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Supporting Information

<table>
<thead>
<tr>
<th>Contents</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction</td>
<td>2</td>
</tr>
<tr>
<td>2. Scale of the patient safety issue</td>
<td>2</td>
</tr>
<tr>
<td>3. National guidelines and related advice</td>
<td>3</td>
</tr>
<tr>
<td>References</td>
<td>6</td>
</tr>
<tr>
<td>Appendix - Implementation check list and rationale</td>
<td>7</td>
</tr>
</tbody>
</table>
1. Introduction

Ensuring that pregnancy has been considered prior to surgical intervention should be an integral part of preoperative assessment of all female patients of childbearing potential. Preoperative assessment may take place weeks in advance of the planned operation and pregnancy status may change during the intervening time. The practice of checking and documenting current pregnancy status in the immediate preoperative period has been shown to be inconsistent. If a previously unknown pregnancy is detected, the risks and benefits of the surgery can be discussed with the patient. Surgery may be postponed or anaesthetic and surgical approaches modified if necessary. In emergency situations, confirmation of pregnancy should not delay treatment and should be judged within clinical assessment of risk.

The importance of checking for pregnancy is well established in certain areas of clinical practice, such as gynaecological surgery or ionising radiation. However, in other areas such as general surgery, there may be less awareness of the need for routine checking.

2. Scale of the patient safety issue

Incident data from the National Reporting and Learning System (NRLS)

The following incident triggered a review of incidents reported to the National Reporting and Learning System (NRLS) on this issue:

“Patient had laparoscopy, during procedure patient found to be pregnant. Failed to do pregnancy test prior to procedure. Patient went on to miscarry.”

A search of the NRLS database from October 2003 to 19 November 2009 revealed 42 relevant incidents. These reports describe that either the pregnancy status was not documented on the theatre checklist, preoperative history was not obtained or a pregnancy test was not performed. In three cases there was a spontaneous abortion following the procedure.

The following free text descriptions are examples of the type of incidents found in the NRLS.

Abandoning surgery on the discovery of a pregnancy during a procedure:

“Patient consented for abdominal hysterectomy. On opening the patient and examining the patient Mr. X noticed the uterus was soft and bulky. He performed a pregnancy test which was positive and an ultrasound which confirmed a positive pregnancy. Procedure was therefore abandoned and the wound closed. The pregnancy was subsequently lost.”

Miscarriage following a procedure leading to a complaint:

“Pt informed me that she had been admitted post-op with PV bleeding and a miscarriage diagnosed therefore pregnant during surgery. Subsequent complaint raised. No pre-op pregnancy test. No mention in notes re (question to patient about pregnancy).”

Radiographer asked to carry out investigation on patient under anaesthesia:
“I arrived in theatre as the radiographer for the first back surgery case on the day on a female patient. The patient was within the age range for me to obtain a pregnancy status before commencement of surgery. Unfortunately, the patient was under anaesthetic. I asked the surgeon and anaesthetist for this info. They were unable to confirm pregnancy status. Pregnancy status is routinely not ascertained from relevant patients in these circumstances.”

Data from the National Health Service Litigation Authority (NHSLA)
NHSLA data was reviewed and 12 claims were identified where no pregnancy checks were performed prior to surgical procedures.

Feedback from NHS organisations
A recent straw poll at a theatre manager event returned some feedback that was indicative of the issues that have come from this review:

- radiographers in some trusts refusing to do X-rays during surgery until status is established;
- some patients have had to be catheterised during surgery and are tested at this point.

In addition, the NPSA obtained a number of pre-operative checklists from a range of organisations, some of which failed to include routine check of pregnancy status.

3. National guidelines and related advice

No specific guidance was found on confirming pregnancy status in the immediate preoperative period. The NPSA recommends the following steps in this Rapid Response Report:

1. Local preoperative assessment policies should be reviewed to ensure that pregnancy status is checked within the immediate preoperative period in accordance with NICE guidelines.

2. The check should be recorded on preoperative documentation used by staff performing final clinical and identity checks before surgical intervention.

The following guidance is available on the identification of pregnancy during preoperative assessment.

National Institute for Health and Clinical Excellence (NICE) guideline on preoperative tests

This guideline makes recommendations on the appropriate use of routine preoperative tests for patients before elective surgery.

NICE recommends that pregnancy testing should be carried out for a woman who says it is possible that she may be pregnant. Testing may also be considered for a woman with

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All the recommendations are grade D recommendations, based upon level IV evidence – that is, expert opinion derived from a consensus development process.
a history of last menstrual period or who says that it is not possible for her to be pregnant. Informed consent should be obtained for testing.

The following notes are also included in the guideline:

- The need to test for pregnancy depends on the risk presented by the anaesthetic and surgery to the fetus.
- All women of childbearing age should be asked whether or not there is any chance that they may be pregnant.
- Women must be made aware of the risks of surgery to the fetus.
- A pregnancy test should be carried out with the woman’s consent if there is any doubt about whether the woman may be pregnant.
- Before having a chest X-ray, all women of childbearing age should be asked sensitively whether they may be pregnant.

The Royal College of Obstetricians and Gynaecologists (RCOG) guidance on obtaining valid consent\(^2\) recommends that ‘all reasonable steps should be taken to exclude pregnancy before embarking upon any surgical procedure’.

The American Society of Anesthesiologists (ASA) Practice Advisory for Preanesthesia Evaluation\(^3\) includes a sentence on pre-anesthesia pregnancy testing. It states: ‘The Task Force recognises that a history and physical examination may be insufficient for identification of early pregnancy. Pregnancy testing may be considered for all female patients of childbearing age. Clinical characteristics to consider include an uncertain pregnancy history or a history suggestive of current pregnancy.’

‘A guide to preoperative pregnancy testing for the nurse practitioner’ was published in the US in 2000.\(^4\)

**Advice from clinical networks**

Drafts of this Rapid Response Report and the supporting information were circulated to stakeholders for comment. The feedback from professional organisations, such as the Royal College of Anaesthetists, the Royal College of Obstetricians and Gynaecologists, the Royal College of Paediatrics and Child Health and the Royal College of Nursing, highlights the absence of guidance that is specific about the steps that should be taken to identify pregnancy preoperatively.

It is suggested that local organisations should consider the following points:

- The definition of ‘relevant female patient’. Organisations will need to consider whether this should include all females who have started menstruating, regardless of age, and whether to exclude women who are not sexually active, who are infertile, who have been sterilised or who have an intrauterine contraceptive device or contraceptive implant. NICE guidelines do not specify age ranges for women of childbearing age, but some local organisations have interpreted this as 12-55 years.

- Staff should be sensitive to particular circumstances in which the question of possible pregnancy should not be asked, such as women undergoing surgery for removal of retained products of conception (miscarriage).
• The particular considerations required in checking pregnancy status of patients under 16.

• The unreliability of last menstrual period (LMP) as a sole indicator for potential for pregnancy.

• Whether blanket pregnancy testing should be considered locally.

• The need for referral to local ante natal care if required

**Related advice about checking pregnancy status**

The Health Protection Agency has published practical guidance on how and when to prevent or reduce unnecessary fetal exposure to ionising radiation. In the first instance the referring clinician should check the pregnancy status of females of reproductive potential. However, when the patient attends for examination she should be asked again whether or not she might be pregnant. Action taken depends on the answer to the question and the risk of exposure.

The guidance advises that there should be agreed procedures in place in all clinical imaging facilities to cover obtaining information for patients under the age of 16. Procedures should also deal with unconscious patients, patients whose first language is not English and those with special needs.

Further advice on the duty of confidentiality towards young people are included in ‘Service standards on confidentiality’ published by the RCOG and in the Department of Health ‘Best practice guidance for doctors and health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health’.

5

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7

8
References


The table below gives suggested actions that organisations may wish to use locally as assurance of compliance with this Rapid Response Report (RRR).

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<th>Action</th>
<th>Rationale</th>
<th>Suggested assurance of compliance</th>
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<tbody>
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<td>1. Local preoperative assessment policies should be reviewed to ensure that pregnancy status is checked within the immediate preoperative period in accordance with NICE guidelines.</td>
<td>There is already a NICE guideline on preoperative testing that includes pregnancy testing. This will have informed local policy. Inclusion of the documented check on information used by staff at final checking point will reinforce the importance of this information being current and accessible throughout the surgical pathway.</td>
<td>Evidence of updated policies in line with this advice.</td>
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<td>2. The check should be recorded on preoperative documentation used by staff performing final clinical and identity checks before surgical intervention.</td>
<td>Many organisations have a preoperative document that is used when patients are admitted to hospital for a procedure. This gives opportunity to confirm pregnancy status in adequate time according to local guidance and reduce the risk of the issues as defined in this RRR.</td>
<td>This can be added to preoperative documentation that is in local use. Consideration may be given to including this on the surgical site checklist.</td>
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<td>Organisations should demonstrate robust reporting measures for incidents relating to the confirmation of pregnancy and any associated actions that may come from this (which may include local audit).</td>
<td>The relatively low numbers reported to the National Reporting and Learning System (NRLS) may reflect under reporting and a local strategy to capture all of these incidents will assist in assessment of issue and support local audit of compliance.</td>
<td>Inclusion in reporting governance strategy and monitoring of incident data at least annually by relevant clinical governance group.</td>
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