

Full Length Research

Informed consent for antenatal fetal anomaly scan

¹Dodampahala S.H., ²Wijeratne N.

¹Principal Author is an Associate Professor in Obstetrics and Gynaecology, Department of Obstetrics and Gynaecology,

²Faculty of Medicine, University of Colombo, Srilanka. Corresponding author's email: hemdodam@gmail.com

^{1,2} 189/20 Sama Mawatha, Nawala Road, Nugegoda, Sri Lanka

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The objectives of prenatal screening and testing for fetal abnormality include the identification of: Anomalies that are not compatible with life, Anomalies associated with high morbidity and long-term disability, Fetal conditions with the potential for intrauterine therapy, Fetal conditions that will require postnatal investigation or treatment. The study analyzed the current requirement by client and doctors in obtaining the consent, in order to develop a structured protocol to obtain consent.

Methodology: A descriptive cross sectional study using qualitative methods was conducted for the above study. Hundred (n=100) mothers awaiting anomaly scans at the De Soyza maternity hospital, Professorial unit were interviewed by the researchers to obtain their perspectives on consent obtained for the anomaly scan. Twenty (n=20) medical officers of all grades underwent a focus group discussion on their perspectives of obtaining consent for the anomaly scan. Data were analyzed through coding of the transcribed focus group discussions and extraction of main themes.

Results: Medical officers of all grades participated in the focus group discussion from intern medical officers to consultant obstetricians. All were in agreement that consent obtaining procedure adopted by the medical officers in the current setting is inadequate. Only verbal consent is obtained usually at the busy clinic set up without allowing the mother adequate time to consider whether she wishes to undergo the anomaly scan. The mother is rarely informed of what the anomaly scan entails and the indication for the procedure. Details on what her options if an anomaly is detected are rarely discussed. Consent is usually not obtained by the doctor who performs the scan and does not involve the partner in the decision making process.

Conclusions: The current practice adopted in obtaining consent prior to routine antenatal fetal anomaly scan was inadequate, with little information being provided to the mother and consent not being specifically sought prior to the scan procedure.

Key words: Informed consent/ antenatal scan/fetal anomaly/counseling

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INTRODUCTION

Some form of prenatal screening is offered routinely to every pregnant woman in order to identify those at high risk of having an affected child. Screening include detailed maternal history, detailed genetic history, maternal serum screening and ultrasound.

A detailed ultrasound scanning is useful in monitoring the development of the fetus, detecting both major and

minor defects hence offering a diagnosis as well as identifying those at high risk for whom further enquiries are necessary (Barr and Skirton, 2013).

In the West, scans are not compulsory and a mother-to-be can decide whether or not she would like to get a scan (Josephine et.al, 2007). Unlike the West, in our country, many doctors advise scans at specified intervals

to ensure that pregnancy is progressing well and baby is doing fine.

The objectives of prenatal screening and testing for fetal abnormality include the identification of:

- Anomalies that are not compatible with life
- Anomalies associated with high morbidity and long-term disability
- Fetal conditions with the potential for intrauterine therapy
- Fetal conditions that will require postnatal investigation or treatment.

For 90-95% of people, prenatal diagnosis brings reassurance but, for those who receive an unfavorable result there can be practical benefits of having advance warning of the child's disability, such as early access to care and treatment and allowing the family time to come to terms with the child's disability. Some women will, however, opt to terminate an affected pregnancy (Josephine et. al., 2007). However this option is not available in Sri Lanka and women have to continue with pregnancy even if anomaly is detected.

In some cases the disability diagnosed will arise the need for a termination of pregnancy but in Sri Lankan setting this is illegal, though some women may wish to consider this option. At whatever stage fetal abnormality is diagnosed, women and their partners need good quality information about the implications of the result and the options open to them (Alderson et. al, 2006). So clients need information about all these beforehand but the problem is to what extent, by whom, at what stage, to whom etc.

Written information should be provided to all women giving details of the nature and purpose of the screening proposed, the procedure used, details of detection rates for defined common conditions, the meaning of a positive and negative screening result, and possible actions to be taken if a normal or abnormal result is obtained (van Zwieten et. al, 2006). Based on this information, women should be free to opt into, or out of, any form of prenatal screening. The option of having no screening at all should be offered as a reasonable and acceptable way forward. In addition the client should be told negative screening won't rule out all diseases such as cerebral palsy, mental retardation or autism (van Zwieten et. al, 2006).

Further obstetric medical practice is increasingly litigious and the aims of screening ultrasound and the limitations (false-negative and false-positive rates) should be explicit not only to the referring clinician but also to the expectant parents prior to screening. (Second trimester scans, Baby Center - India, 2007). The diagnostic accuracy of ultrasound should be known in order that the expectant mother can give informed consent (Second trimester scans, 2007).

Even though there are few studies about these issues in the western literature for Sri Lankan setting data is unavailable. There should be a way to ensure the protection of clients medical ethics regarding prenatal diagnosis by using modern ultrasound scanning. Therefore to achieve this goal by preparing a validated protocol for prenatal scanning is priceless (McCoyd, 2007).

The process of obtaining consent for fetal anomaly scan needs to be formalized to protect the needs of the client as well as the service provider. If a validated protocol for obtaining consent for prenatal scanning was developed it would aid the healthcare worker in aligning to a standard manner in obtaining consent. (van Zwieten et al., 2006).

This decline shows that offering the option of "selective consent" has the potential to overcome the previously reported high uptake of ultrasound screening.

Selective consent can be easily accommodated by the early pregnancy scan because its pregnancy monitoring functions (assessing gestation and viability, and identifying multiple pregnancies) are distinct from its screening functions. Therefore, couples who wish to decline screening for chromosomal abnormalities do not have to forgo "seeing the baby" or accurately dating the pregnancy. (Pauli-Magnus, Dewald and Cierpka, 2001).

OBJECTIVES

1. To assess the current practice adopted in obtaining consent prior to routine antenatal 2nd trimester fetal anomaly scan.
2. To analyze the clients needs when obtaining informed consent for prenatal fetal anomaly scan.
3. To analyze the requirement by the medical officers when obtaining informed consent for fetal anomaly scan.
4. To develop a checklist/protocol for obtaining consent for fetal anomaly scan to be used by the doctors.

METHODOLOGY

A descriptive cross sectional study using qualitative methods was conducted for the above study. Hundred (n=100) mothers awaiting anomaly scans at the De Soyza maternity hospital, Professorial unit were interviewed by the researchers to obtain their perspectives on consent obtained for the anomaly scan. Twenty (n=20) medical officers of all grades underwent a focus group discussion on their perspectives of obtaining consent for the anomaly scan. Data were analyzed through coding of the transcribed focus group discussions and extraction of main themes. Ethical clearance was obtained from the Ethics Review committee of the Faculty of Medicine, Colombo prior to commencement of the study. Only participants who

Table 1. Frequency distribution of the antenatal mothers in the study sample by age

Age group (years)	Frequency	Percentage (%)
15 – 19	5	5
20 – 24	22	22
25 - 29	35	35
30 - 34	24	24
35 – 39	12	12
≥ 40	2	2
Total	100	100

Range : 17- 40 years, Mean age : 28years
SD: 5.14

consented to take part were included.

Focus group discussion with five medical officers and in depth interviews with ten pregnant mothers were the study methods employed to collect data.

The tools were pre tested and validated for use in the study.

All content of focus group discussions and in depth interviews were audio taped and transcribed on the same day by the researchers (McCoyd, 1997).

RESULTS

Medical officers of all grades participated in the focus group discussion from intern medical officers to consultant obstetricians. All were in agreement that consent obtaining procedure adopted by the medical officers in the current setting is inadequate. Only verbal consent is obtained usually at the busy clinic set up without allowing the mother adequate time to consider whether she wishes to undergo the anomaly scan. The mother is rarely informed of what the anomaly scan entails and the indication for the procedure. Details on what her options if an anomaly is detected are rarely discussed. Consent is usually not obtained by the doctor who performs the scan and does not involve the partner in the decision making process.

All doctors were of the view that the anomaly scan and

especially its results have a profound psychological impact on the patient. They expressed views that the scan may help mothers adjust to the birth of an abnormal baby and at the same time provide relief if no anomaly is detected.

All doctors agreed that consent needs to be taken in a proper manner, preferably using a structured consent form. They felt this would be acceptable to both the patient and doctor and would minimize litigation chances. They also felt it was the right of the mother to obtain this information.

The doctors were able to provide suggestions on improvements that could be made to the current procedure in obtaining consent for the fetal anomaly scan without overburdening the system. They suggested a two step process whereby at the clinic visit, a scan is requested and the patient is briefly explained what the scan entails. Then the consent form along with an information sheet is provided to the mother to take home and bring back on the scan date after reading at leisure. Before the scanning clarifications could be made and written consent provided by the mother.

Ten pregnant mothers provided their views on undergoing the fetal anomaly scan and the consent obtained from them through in depth interviews. Most mothers were of low socio economic groups and were educated upto secondary schooling. All ten were unaware as to why they were undergoing the anomaly scan and what the procedure would require. Most were requested by the obstetrician to “get a scan” and were directed to the radiological investigation unit from the clinic with a request form. Most were unaware that detection of fetal abnormalities was the purpose of the scan and all were unaware that termination of pregnancy on grounds of fetal anomaly was prohibited in the local legal context.

All were keen that information of a general nature be provided to the couple before the scan, for a decision to be made by the parents whether they wish to undergo the scan. The view that “what they wish to tell us is in their hands” was expressed by a majority of mothers. They felt verbal consent would be adequate as no invasive procedure is performed but wished to be told by the “big doctor”, the consultant in charge of their well being.

One mother was of the opinion that adverse effects of the scan should not be told prior to the scan as it would put the mother in an unduly anxious situation which may lead to non-acceptance of scans. She felt mothers would shy away from scans if they are given too much information which may scare them. Mothers felt that the power difference between doctor and patient prevented them from requesting for information but implied that verbal information given in a responsible manner by an informed medical officer to the couple in an unhurried manner would facilitate the consent giving procedure for anomaly scan enormously. Table 1, 2, 3 and 4

Table 2. Frequency distribution of the antenatal mothers in the study sample by ethnicity and religion

Characteristic	Frequency	Percentage (%)
Ethnicity		
Sinhala	82	82
Tamil	8	8
Muslim	10	10
Religion		
Buddhist	79	79
Hindu	8	8
Islam	10	10
Roman catholic	3	3

Table 3. Frequency distribution of antenatal mothers by the level of education

Characteristic	Pregnant mother	
	Frequency	Percentage
Highest Educational attainment		
Year 1 – 5 (primary)	2	2
Year 6-10 (secondary)	16	16
G.C.E O/L	44	44
G.C.E A/L	31	31
Degree/Diploma and above	7	7
No schooling	0	0
Total	100	100

G.C.E O/L : General Certificate of Education (Ordinary level)

G.C.E A/L : General Certificate of Education (Advanced level)

Table 4. Frequency distribution of the families of the antenatal mothers in the study sample by the social class

Social class	Frequency	Percentage
Low	34	34
Middle	60	60
High	6	6
Total	100	100

CONCLUSIONS

The current practice adopted in obtaining consent prior to routine antenatal fetal anomaly scan was inadequate, with little information being provided to the mother and consent not being specifically sought prior to the scan procedure. Medical officers view structured written consent forms as a useful commodity which would improve patient care in obtaining consent for anomaly scan. A two step process of consent taking is also seen as useful.

Pregnant mothers were also of the opinion that they are poorly informed of the purpose and consequences of the fetal anomaly scan. They felt provision of information in a proper manner would facilitate consent giving by empowering them to make choices.

RECOMMENDATIONS

A checklist based on the above results for obtaining consent for fetal anomaly scan was developed by the researchers and will be made available to all units freely. This would enhance patient autonomy as well as protect the doctor from litigious procedures. We hope to obtain feedback from the medical officers in the units under review and include this as an official document to be used in this procedure.

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