

An Audit Of Informed Consent For Elective Gynaecological Surgery In A District General Hospital

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Abstract

Objective: To measure compliance with standards in available guidelines for informed consent for elective gynaecological surgery and to make recommendations to improve the process of consenting in the obstetrics and gynaecology unit. **Methods:** We retrospectively studied the medical notes of patients undergoing 3 types of elective gynaecological surgery over a seven-month period. These were assessed for the presence of consent forms, the legibility of the doctor's name, and his/her suitability and the extent to which risks of the operations were documented. **Result:** Of the 54 patients' notes assessed, all contained signed NHS consent forms with signatures of doctors and patients. The names of two doctors were not legible. All the identified doctors were assessed suitable to take consent. The documentation of risks was found to be incomplete. **Conclusion:** The audit revealed the universal problem of incomplete documentation of risks. We recommend that this can be improved with use of operation-specific consent forms, a pro forma or aid memoir e.g. patient's information leaflets

INTRODUCTION

Consent is an ethical and legal requirement that must be obtained before any procedure is carried out in clinical practice. When obtained based on balanced information, it practically improves patients' satisfaction in virtually all outcomes.

In our ever increasingly litigious world of medicine, informed consent has become more sophisticated and involves much more than completing a form. Cardinal to this is the comprehensive, relevant and accurate risk disclosure; hence the introduction of the new consent forms by the Department of Health with a mandate for use by April 2002¹.

A recent audit on consent in Dumfries and Galloway Royal Infirmary (DGRI) revealed inadequate documentation² and because it is very important for clinicians to be familiar with the guidance relevant to their practice, we audited our practice to assess adherence to available guidelines and to make appropriate recommendation.

METHOD

A form was designed to collect data from patients' case notes retrieved with the help of the Audit Unit. We retrospectively reviewed the available 54 notes of patients

who had elective total abdominal hysterectomy, vaginal hysterectomy and pelvic floor repair and laparoscopic surgery during the study period of January 2008 to July 2008.

The patients were identified from the theatre register. A record was made of the presence of written consent form, legibility of doctors' name, and the suitability of the doctor, the timing of the consent and the extent of documentation of serious and frequently occurring risks.

The audit measured compliance against standards within the guidelines of the General Medical Council, Dumfries and Galloway Royal Infirmary Consent Policy and the recommendation of Royal College of Obstetricians and Gynaecologists (RCOG). Obtained data were entered into electronic spreadsheet and analysed using Microsoft Excel software package.

RESULT

Of the 54 patients reviewed, 26 of the patients had total abdominal hysterectomy, 12 had vaginal hysterectomy and 16 had diagnostic or operative laparoscopy.

A written consent form was present in all case notes. The name of the doctor was not legible in 2 cases (3.7%). All the identified doctors were assessed suitable to take consent, as

it is only first year foundation doctors that are not suitable to take patients' consent in DGRI. The maximum and minimum interval between the time of consent and the time of the operation were 9 weeks (diagnostic laparoscopy) and few hours (total abdominal hysterectomy) respectively.

81.5% (44) of patients were consented within 24 hours to the time of surgery. 10(62.5%) out of 16 patients undergoing laparoscopy were consented on the morning of surgery in the Day Surgery Unit, while the other patients were consented either in clinic or as in-patients a day before surgery.

Table 1 showed the number of patients that were consented by each category of doctors i.e. consultants, staff grade doctors, level 3 and 2 specialty trainee doctors, general practice vocational trainees and 2nd year foundation doctors. Most of the patients (48%) had their consent taken by consultants. This was in line with the hospital consent policy.

Figure 1

Table 1 Who Took The Consent? (n=54)

Grade of Doctor	Number of patients	%
Consultant	26	48.1
Staff Grade	7	13.0
Specialty Trainee- year 3	5	9.3
Specialty Trainee- year 2	9	16.7
GP Vocational Trainee	3	5.6
Foundation Year 2	2	3.7
Not Clear	2	3.7

Table 2 shows the proportion of the patients operated by each grade of doctors. Again, consultants performed most of the operations (64.8%). 20.3%, 5.6% and 9.25% were performed by speciality level 3 and 2 doctors and staff grade doctors respectively.

Figure 2

Table 2 Who Operated? (n=54)

Grade of Doctor	Number of patients	%
Consultant	35	64.8
Staff Grade	6	9.25
Specialty Trainee- Year 3	11	20.3
Specialty Trainee- Year 2	3	5.6

With respect to the documentation of risks as recommended by the Royal College of Obstetrician and Gynaecology Consent Advice for gynaecological procedures, Table 3 shows the extent of documentation the associated risks in percentages.

The most frequently documented risks are the general risks of surgery such as bleeding (79.6%), infection (81.6%)

venous thromboembolism (58.9%), bowel injuries (81.5%) and urinary tract injuries (79.6%).

Tab. 3 also shows the extent of documentation of operation-specific risks of each type of procedures. For abdominal hysterectomy, the risks of oophorectomy for unsuspected disease and early menopause were documented in 15.4% and 30.7% respectively. In cases of vaginal hysterectomy, dyspareunia was not documented in any of the forms. While in cases of laparoscopic sterilisation, the documentation of risks of unwanted and ectopic pregnancies was 100%. Other risks were as shown in the table.

Figure 3

Table 3 Risk Documentation as Recommended by the RCOG Consent Advice

Risks	Expected frequency	Observed Frequency	%
General			
Bleeding	54	43	79.6%
Infection	54	44	81.6%
Venous Thromboembolism	38	22	58.9%
Bowel Injuries	54	44	81.6%
Urinary Tract Injuries	54	43	79.6%
Blood Transfusion	54	3	5.6%
Pain	54	7	13.0%
Return To Theatre	38	4	10.5%
Risk of Death	54	0	0%
Abdominal Hysterectomy			
Early Menopause	13	4	30.8%
Oophorectomy	13	2	15.4%
Urinary Frequency	26	0	0%
Delayed Wound healing	26	1	3.8%
Keloid Formation	26	1	3.8%
Vaginal Hysterectomy			
Dyspareunia	12	0	0%
Urinary Retention	12	0	0%
Urinary Frequency	12	0	0%
Laparotomy	12	4	33.3%
Recurrence	12	4	33.3%
Laparoscopic Surgery			
Laparotomy	16	11	68.8%
Unwanted pregnancy	8	8	100%
Ectopic Pregnancy	8	8	100%
Uterine Perforation	16	1	6.25%
Failure to Identify disease	8	1	12.5%
Failure to enter abdomen	16	1	6.25%

DISCUSSION

It is impressive that the 48% of the patients had their consent obtained by consultants compared to 33% quoted in the previous hospital audit ². Though, the consultant is ultimately responsible for ensuring that the patient has genuinely consented to the planned procedure, the crucial team working principle of the NHS allows for other team members who can either carry out the procedure or has adequate knowledge of it or understand the risks that are involved to obtain consent. Likewise, consultants did a large proportion of the operations; this is considered appropriate

as consultants obtained most of the consent ¹. Furthermore, consent should not be routinely left to junior doctors.

The literature is little and extant regarding timing of consent and in fact some believe there is no right answer about ideal time and place to sign consent; each unit should determine the best local practice. However, it is important that patient be given sufficient chance to absorb the information necessary for them to make their decision. Our practice of consenting patients mainly within 24 hours before surgery, following previous counselling in the outpatient clinic along with the use of patient information leaflets sent to them before admission is deemed in line with the guideline. Also, if significant time has elapsed between time of consent and the time of the procedure it is important to reaffirm that the patient has not changed her mind ^{3,4}.

Since the introduction of the new consent forms, doctors are required to document serious and frequently occurring risks on the consent forms. More so, evidence has shown that gynaecological patients do want to know all risks and they react differently if they are not told of complications that happened to occur ⁵. Using the RCOG consent advice ³, our result showed great variability for the documentation of risks.

We observed that the most commonly recorded risks were the serious and frequently occurring risks of major surgery - bleeding, infection, venous thromboembolism and organ (urinary tract and bowel) injuries, while operation-specific risks were poorly documented e.g. dyspareunia for vaginal hysterectomy, uterine perforation for laparoscopic surgery and risk of oophorectomy and menopause for abdominal hysterectomy with ovarian conservation. The complete documentation of risks of unplanned pregnancy and ectopic pregnancy was attributed to the use of a pro forma for patients undergoing laparoscopic sterilisation in the hospital.

This inadequate documentation of risks has been highlighted in similar audits done in other departments across the UK. Robert et al. found that although the risk documentation improved with the use of the new consent form, patients were not necessarily told the most appropriate risks to ensure valid consent ⁶. Edwards et al demonstrated improved risk documentation in a re-audit but concluded that there is need for more pragmatic means of sustaining complete risk documentation ⁷. Bruce Campbell noted that handwriting serious and frequently occurring risk is tedious, time

consuming and likely to be incomplete and so potentially exacerbating the medico-legal difficulty rather than preventing them ⁸.

The documentation of risks as shown in our audit is universally poor. There is need for local professional consensus as to what constitute risks that should be discussed and documented. A plenary session to familiarise everyone with the spectrum of risks will be necessary.

The use of aide memoir e.g. patient information leaflets may help as repeated flawless recall of all risks is impractical. The use of operation-specific consent form or pro forma with pre-printed information on the patient's condition, treatment options, benefit and risks of the procedure all in terms understood by the patient will ensure that no information is left unmentioned. Above all clinicians should receive adequate training in conveying relevant information that is pivotal to women's decision-making process

CONCLUSION

This audit reflects great variability and incomplete documentation of risks that has been found to be universal. The use of aid memoir and operation-specific consent form or a proforma will ensure accurate and comprehensive discussion and documentation of serious and frequently occurring risks of surgical procedures particularly the operation specific ones.

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