	06	20
5)	Total Duration of service(in yrs)		
	a) ≤5	18	60
	b) 6-10	7	23.34
	c) 11-15	1	3.33
	d) ≥16	4	13.33

Objective-1: To assess the awareness regarding informed consent of Assisted Reproductive Techniques among nurses of selected Private Fertility Clinics

Table- 2 Frequency and Percentage Distribution of staff nurses according to level of knowledge regarding informed consent of Assisted Reproductive Techniques

N=30

Level of Knowledge	Knowledge Score	n	%
Good	14-18	1	3.34
Average	9-13	17	56.66
Below Average	< 9	12	40.00

Max Score=18Min Score=0

The data revealed that majority of staff nurses had average knowledge 17(56.66%) regarding informed consent of ART. 12(8.34%) nurses had below average knowledge followed by only 1(3.34%) staff nurse had good knowledge regarding informed consent of ART.(Table-2)

Fig 1- showed that Out of Total(30 Nurses)7(23%) staff nurses had achieved maximum score of understanding about informed consent.2(6.67%) staff nurses had scored maximum regarding ethical principles and only 1(3.33%) staff nurses had scored maximum regarding role & responsibilities. So above findings revealed that they had very less awareness of definition, purposes, ethical principles and responsibilities of informed consent of ART.

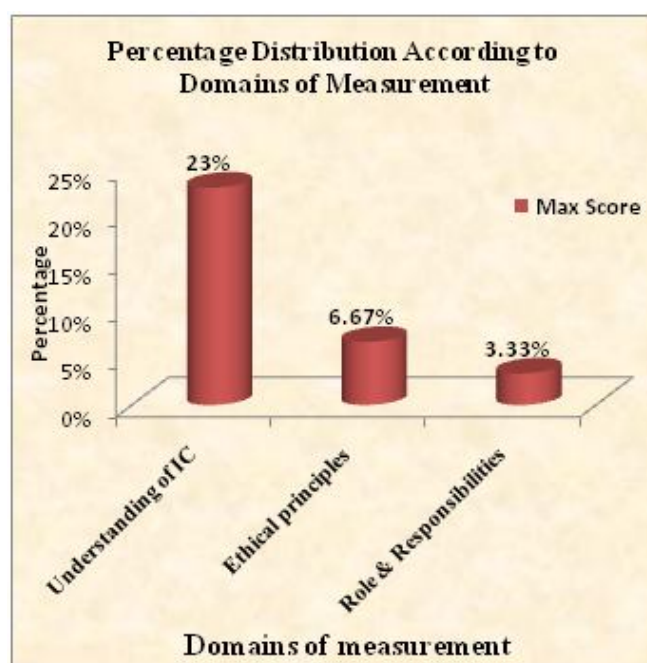


Fig 1 showing percentage distribution of knowledge score according to domains of measurement.

Objectives: 2 To find out the association between awareness regarding informed consent of Assisted Reproductive Techniques among nurses of selected Private fertility Clinics regarding selected demographic variables

Table 3 revealed that there is no significant association of knowledge score with selected demographic variables as there p value is greater than 0.05 level of significance.

Table 3 Association of Awareness Score with selected Demographic Variables
N=30

Variables		Sum of squares	df	F	Sig.
1.Age					
a)21-30	Between	10.5	9	1.07	.424 ^{NS}
b)31-40	Groups		20		
c)41-50	Within	21.8	29		
d)51-60	Groups				
	Total	32.3			
2.Marital status	Between	3.01	9	1.50	.213 ^{NS}
a)Single	Groups		20		
b)Married	Within	4.45	29		
	Groups				
	Total	7.46			
3.Educational status	Between	11.43	9	.865	.570 ^{NS}
a)GNM	Groups		20		
b)B.Sc. Nursing	Within	29.37	29		
c)M.Sc. Nursing	Groups				
d)Any other diploma	Total	40.80			
4.Experience of services	Between	10.28	9	1.16	.366 ^{NS}
a)≤5	Groups		20	7	
b)6-10	Within	19.58	29		
c)11-15	Groups				
d)≥16	Total	29.86			

NS-Non significant at $p>.05$ level of significance

Discussion: Observing patient's rights is the most important ethical issue in a hospital which should absolutely be considered. Implementing ethical principles and respecting them are two main factors for patients' care. It is important that medical staff pay enough attention to its various aspects. The findings of this study revealed that majority of nurses 56.66% had average knowledge regarding informed consent of ART followed by 40% had below average and 3.34% had good knowledge respectively. They have very less awareness regarding understanding, ethical principles and responsibilities of Informed consent procedure of ART. NejadEsmaeil (2011) had conducted study on 156 nurses selected randomly from teaching hospitals in Tehran which also revealed that 41.6% of nurses have weak knowledge regarding patients' rights and ethical considerations¹²

V. CONCLUSION

In conclusion, the results of the present study demonstrated that nurses who participated in this study had insufficient knowledge about the definition, techniques, purposes, ethical principles, role & responsibilities of ART.

Generally, 40% nurses had below average knowledge regarding informed consent and considering the fact that awareness and knowledge can be the base of nurses' performance, the implementation of awareness program regarding informed consent procedure of ART is highly recommend. Holding educational conferences, seminars, workshops and academic panels for nurses and nursing students will help to overcome difficulties in implementation of ethical principles during ART.

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