



**University of Dundee**

**National multicentre audit of pregnancy status in general surgery admissions in Scotland**

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### National multicentre audit of pregnancy status in general surgery admissions in Scotland

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3 National multicentre audit of pregnancy status in general  
4 surgery admissions in Scotland  
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60

## National multicentre audit of pregnancy status in general surgery admissions in Scotland

### Abstract

#### Background:

Documentation of pregnancy status is an integral component of the assessment of females of reproductive age when admitted to hospital. Our aim was to determine how accurately pregnancy status was documented in a multicentre audit of female admissions to general surgery.

#### Methods:

A prospective multicentre audit of elective and emergency admissions was performed in 18 Scottish centres between 0800 on 11/05/2015 and 0759 on 25/05/2015. The lower age limit was the minimum age for admission to the adult surgical ward, up to the age of 55 years.

#### Results:

2743 admissions with 612 (22.3%) females of reproductive age. 82 exclusions leaving a final total of 530; 169 (31.9%) elective and 361 (68.1%) emergency. Documentation of pregnancy status was achieved in 274 (50.7%) cases; 52 (30.8%) elective and 222 (61.5%) emergency. 318 (88.1%) of the emergency admissions had abdominal pain. Of these, 211 (62.9%) had a documented PS. The possibility of pregnancy was established in 227 (43.0%) of cases.

#### Discussion:

Establishing the possibility of pregnancy prior to surgery is poor, particularly in the elective setting. Objective documentation of pregnancy status in the emergency setting in those with abdominal pain is also poor. Our study highlights an important patient safety issue in the management of female patients. We advocate electronic storage of pregnancy test results and new guidelines to cover both elective and emergency surgery. Pregnancy status should form part of the pre-theatre safety brief and checklist.

### Background

The documentation of pregnancy status (PS) is an integral component of the medical assessment of all females of reproductive age (FRA) when admitted to hospital.

In the elective setting, current guidelines advocate that the possibility of pregnancy should be established prior to any procedure requiring a general anaesthetic (1). If there is a possibility of pregnancy then a formal pregnancy test is likely to be performed. Surgery in the early stages of pregnancy constitutes a recognised risk to the fetus and this should form part of the informed consent process prior to undertaking the procedure (2-4). However, in most elective cases the surgery can be safely postponed.

In the emergency setting, when FRA are admitted acutely with abdominal pain the primary concern should be to exclude ectopic pregnancy (EP), and therefore documentation of PS takes on even greater importance.

The primary aim of our study was to determine whether PS was documented in the patient's notes in all FRA admitted to general surgery (GS) in a multicentre setting. The secondary aims were to determine whether the possibility of pregnancy was documented, and whether PS was established prior to any procedure requiring a general anaesthetic during their hospital stay.

### Methods

A prospective national audit of pregnancy status was undertaken. The study was co-ordinated and performed by the Scottish Surgical Research Group (SSRG), a research collaborative formed to facilitate trainee-led clinical research and audit across Scotland in the field of GS (5, 6). The study was performed using a previously trialled protocol that was sent out to all participating centres prior to the commencement of the study. The initial protocol had been modified following the results of the pilot study undertaken at two Scottish centres (7). The study protocol is available as appendix 1. There is currently no gold standard for the objective documentation of pregnancy status. The current requirement is for the objective documentation of the possibility of pregnancy, and this covers the elective setting only. In our study the gold standard we adopted was that 100% of FRA admitted to general surgery with abdominal pain, or requiring a procedure under general anaesthetic or exposure to ionising radiation should have the results of a pregnancy test documented within the medical notes. National approval from the Caldicott guardian was obtained prior to the commencement of the study (8).

### *Centre eligibility*

Any Scottish hospital offering acute and/or elective GS procedures was eligible to participate in the study. A network of surgical trainees working at various acute Scottish hospitals was established. In those hospitals with no dedicated GS trainees, clinical directors for general surgery were invited by email to enrol in the study. Each centre had a trainee (or junior doctor) led

principal investigator, who was responsible for prospectively identifying eligible patients for the study, entering data in to the study database and submitting it centrally for analysis after data anonymisation.

### *Patient eligibility*

All FRA, admitted under the care of GS between 0800 on 11/05/2015 and 0759 on 25/05/2015 were eligible for inclusion in the study. Current guidelines do not specifically define the age range for females of childbearing age but should include all women menstruating, excluding surgery after miscarriage and other exceptions (1, 9). For our study, the lower age limit for FRA was the lower age limit for admission to the adult GS wards of each individual centre, with an upper age limit of 55 years. The centres with the lowest age limit for admission to the adult ward was 14 years, but in the majority of centres the lower limit was 16 years. Patients were excluded if they were male, over 55 years, had previous hysterectomy or sterilisation, postmenopausal, were known to be pregnant or had been admitted electively for a procedure under local anaesthetic or sedation.

### *Outcome measures*

The primary outcome measure is the objective documentation of PS in the patient notes within 24 hours of admission using urine beta human chorionic gonadotrophin ( $\beta$ -hCG). The secondary aims were to determine if a  $\beta$ -hCG result was documented in the patient notes prior to undergoing a procedure requiring general anaesthetic (GA), and whether the possibility of pregnancy was recorded at the point of admission.

### *Data collection*

Data were collected using a password protected study specific Microsoft<sup>©</sup> Excel database. At the end of the study, when data collection was complete the data was anonymised and submitted electronically for analysis. A comprehensive list of the data fields is included in the study protocol. 18 centres submitted data for inclusion in the study. 2 centres admitted elective patients only, and 1 centre admitted emergency patients only. The remaining 15 centres admit both electively and as an emergency.

### Results

The number of patients admitted during the study period varied from centre to centre (range 3 to 245 patients). Results from individual centres are provided in appendices 2 and 3.

2743 patients were admitted during the study period, of which 1359 (49.1%) were female. 891 (38.5%) were elective and 1852 (61.5%) were emergencies. 612 (22.3%) were FRA (Table 1).

FRA (%)	Elective FRA (%)	Emergency FRA (%)
612 (22.3%)	200 (32.7%)	412 (67.3%)

Table 1 – Total numbers of females of reproductive age (FRA) by admission type

Of these, 277 (45.3%) underwent a GA during their admission; 200 (72.2%) electively, and 77 (27.8%) as an emergency.

82 (13.4%) FRA were excluded from the study for the following reasons (Table 2); Insufficient data (n=19), hysterectomy (n=31), sterilisation (n=13), postmenopausal (n=13) and known to be pregnant (n=6).

Total exclusions	Elective exclusions (%)	Emergency exclusions (%)
82	31 (37.8%)	51 (62.2%)

Table 2 – Exclusion data

Therefore, after exclusions, data from 530 FRA was analysed; 169 (31.9%) elective and 361 (68.1%) emergency. Documentation of PS was established in 274 (50.7%) cases; 52 (30.8%) elective and 222 (61.5%) emergency (Figure 1).

In those presenting as an emergency, 318 (88.1%) had abdominal pain. Of these, 211 (62.9%) had a documented PS. In the same cohort, 77 (21.3%) required an emergency surgical procedure under GA, of which 47 (57.6%) had a documented PS prior to their procedure.

The possibility of pregnancy was established in 227 (43.7%) cases, 100 (59.2%) elective and 137 (38.0%) emergencies. In the emergency cohort who required surgery the possibility of pregnancy was established in 23 (29.9%) of cases prior to their surgery.

13 patients with a history of sterilisation were not included in the above analysis. However, on account of a low risk of subsequent pregnancy we have analysed these as a subgroup. 6/13 (46%) had a documented pregnancy status, all of which were negative. There was no documented pregnancy status in the remaining 7 patients.

### Discussion

Our results demonstrate that pregnancy status is poorly documented in general surgical practice, particularly in the elective setting. In 2% of pregnancies there is a need to undergo a GA (10). It is common practice for surgery in the elective setting to be postponed due to the increased risk of spontaneous abortion and neural tube defects if undertaken in the first and second trimester (2-4), with more premature births and low birth weights if undertaken in the third trimester (11).

In the emergency setting, ectopic pregnancy in FRA presenting with abdominal pain should always be considered. In those requiring emergency surgery, PS should be part of the informed consent process. However, surgery should not be unnecessarily delayed, even if pregnancy is established as this may also result in an increased risk of fetal loss in common conditions such as acute appendicitis (12).

In the UK, current guidelines for elective surgery require that the possibility of pregnancy is established preoperatively (1). How this is achieved varies from centre to centre. Some centres ask the question 'Is there any possibility of pregnancy?', and document the pregnancy. If the response is yes then they



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3 proceed to a formal pregnancy test. Others require patients to sign a legal  
4 disclaimer confirming that they are not pregnant. Finally, a smaller number of  
5 centres have adopted a policy of formal pregnancy testing prior to their  
6 surgical procedure.  
7

8  
9 In the emergency setting there are no guidelines in relation to the  
10 documentation of PS. Nevertheless, documentation of PS remains an  
11 essential part of the relevant medical history for each FRA, particularly if they  
12 require a GA or any investigation that exposes them to ionising radiation or  
13 the use of drug treatments that are contra-indicated in pregnancy. It is our  
14 view that this practice should be adopted in both the elective and emergency  
15 setting.  
16

17  
18 The results of our study are representative of current practice within the  
19 National Health Service. The study was undertaken in a multicentre format to  
20 increase cohort size, which was the limitation of the previous pilot study.  
21 Powell-Bowns *M et al* audited the documentation of PS in emergency surgical  
22 admissions across two NHS sites (150 patients in total), both of which  
23 contributed data to our current study. In the first cycle, 30% had a  
24 documented PS, which improved to 75% in the reaudit after the  
25 implementation of change in practice. In those requiring GA, results improved  
26 from 25% to 85%. Our study highlights that poor documentation of PS in  
27 emergency admissions is endemic. Just 61.5% of emergency admissions and  
28 57.6% of those who required emergency surgery had objective documentation  
29 of their pregnancy status. In the elective setting, reports of undiagnosed  
30 pregnancy range from 0.15% to 2.2%, with routine testing costing an  
31 estimated \$2900-\$3300 per positive pregnancy test (10, 13).  
32  
33

34  
35 Our study did not elicit the diagnosis of any unsuspected pregnancies, and  
36 there were no ectopic pregnancies. However, PS was only documented in  
37 50.7% of cases, and just 30.8% of elective cases. 6 (1.5%) emergency  
38 patients were known to be pregnant at the point of admission. They were  
39 excluded from the analysis and none of these required a GA. Further, we  
40 chose to exclude 13 patients with a history of sterilisation from our analysis.  
41 Female sterilisation (all methods) is effective and is associated with a failure  
42 rate of <5/1000 procedures at 1 year post procedure (14). We took the view  
43 that this is an acceptable outcome and the risk of subsequent pregnancy was  
44 therefore negligible in this cohort of patients. Nevertheless 6/13 (46%) had a  
45 negative pregnancy test performed.  
46

47  
48 While there is plenty of anecdotal evidence regarding missed pregnancies  
49 and subsequent surgery or investigations with ionising radiation (the images  
50 of which are often used to bring home the importance of pregnancy testing in  
51 local teaching), understandably there is very little to find in the literature to  
52 commemorate this. It is our belief that there should be a shift in attitude  
53 towards the documentation of PS. New guidelines should be developed to  
54 encompass both elective and emergency surgery. We would advocate that  
55 objective evidence is the only way to establish true PS, and that there is a  
56 limited role for the use of subjective questions. Consideration should be given  
57 to electronic storage of PS results in the same way as blood results are now  
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3 routinely documented and stored. Finally, PS in FRA should form an integral  
4 component of the pre-theatre and anaesthetic checklist, and also the WHO  
5 surgical safety checklist in those who require GA.  
6

### 7 Conclusion

8 Further studies are required to establish the cost of implementing suggested  
9 practice. However, this is likely to be offset against the costs of complications  
10 and the settling of unnecessary fetal death claims in the current litigious  
11 climate. Whilst cost is a factor, it is clear that best practice should be what is  
12 safest for patient and fetus and this includes objective documentation of PS  
13 prior to any surgical procedure requiring a general anaesthetic. In the  
14 emergency setting this takes on even greater importance in those with  
15 abdominal pain regardless of whether emergency surgery is performed.  
16 Finally, our results have been fed back to the individual centres for local  
17 analysis and action. We believe that a national approach to tackling this issue  
18 is appropriate, culminating in electronic storage of pregnancy test results with  
19 re-audit to assess whether this intervention improves compliance with the  
20 documentation of pregnancy status. A pilot study within one of the centres is  
21 planned.  
22  
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24

### 25 **Main messages**

- 26 • Documentation of pregnancy status should be a mandatory component  
27 of the medical assessment of all females of reproductive age when  
28 admitted to hospital with; abdominal pain, prior to any procedures  
29 requiring exposure to ionising radiation, a general anaesthetic or the  
30 use of drug treatments contraindicated in pregnancy.
- 31 • Objective evidence of pregnancy status should be obtained with  
32 informed consent by means of formal  $\beta$ -hCG testing (urine or serum).
- 33 • Subjective assessment of the possibility of pregnancy status should  
34 form part of assessment of gynaecological history but is not sufficient  
35 for clarifying pregnancy status.
- 36 • New guidelines for the documentation of pregnancy status in both the  
37 elective and emergency setting are warranted,
- 38 • Consideration should be given to the electronic storage of pregnancy  
39 test results within individual centres.
- 40 • In those scheduled to undergo a procedure requiring general  
41 anaesthetic, pregnancy status should form a mandatory part of the pre-  
42 theatre and anaesthetic induction checklist and also incorporated in to  
43 the WHO safety checklist.  
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46

### 47 **Research questions**

- 48 • Do female patients admitted to general surgery have an adequate  
49 gynaecological history taken (contraceptive use, date of last menstrual  
50 period etc), with prompt referrals for gynaecological assessment when  
51 a gynaecological diagnosis is made?
- 52 • In females of reproductive age who undergo radiological investigations  
53 requiring exposure to ionising radiation, is pregnancy status  
54 documented prior to their investigation?
- 55 • In female surgical admissions requiring emergency surgical  
56 assessment, what are the common interventions, operative findings  
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3 and final diagnoses?  
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5 Figure Legend

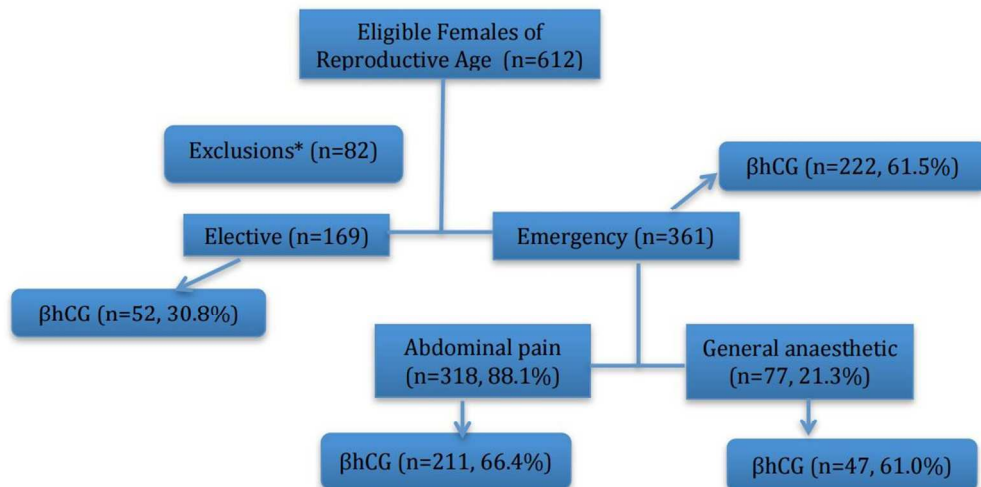
6 Figure 1 – Final elective and emergency cohort data with documented pregnancy status

7 \* for exclusion data see Table 2  
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# Pregnancy testing in surgical admissions for females of reproductive age: protocol for a multicentre audit

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To be added – presumably other trainee or medical student collaboratives

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## Authorship

Any publications will be published under the name of Scottish Surgical Research Group (SSRG) and include the members of the protocol management group and regional contacts. This is in line with the policy of similar projects led by other research collaboratives. Each centre or specialty submitting data for inclusion in the study will be eligible for citing up to 3 names as collaborators in the study.

## Introduction

Abdominal pain is the leading cause of admission to acute surgical receiving units (ASRU) in the developed world, with reported mortality ranging from 0.4 to 4.4% (1, 2). 30-day mortality rises to approximately 8.0% in those requiring emergency surgical intervention (1, 3). Acute abdominal pain may be due to life threatening conditions such as ruptured aortic aneurysm, peritonitis, perforated viscus, strangulated herniae and ischaemic bowel. Approximately one third of ASRU admissions are females of reproductive age group (FRA). In this cohort, ectopic pregnancy (EP) should be high on the list of differential diagnoses.

In EP, the fetus develops outside the uterus. An imbalance in the tightly regulated interaction between the tubal epithelium, tubal fluid, and tubal contents can result in EP. Aberrant oocyte migration is often associated with abnormal fallopian tube anatomy. This can result from tubal pathology (inflammation, endometriosis, previous EP), surgery (tubal surgery, abdominal surgery), infertility treatment, contraception (coil, progesterone-only pill, morning after pill) or in utero diethylstilbestrol exposure. Multiple molecular factors play a role in the pathophysiology of EP. These include lectin, integrin, matrix-degrading cumulus, prostaglandins, growth factors, and cytokines. These factors promote premature fetal implantation outside the uterus. As the EP grows, it will cause the fallopian tube to rupture with potentially fatal results (4).

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3 EP ruptures most frequently at 6-12 weeks following conception (4, 5). It may  
4  
5 therefore manifest in patients who are unaware that they may be pregnant.  
6

7 EP is the leading cause of death in early pregnancy and affects 16,000  
8  
9 women annually in England and Wales. 87 deaths were reported between  
10  
11 1996 and 2006 in the UK. Of these, 56 were directly attributed to a failure to  
12  
13 diagnose and thereby treat the condition (5).  
14  
15

16  
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18 All clinicians working within emergency departments or ASRU should be  
19  
20 aware of the risk of EP when assessing FRA. The classical presentation of EP  
21  
22 is with a symptomatic triad; lower abdominal pain, vaginal bleeding and  
23  
24 amenorrhoea. An associated history of syncope is also highly suggestive of  
25  
26 ruptured EP. However, atypical presentations are well recognised. EP has  
27  
28 also been reported in breastfeeding patients and those with a history of tubal  
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30 ligation (6).  
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36 In addition to baseline observations and standard investigations, pregnancy  
37  
38 status, gynaecological history (GH) and use of contraception should be noted.  
39  
40 Pregnancy status should be confirmed with a human chorionic gonadotrophin  
41  
42 (hCG) test. Beta human chorionic gonadotropin ( $\beta$ -hCG) is the most sensitive  
43  
44 and specific hCG for mammalian embryogenesis (5).  $\beta$ -hCG is present in both  
45  
46 urine and serum. Urine assays detect from 25-100 million international  
47  
48 units/millilitre (mIU/ml), serum assays detect from 2 mIU/ml. A viable  
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50 pregnancy that is 6 weeks from LMP will have >1000 mIU/ml (4, 7).  
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54 Therefore, EP can usually be confidently excluded with a negative urine or  
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3 serum  $\beta$ -hCG level. However, there are documented cases of EP in the  
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5 presence of either a normal urine  $\beta$ -hCG or serum  $\beta$ -hCG (6).  
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9  
10 In addition, consideration of pregnancy status should be documented prior to  
11  
12 undertaking any surgical procedure as per current NICE (National Institute for  
13  
14 Health and Care Excellence) guidelines (8). However, these guidelines are  
15  
16 specifically referring to surgery in the elective setting. In 2010, the National  
17  
18 Patient Safety Agency (NPSA) published a rapid response report on checking  
19  
20 pregnancy before surgery (9). They advocate that consideration of pregnancy  
21  
22 should be an integral part of the preoperative assessment in FRA. This should  
23  
24 be recorded on preoperative documentation used by staff performing the final  
25  
26 clinical and identity checks before the proposed surgical intervention.  
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### 32 **Primary aim**

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34 The primary aim is to determine the percentage of patients with a documented  
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36 pregnancy status; within 24 hours of being admitted as an emergency with  
37  
38 abdominal pain, prior to emergency or elective surgery. The surgery  
39  
40 performed in both the emergency and elective setting should require a  
41  
42 general anaesthetic.  
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### 48 **Secondary Aims**

- 49  
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51 (i) To determine the percentage of FRA patients admitted as an  
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53 emergency to general surgery.  
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55 (ii) To what extent is a gynaecological history taken? Appropriate  
56  
57 indicators include; date of last menstrual period (LMP), use of  
58  
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2  
3 contraception, sexual activity, gynaecological symptoms (see  
4 Appendix).  
5  
6

- 7 (iii) To determine how many cases are discussed with gynaecology and  
8 how many receive formal gynaecological assessment (formal  
9 history / examination / investigation). Examination includes PV  
10 exams and vaginal swabs. Investigation includes either  
11 transabdominal or transvaginal ultrasound performed by the  
12 gynaecology team.  
13  
14  
15  
16  
17  
18  
19  
20 (iv) Determine how pregnancy status was documented. Was this by  
21 urine or serum  $\beta$ hCG.  
22  
23  
24 (v) Determine where and how pregnancy status was documented in  
25 the medical or nursing notes.  
26  
27  
28  
29 (vi) Determine the radiation prone procedures performed as an  
30 emergency in FRA (chest X-ray, abdominal X-ray, abdominal or  
31 pelvic ultrasound and computed tomography scan). When were the  
32 investigations requested and when were they performed. Was  
33 pregnancy status known before the investigation was requested  
34 and completed.  
35  
36  
37  
38  
39  
40  
41  
42 (vii) Record the nature and findings of the surgical procedures  
43 performed under general anaesthetic in FRA in both emergency  
44 and elective cases.  
45  
46  
47  
48  
49 (viii) Document if gynaecological assessment was requested intra-  
50 operatively in both emergency and elective cases.  
51  
52  
53  
54 (ix) In cases requiring surgery and where pregnancy status was not  
55 established as part of the clerk-in process, what safeguards are in  
56  
57  
58  
59  
60

1  
2  
3 place to establish pregnancy status prior to knife to skin (is  
4  
5 pregnancy status on the pre-theatre checklist, is pregnancy status  
6  
7 checked prior to induction of anaesthesia and/or knife to skin).  
8

- 9  
10 (x) To determine local protocols for documenting pregnancy status in  
11  
12 both the acute and elective setting in FRA. This will involve  
13  
14 providing copies of blank medical and nursing clerk-in proformas,  
15  
16 pre-theatre checklists and WHO pre surgery checklists.  
17  
18  
19

## 20 21 **Definitions**

22  
23 Females of reproductive age (FRA)

- 24  
25 • Lower limit is the minimum age where patients are admitted to the adult  
26  
27 general surgical ward.
- 28  
29 • Upper limit is 55 years old.  
30  
31  
32  
33  
34

## 35 36 **Exclusion criteria**

- 37  
38 • Male patients
- 39  
40 • Patients admitted to a paediatric ward
- 41  
42 • Patients over 55 years old
- 43  
44 • Previous hysterectomy
- 45  
46 • Patients who undergo a surgical procedure using local anaesthetic  
47  
48 (may still be included in emergency cohort not undergoing surgery  
49  
50 under general anaesthetic, but excluded from elective cohort).  
51  
52  
53  
54

## 55 56 **Audit standards**

57  
58  
59  
60

**Emergency setting**

1. Documentation of pregnancy status in FRA within 24 hours of admission in either the medical or nursing notes, or prior to any surgical procedure requiring general anaesthetic or radiation prone procedure
  - (i) Is there a possibility of pregnancy?
  - (ii) Date of last menstrual period
  - (iii) Use of contraception; coil, OCP, implanon etc
  - (iv) Urine or serum  $\beta$ -hCG result

**Elective setting**

1. Documentation of pregnancy status prior to the proposed surgical procedure
  - (i) Is there a possibility of pregnancy?
  - (ii) Date of last menstrual period
  - (iii) Use of contraception; coil, OCP, implanon etc
  - (iv) Urine or serum  $\beta$ -hCG result

## Methods

### Eligible centres

Scottish hospitals that provide acute surgical services are eligible to submit data for the study. In addition, Scottish centres that offer elective surgical procedures are also eligible to submit data. A team of junior doctors should assume responsibility for data collection and ensure that Caldicott principles are adhered to. National Caldicott approval has been obtained for the project.

Centres will be invited to register for the study and submit data. Dissemination of the existence of the study will be via committee members of the SSRG.

Centres which do not have recognised training posts in general surgery will be identified, contacted and formally invited to participate in the study by email.

### Participants studied

Any FRA admitted acutely to a surgical specialty with abdominal pain, or electively for a planned general surgical procedure under general anaesthetic will be eligible for inclusion in the study.

### Identification of eligible patients

Each centre should prospectively identify eligible patients for the study between 08:00 on 11/05/2015 and 08:00 on 25/05/2015.

Electronic records of acute and elective admissions or junior doctor handover sheets should be scrutinised to identify eligible patients for the study. Data extraction should involve capture of a unique hospital number and completion

1  
2  
3 of the study proforma for each eligible patient and stored on a secure  
4  
5 database as per Caldicott Principles. Data should be collected and thereafter  
6  
7 submitted timeously for analysis at the end of the data collection period. A  
8  
9 record should also be kept of the total number of admissions and the gender  
10  
11 distribution (total males versus total females).  
12  
13

14  
15  
16 Each centre will be asked to complete a questionnaire about existing  
17  
18 protocols for pregnancy testing in the elective and emergency setting. Further,  
19  
20 there will be an opportunity to anonymously report historical near misses or  
21  
22 adverse events as a result of failure to document pregnancy status in FRA.  
23  
24  
25

## 26 27 **Audit phases**

### 28 29 **Pilot:**

30  
31 An audit of current practice has previously been performed within NHS  
32  
33 Tayside. The initial audit cycle of 100 patients demonstrated that 30% of  
34  
35 acute admissions had a documented  $\beta$ -hCG within 24 hours of admission.  
36  
37 With such disappointing results the medical admission document had a  
38  
39 prompt inserted with space to document; date of last menstrual period, use of  
40  
41 contraception, urinalysis and  $\beta$ -hCG results. A second audit cycle was then  
42  
43 undertaken. This improved the accuracy of documentation of  $\beta$ -hCG in 50  
44  
45 patients to 74%. A snapshot audit was completed in a cohort of elective  
46  
47 patients. In 17 of 22 patients there was no documentation of  $\beta$ -hCG prior to  
48  
49 the proposed surgical procedure.  
50  
51  
52  
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54

### 55 56 **Main audit:**

57  
58  
59  
60



1  
2  
3 The period of data collection in registered, eligible centres will be undertaken  
4  
5 between 0800 on 11/05/2015 and 0800 on 25/05/2015. All registered centres  
6  
7 will have access to a detailed study protocol, study proforma (elective and  
8  
9 emergency) and study database with instructions for returning data for  
10  
11 analysis centrally. A minimum of 10 centres is expected to submit data.  
12  
13

### 14 15 16 **Study Proforma**

17  
18 There are two proformas for this study. The first relates to FRA admitted as an  
19  
20 emergency (see Appendix 1) and the second relates to FRA who undergo  
21  
22 elective surgery (see Appendix 2).  
23

24  
25 At the end of the period of data collection each centre should enter the  
26  
27 appropriate data into the excel database that will be distributed at the same  
28  
29 time as the study proformas.  
30  
31

### 32 33 34 **Data storage**

35  
36 Each centre will be responsible for entering data into a study specific  
37  
38 database, access to which will be distributed by email to all registered centres  
39  
40 prior to the commencement of the period of data collection.  
41

42  
43 Completed databases should be submitted centrally to the following email  
44  
45 address: [michaelwilson3@nhs.net](mailto:michaelwilson3@nhs.net)  
46

47  
48 For the avoidance of doubt, no patient identifiable data should be submitted  
49  
50 centrally for analysis.  
51

### 52 53 54 **Data submission**

1  
2  
3 At the end of the period of data collection (0800 on 25/05/2015), the  
4  
5 completed excel database should be anonymised and contain no patient  
6  
7 identifiable data. Each patient should be allocated a unique centre specific  
8  
9 number. The file should be named according the name of the submitting  
10  
11 centre (see Appendix 3 for instructions on how to anonymise data and name  
12  
13 the excel database before central submission). Data should be submitted  
14  
15 centrally by email from an nhs.net registered email account to  
16  
17 [michaelwilson3@nhs.net](mailto:michaelwilson3@nhs.net) for analysis.  
18  
19

## 20 21 22 23 **Data analysis**

### 24 25 Emergency admissions

26  
27 The total number of patients (including gender) presenting as an emergency  
28  
29 to each centre will be recorded, as will the total number of admissions. The  
30  
31 proportion of FRA will be calculated, and from this the percentage of patients  
32  
33 with a documented pregnancy status within 24 hours of admission will be  
34  
35 established.  
36  
37

### 38 39 40 41 Elective admissions

42  
43 The total number of patients (including gender) admitted electively for a  
44  
45 procedure under general anaesthetic to each centre will be recorded, as will  
46  
47 the total number of patients. The proportion of FRA will be calculated, and  
48  
49 from this the percentage of patients with a documented pregnancy status prior  
50  
51 to the proposed surgical procedure will be established.  
52  
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2  
3 Data will be tested for distribution and differences between groups compared  
4  
5 using unpaired t-tests, Mann-Whitney U tests and Chi squared tests as  
6  
7 appropriate.  
8  
9

### 10 11 **Publication of results**

12  
13 The report of this audit will be prepared in accordance to guidelines set by the  
14  
15 STROBE (Strengthening the Reporting of Observational Studies in  
16  
17 Epidemiology) statement for observational studies (10). Papers will be drafted  
18  
19 by a writing group and submitted on behalf of all collaborators. Each centre  
20  
21 submitting data will have up to 3 data collectors listed as a collaborator.  
22  
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24  
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Centre	Total FRA	Elective FRA	Emergency FRA	Total $\beta$ -hCG	Elective $\beta$ -hCG	Emergency $\beta$ -hCG
A	68	23 (33.8%)	45 (66.2%)	36 (52.9%)	12 (52.2%)	24 (53.3%)
B	20	6 (30.0%)	14 (70.0%)	15 (75.0%)	5 (83.3%)	10 (71.4%)
C	3	2 (66.6%)	1 (33.3%)	1 (33.3%)	1 (50.0%)	0 (0%)
D	25	8 (32.0%)	17 (68.0%)	6 (24.0%)	0 (0%)	6 (35.3%)
E	37	10 (27.0%)	27 (73.0%)	20 (54.1%)	0 (0%)	20 (74.1%)
F	14	14 (100%)	0 (0%)	8 (57.1%)	8 (57.1%)	
G	28	6 (21.4%)	22 (78.6%)	19 (67.9%)	1 (16.7%)	18 (81.8%)
H	26	10 (38.5%)	16 (61.5%)	16 (61.5%)	3 (30.0%)	13 (81.3%)
I	48	7 (14.6%)	41 (85.4%)	31 (64.6%)	5 (71.4%)	26 (63.4%)
J	9	5 (55.6%)	4 (44.4%)	9 (100%)	5 (100%)	4 (100%)
K	42	15 (35.7%)	27 (64.3%)	18 (42.9%)	1 (6.7%)	17 (63.0%)
L	22	4 (18.2%)	18 (81.8%)	17 (77.3%)	4 (100%)	13 (72.2%)
M	32	2 (6.2%)	30 (93.8%)	16 (50.0%)	1 (50.0%)	15 (50.0%)
N	31	13 (41.9%)	18 (58.1%)	13 (41.9%)	0 (0%)	13 (72.2%)
O	33	19 (57.6%)	14 (42.4%)	6 (18.2%)	2 (10.5%)	4 (28.6%)
P	29	0 (0%)	29 (100%)	11 (37.9%)		11 (37.9%)
Q	59	21 (35.6%)	38 (64.4%)	32 (54.2%)	4 (19.0%)	28 (73.7%)
R	4	4 (100%)	0 (0%)	0 (0%)	0 (0%)	
<b>TOTAL</b>	<b>530</b>	<b>169 (31.9%)</b>	<b>361 (68.1%)</b>	<b>274 (51.7%)</b>	<b>52 (30.8%)</b>	<b>222 (61.5%)</b>

Appendix 2 – Documented pregnancy status data from contributing centres for elective and emergency admissions

Centre	Abdominal pain	Beta hCG	Emergency surgery	Beta hCG
A	32 (71.1%)	18 (56.3%)	7 (15.2%)	5 (71.4%)
B	13 (92.9%)	9 (69.2%)	3 (18.8%)	2 (66.7%)
C	1 (100%)	0 (0%)	0 (0%)	0 (0%)
D	14 (82.4%)	5 (35.7%)	4 (23.5%)	1 (25.0%)
E	27 (100%)	20 (74.1%)	3 (8.1%)	1 (33.3%)
F				
G	22 (100%)	18 (81.8%)	2 (8.3%)	2 (100%)
H	16 (100%)	13 (81.3%)	0 (0%)	0 (0%)
I	33 (80.5%)	26 (78.8%)	7 (15.2%)	5 (71.4%)
J	4 (100%)	4 (100%)	2 (50.0%)	2 (100%)
K	25 (92.6%)	16 (64.0%)	13 (44.8%)	8 (61.5%)
L	15 (83.3%)	11 (73.3%)	3 (14.3%)	3 (100%)
M	28 (93.3%)	15 (53.6%)	9 (29.0%)	5 (55.6%)
N	16 (88.9%)	13 (81.3%)	1 (5.6%)	1 (100%)
O	12 (85.7%)	4 (33.3%)	6 (42.9%)	3 (50.0%)
P	25 (86.2%)	11 (44.0%)	7 (23.3%)	2 (28.6%)
Q	35 (92.1%)	28 (80.0%)	10 (24.4%)	7 (70.0%)
R				
<b>TOTAL</b>	<b>318 (88.1%)</b>	<b>211 (66.4%)</b>	<b>77 (21.3%)</b>	<b>47 (61.0%)</b>

Appendix 3 – Documented pregnancy status from contributing centres in emergency patients who required a general anaesthetic and presented with abdominal pain