
# National Miscarriage Misdiagnosis Review

April 2011

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**Foreword**

In early June 2010, reports of cases of misdiagnosis of miscarriage appeared in the Irish news media, leading to widespread concern and public discussion about diagnosis of early pregnancy loss.

The HSE responded to this issue as a Serious Incident and set up a group to lead a national review of cases identified. The National Miscarriage Misdiagnosis Review was tasked with providing an analysis of all of the cases involved in this incident.

While this national review reports on the management of those cases, it is not designed to provide a detailed personal report to each woman; this is being provided to women through an individual systems analysis investigation being carried out within each hospital.

The core purpose of this report is to aggregate the outcomes of the reported cases, in order to identify trends about the causes of the misdiagnoses. This analysis has allowed national recommendations for service improvements to be developed.

Miscarriage is the most common complication of early pregnancy, occurring in one in five of all pregnancies, and for many people is a source of enormous distress and grief. The misdiagnoses which were identified as part of this process will undoubtedly have served to amplify that distress for the women involved, and for many other people affected by this issue.

The hazards of the use of ultrasound to diagnose a miscarriage in very early pregnancy have been repeatedly highlighted since the introduction of the technique in the 1970s and there have been recent reports of misdiagnosis of miscarriage from the United Kingdom and Australia.

The HSE and all its funded hospitals involved in the review would like to apologise to women who experienced a misdiagnosis of miscarriage, and to their partners and families. Their willingness to share their experiences has been invaluable in allowing this review to learn from their cases and make recommendations for improvement in current and future early pregnancy services.

Reviews of this kind serve to increase awareness and knowledge within healthcare facilities and among clinicians, and when considered with the recently published HSE National Clinical Guidelines on Ultrasound Diagnosis of Early Pregnancy Miscarriage, this report should go a significant way to ensuring high standards of diagnosis and care are maintained in all Irish maternity hospitals and facilities.

Thanks are due to all those who contributed to the timely completion of this review, including staff at all hospital sites, and all the members of both the clinical review team and the incident management team.

Most of all, we thank the women who experienced a possible misdiagnosis of miscarriage and took the time to report their experiences.

**Professor William L. Ledger, Chair, Clinical Review Team**
**Cora McCaughan, Chair, Incident Management Team**
April 2011

**Miscarriage Misdiagnosis Review**

**Membership of Incident Management Team**

- Cora McCaughan, HSE Serious Incident Management Team (SIMT), Chair
- Prof William Ledger, Head of Department of Obstetrics and Gynaecology, University of Sheffield
- Dr. Michael Robson, Master, National Maternity Hospital, Holles Street
- Sheila Sugrue, HSE Midwifery Lead
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- Dr. Joe Devlin, Quality and Clinical Care Directorate
- Cathriona Molloy, Patient Advocacy Co-ordinator, Patient Focus
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  (Replaced by Greg Price, January 2011)
- Grace Turner, Obstetrics and Gynaecology Programme Manager, Royal College of Physicians of Ireland
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**Membership of Clinical Review Team**

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- Annette Macken, HSE Systems Analysis Advisor to the Clinical Review Team

## Executive Summary

### Introduction

On June 9th 2010, reports of 2 initial cases of misdiagnosis of miscarriage were reported in the Irish news media. A diagnosis of miscarriage had been made in error, and medical or surgical intervention was recommended to women, but subsequently it was found that the pregnancy was viable and the women went on to continue their pregnancies. Over the following weeks, several other women raised similar concerns with their hospitals.

The Health Service Executive (HSE) put in place a series of immediate responses to the initial reports of misdiagnosis in early June 2010. Maternity hospitals and Early Pregnancy Assessment Units (EPAUs) around the country set up dedicated helplines, to provide information and support to women and their families who had questions about their diagnosis of early pregnancy loss.

On June 10th 2010, a joint letter was sent by Dr. Tony Holohan, Chief Medical Officer at the Department of Health and Children, and Dr. Barry White, National Director for Quality and Clinical Care with the HSE, to all public and private obstetric and gynaecological facilities. The letter advised these facilities to immediately ensure that the decision to use drugs or surgical intervention in women who had a diagnosis of miscarriage was always approved by a Consultant Obstetrician.

The HSE then set up a National Miscarriage Misdiagnosis Review to manage the incident and examine any similar cases that had occurred over the previous five years where drug or surgical treatment was recommended following a diagnosis of miscarriage, and where subsequent information demonstrated that the pregnancy was viable.

The terms of reference stated that the review team was to be responsible for:

1. The satisfactory investigation of cases (systems analysis) to determine the causes and the response to the cases, and making recommendations as required.
2. Ensuring that any immediate risks identified during the course of the review were communicated immediately to the HSE for urgent management.
3. Providing their report to the then National Director of Quality and Clinical Care, HSE, who committed that this would be published.

A five year timeframe (from 18th June 2005 to 18th June 2010) was agreed by the review team as being likely to encompass all cases that would be relevant to current practice and to allow the team to identify trends and patterns in the systems causes of these misdiagnoses. However the review team also considered any cases specifically submitted by service users that fell outside the five year timeframe, and cases identified through the Clinical Indemnity Scheme (CIS), where the case informed the work of the review team and the development of national standards.

### Methodology

Hospitals set up dedicated helplines for service users immediately following the reports of cases on June 9th 2010. Over the subsequent weeks, a total of 409 calls were made to these hospital helplines. All public and private maternity sites in Ireland were asked by the HSE to review their records as part of this review.

Hospitals were given specific instructions by the clinical review team on how to assess the cases of the women who made contact, and to identify those cases which should be referred to the national review. This was done through a review of all callers' clinical records, of existing relevant hospitals files, complaints, incidents or reports to the CIS. Hospitals used these sources to identify any cases that met the review case definition.

The clinical review team agreed a preliminary questionnaire which was completed by a Consultant Obstetrician/Gynaecologist in respect of each case. This questionnaire allowed all the relevant information about the case to be collected and forwarded for review, but also preserved the anonymity and privacy of the service user. The purpose of the questionnaire was to establish the overall numbers of potential cases of miscarriage misdiagnosis and to provide an overview of each case.

Information was also provided by each hospital via a second questionnaire, giving details of existing policies, guidelines and standards, infrastructure and resources relevant to this review. This questionnaire was completed by the Hospital Manager/Chief Executive Officer. The purpose of the second questionnaire was to determine the level to which each site complied with standards in the management of early pregnancy.

A third questionnaire was issued to all hospitals. This required that each hospital follow a robust and clear process for examining the records of all women who had made contact with the hospital and had expressed a concern that their case met the definition of the review.

Each Hospital Manager/CEO and Clinical Director was asked to verify that clinical records were examined in a systematic and transparent manner, in order to provide assurance to the service users involved, and to the HSE, that this screening process was comprehensive.

Detailed information about each case that was identified as a potential case of miscarriage misdiagnosis was then collected using a fourth questionnaire. The clinical review team designed the questionnaire to collect all clinical and other relevant information. The data items requested were informed by the findings of similar reviews of cases of miscarriage misdiagnosis conducted internationally. A detailed chronology of events in each case was constructed. As in previous questionnaires, all responses were anonymised.

Questionnaire 4 also gathered information on the clinical governance and incident management systems that were in place at the time of the potential miscarriage misdiagnosis. For each case identified, hospitals were asked to forward servicing and maintenance histories for ultrasound scanning machines used at the time of the case, copies of formal scan reports, copies of scan images and copies of blood test results.

Samples of all four questionnaires are appended to this document.

At the request of the Review Team, the Clinical Indemnity Scheme (CIS) provided details on cases that had become known to them through the STARSWeb national healthcare incident reporting system. Hospitals notify the CIS when an adverse event has occurred or where a possible adverse incident is identified through the complaints process.

The CIS provided the Review Team with details of twelve relevant cases. Where possible, these were reconciled with cases that had been previously identified via hospitals. Of the twelve cases; one was novel and was included in the analysis; one was the subject of legal proceedings and no information was made available to the Incident Management Team, and the other ten were either already known to the review or found not to meet the terms of reference.

In addition to this national review, which would identify trends and examine cases to aggregate the contributory factors, each individual hospital was required to carry out a detailed systems analysis investigation of the care provided to the individual women in these cases. The review team requested that those hospitals that had recorded an incident of miscarriage misdiagnosis that fell within the terms of reference for the review submit any available systems analysis investigation reports to the clinical review team to be considered as part of the overall review process.

**Results of the Review**
Between June 10th and the end of October 2010, 409 calls were received by 19 public maternity hospital helplines. 136 callers were reassured on calling that their concerns were unfounded and did not require review within the hospital.

273 clinical files were reviewed by hospitals and of these, 33 cases that may have met the case definition for the review were referred to the clinical review team. Of these 33, one case was found to be a duplicate return (from the hospital and from the CIS), bringing the overall total to 32.

The clinical review team met seven times to examine and discuss the cases. Further information and clarification was obtained where necessary. Each stage of the clinical care delivered and decision-making was assessed and the team considered whether there was evidence of clinical error, mechanical failure or inadequacy, or failure of support systems.

Not all of the 32 cases considered had evidence of failings in management. Some had correct clinical management and appropriate imaging and support. Of the 32 cases forwarded for consideration to the Clinical Review Team, eight cases were closed as they did not meet the terms of reference, leaving 24 cases that met the terms of reference for the review. Of the 24 confirmed cases, 18 of these cases occurred within the five year period June 2005 – 2010.

A further case which was referred to the review team through the Clinical Indemnity Scheme is currently going through legal proceedings and information on this case was not made available to the team for review and inclusion in their findings.

A database was compiled to allow comparison of findings and identify patterns of practice that led to the possible misdiagnosis of miscarriage. The findings from each hospital's individual systems analysis investigation, together with the findings from the national clinical review of cases, were used to develop a series of recommendations for overall improvement in services.

**Clinical Summary of Misdiagnoses**
In the 24 cases where a misdiagnosis of miscarriage took place, Consultants and Registrars accounted for 79% of the professionals who made the primary diagnosis of miscarriage or suspected miscarriage. Fourteen of the initial ultrasound scans were conducted at 7 weeks completed weeks gestation or less. In 15 of the cases reviewed, the second ultrasound did not show any change in the diagnosis. Thirteen of the second ultrasound scans were also conducted at 7 weeks completed gestation or less.

Misoprostol is a medication used, in the case of early miscarriage and death of the fetus, to help the body begin the miscarriage process. Methotrexate is used in the treatment of ectopic pregnancy. Misoprostol or Methotrexate was prescribed in 8 cases. The prescribing clinicians were mainly at Registrar or Consultant level. In one case a Senior House Officer prescribed the treatment.

Six women had an operative procedure, either evacuation of retained products of conception (ERPC) or an endometrial curettage. Twenty two of the women reviewed (92%) went on to have a live birth and two women suffered a miscarriage.

Several clinicians reported significant years of experience in conducting ultrasound in early pregnancy, but formal training in early pregnancy ultrasound was reported by only three of the clinicians who made initial diagnoses. In 12 cases the review team found there was no mandatory training in ultrasound within the hospital at the time the case occurred.

Eight hospitals did not have an Early Pregnancy Assessment Unit (EPAU) at the time of the misdiagnosis. Of these units, all but two now have an EPAU. Staffing arrangements varied across the sites. The hospitals/units reported that EPAUs were staffed by Consultants or Registrars, midwives or staff nurses, ultrasonographers with some clerical support and support also provided by maternity care assistants. The majority of ultrasound machines were properly maintained and serviced and were less than five years old at the time of misdiagnosis. In 6 cases (25%) the scanning machine used at the first scan was older than five years.

Hospitals were asked to provide details on what type of supports were offered to women when their ongoing pregnancy was confirmed. The findings indicate that there was no consistency to the types of supports offered to women. The Miscarriage Association of Ireland reports a poor referral rate from hospitals or maternity units. However, Clinical Midwife Specialists support or provide follow up for women who suffer miscarriage in 40% of maternity hospitals/units.

**Summary of Recommendations**

**Guidance**
The HSE should develop, disseminate and implement national guidelines for the management of early pregnancy complications. As of February 2011, such national guidelines have been developed by the HSE and are being implemented across all maternity sites. This rapid response is welcomed by the Review Team.

**Facilities and Equipment**
All units that provide emergency gynaecological care should have a dedicated early pregnancy assessment unit with adequate staffing, equipment, facilities and opening times to meet local needs.

High quality transvaginal ultrasound scanning is essential for safe practice in the clinical management of early pregnancy complications. This has implications for provision of equipment, proper facilities and trained staff.

The quality and suitability of ultrasound equipment in current use for investigation of suspected miscarriage should be reviewed, with supply of replacement machines where necessary.

**Clinical Management**
A second ultrasound examination should be performed in cases where

- the initial examination is performed “out of hours”,
- the initial examination is performed by a trainee doctor

A second ultrasound examination should be offered as an option to women in cases where

- the initial examination is performed by a single handed practitioner (e.g. a clinician, a midwife or sonographer working alone in an EPAU).

Any service user who requests a second ultrasound examination before action is taken should be provided with this service. No intervention (medical or surgical) should occur until the second ultrasound is performed and the result is known.

If a service user prefers to delay a medical or surgical procedure in order to allow time to pass before later confirmation of the diagnosis with ultrasound +/- hCG testing then this wish should be respected. Delay may be the best policy if the pregnancy is below eight weeks gestation and the clinical picture is stable without excessive bleeding or pain.

Approval from a named Senior Obstetrician must be recorded in the case notes before surgery for evacuation of retained products of conception or prescription of Misoprostol in early pregnancy.

In a case of negative laparoscopy for ectopic pregnancy, no intrauterine procedure should take place unless approved by a Senior Obstetrician.

**Education, training and accreditation**
The HSE should implement multidisciplinary education programmes for all staff involved in early pregnancy care. This will include training in basic counselling skills, support techniques and other issues around problems in early pregnancy.

The HSE, in partnership with the Institute of Obstetricians and Gynaecologists, University College Dublin School of Medicine and Medical Science (or other universities) should implement a national training programme for all trainees in obstetrics and gynaecology starting in 2011, and a training programme in ultrasound in early pregnancy open to midwives, sonographers, general practitioners and other health care professionals.

All trainees in obstetrics and gynaecology must complete training in early pregnancy ultrasound before they undertake any unsupervised ultrasound examinations in cases of suspected miscarriage or other problems in early pregnancy.

All medical staff involved in early pregnancy ultrasound should maintain a personal log of cases which they have scanned, and their outcome. The log should be reviewed at the time of the annual appraisal. The doctor should attend a course in obstetric ultrasound at least once every five years. Such attendances should be included in the log and validated at the appraisal.

**Support for Women**
If a woman has experienced early pregnancy loss, the news should be broken to her sensitively, in an environment that provides privacy and with time for questions to be answered fully. Relevant information leaflets should be given to the service user, and contact details should be provided for a named liaison person within the hospital for follow up support and counselling.

If a woman has experienced early pregnancy loss, this information should be communicated to the general practitioner as soon as possible.

Each unit should develop a policy for supporting women who have suffered an adverse incident in their hospital related to miscarriage. Access to independent advocacy and a hospital appointed dedicated service user liaison person should be provided as part of a complaints structure.

## Section 1
## Background to the Review and Early Pregnancy Loss

### 1.1 Early Pregnancy Loss

Approximately one in five pregnancies ends in miscarriage. Sometimes miscarriage can happen very early in pregnancy, before the woman realises she is pregnant. In this situation a menstrual period may be later and heavier than usual and sometimes the woman may not even suspect she has had a miscarriage. However, most miscarriages happen between the sixth and twelfth week of pregnancy, i.e. from the fourth to tenth week after conception.

Clinical signs of miscarriage include bleeding and / or pain. Symptoms vary from person to person, both in the severity of pain and extent of bleeding, and some women who have experienced more then one miscarriage describe different symptoms each time. Sometimes bleeding and spotting can occur in early pregnancy, and indeed sometimes throughout pregnancy, with the pregnancy proceeding normally.

Once a miscarriage has been confirmed, management can either be conservative, treated with drugs to induce a miscarriage, or surgical evacuation of the miscarriage as a formal procedure in theatre, usually requiring a general anaesthetic. In certain circumstances it may be a combination of the above options and the appropriate treatment will depend on the severity of the presenting symptoms, the gestation of the pregnancy and also the wishes of the woman in conjunction with the advice of her doctor.

Each individual reacts differently to pregnancy loss and copes differently with grief. There is no right or wrong way to cope with such a loss. Most women and their partners find the experience deeply distressing but women and men can sometimes have differing reactions. The emotional aspect of the miscarriage is probably the most difficult. Parents begin their relationship with their baby long before the birth and therefore it is quite natural for them to experience grief for babies who die before they are born. For too many women and their partners, their distress is made worse by a lack of understanding amongst those around them. Many people who have no experience of miscarriage do not understand the depth of feeling experienced by women for a baby who was lost in the first trimester of pregnancy.

If a woman is told by a medical professional that a pregnancy is non-viable and will end in miscarriage, and then goes through this grief reaction, the discovery that there was a misdiagnosis and the pregnancy is actually viable will undoubtedly be a source of distress, confusion and anger for the woman and her partner. It is at this time that adequate support is required more than ever.

### 1.2 Immediate Responses to this Incident

The HSE put in place a series of immediate responses to the initial reports of misdiagnosis in early June 2010. Maternity hospitals and Early Pregnancy Assessment Units (EPAUs) around the country set up dedicated helplines, to provide information and support to women and their families who had questions about their diagnoses of early pregnancy loss. The HSE issued a guidance document to all hospital sites, outlining methods for setting up and running information lines, to ensure that service user queries were handled promptly and properly.

On June 10th 2010, a joint letter was sent by Dr. Tony Holohan, Chief Medical Officer at the Department of Health and Children and Dr. Barry White, National Director for Quality and Clinical Care with the HSE, to all public and private obstetric and gynaecological facilities. This advised the facilities to ensure immediately that the decision to use drugs or surgical intervention in women who had a diagnosis of miscarriage was always approved by a Consultant Obstetrician. A copy of this letter is appended to this document.

The HSE then set up a Miscarriage Misdiagnosis Incident Management Team to manage the incident response and to identify and review any cases that had occurred over the previous five years (from 18th June 2005) where drug or surgical treatment was recommended following a diagnosis of miscarriage, and where subsequent information demonstrated that the pregnancy was viable.

### 1.3 The Work of the Review

The HSE set up the National Miscarriage Misdiagnosis Review to examine cases over the past five years where a diagnosis of miscarriage had been made in error, and medical or surgical intervention was recommended to a woman, but subsequently it was found that the pregnancy was viable and the woman went on to continue her pregnancy.

The Terms of Reference for this Review were that the Review Team was to be responsible for:

The satisfactory investigation of cases (systems analysis) to determine the causes and the response to the cases, and make recommendations as required.

Ensuring that any immediate risks identified during the course of the review were communicated immediately to the HSE for urgent management.

Providing their report to the National Director of Quality and Clinical Care, HSE, who committed that this would be published.

A five year timeframe was agreed by the review team as being likely to encompass all cases that would be relevant to current practice and to allow the team to identify trends and patterns in the systems causes of these misdiagnoses.

However the review team also agreed to consider any cases submitted by service users that fell outside the five year timeframe, and also to consider cases identified through the Clinical Indemnity Scheme (CIS), where the case informed the work of the review team and the development of national standards.

Details of the Miscarriage Misdiagnosis Review and its terms of reference were announced on June 18th, 2010. The clinical review team was chaired by an independent expert in Obstetrics and Gynaecology, Professor William Ledger, Head of the Department of Obstetrics and Gynaecology at the University of Sheffield, and included medical and nursing/midwifery experts, along with service user representation from Patient Focus.

A Review Procedure Document issued to all maternity hospital sites later in June 2010, setting out the steps required to refer cases to this review. Private maternity sites were also asked to refer cases for review. This document covered:

- Governance arrangements
- Procedures for reviewing files within the hospital
- Verification of cases which were not to be included in the review
- Procedure for identifying cases which were to be included in the review
- Procedure for referring cases to the review
- Procedure for communication with and support for service users involved

The purpose of the review was to identify the causes of the miscarriage misdiagnoses and to recommend actions necessary to address these causes so as to prevent recurrences as far as possible.

The objectives of the review were:

- To review the hospital systems analysis investigations undertaken of the cases submitted to the review team and additional specific clinical information in relation to cases identified to identify the causes of specific cases and recommended actions to address them.
- To review the arrangements in Early Pregnancy Assessment Units (EPAUs) and whether they adhered to accepted standards

**1.4. Governance Arrangements**

Miscarriage Misdiagnosis Incident Management Team

The Miscarriage Misdiagnosis Incident Management Team oversaw all aspects of the national response to this matter. The team included representation from the HSE's Serious Incident Management Team, Integrated Services, a Service User / Service user Advocate, HSE Advocacy Services, Medical, Nursing and Midwifery experts, Communications, and support staff.

Miscarriage Misdiagnosis Clinical Review Team

The clinical review team was a sub-group of the Incident Management Team and was responsible for carrying out the clinical review of the cases included in the review.

Hospital Response Team:

A dedicated Response Team was set up in each hospital. Guidance provided by the Incident Management Team to the hospitals recommended that the Hospital Response Teams should include the following types of staff:

Senior Hospital Manager/CEO; Hospital Clinical Director; Consultant Obstetrician /Gynaecologist; Senior Nurse Manager/Midwife; Quality and Safety Manager/Service user Liaison; Risk Manager/Advisor; Complaints Officer; Medical Social Worker; Bereavement Specialist /GP Liaison Nurse ; Chaplain; Medical Records Officer; Administrative Support.

The hospital response teams linked with the Clinical Review and the Incident Management Teams, and was responsible for carrying out or overseeing the individual hospital based systems analysis investigations of each case that met the inclusion criteria.

**Section 2**
**Review Methodology**

The Miscarriage Misdiagnosis Review was tasked with providing an analysis of all relevant anonymised cases forwarded to the review team from hospital sites. While it would report on the management of those cases, the core purpose of the review was to aggregate the outcomes of the cases reported and identify any commonalities between them. The review would also examine and quality-assure individual hospitals' investigations of the cases included in the national review.

The review would also carry out a review of existing infrastructure, equipment, staffing levels, guidelines and operating policies within Early Pregnancy Assessment Units (EPAUs) or Maternity facilities. This would allow any gaps in infrastructure to be identified.

Both these streams of work would allow the review to provide overall national recommendations for service improvements.

It is important to note that this report is not designed to provide a detailed personal account or analysis of their care to each woman involved– this personal report will be provided through an individual systems analysis investigation being carried out within each hospital at the request of the National Miscarriage Misdiagnosis Review.

The review's methodology is set out in the diagram below.

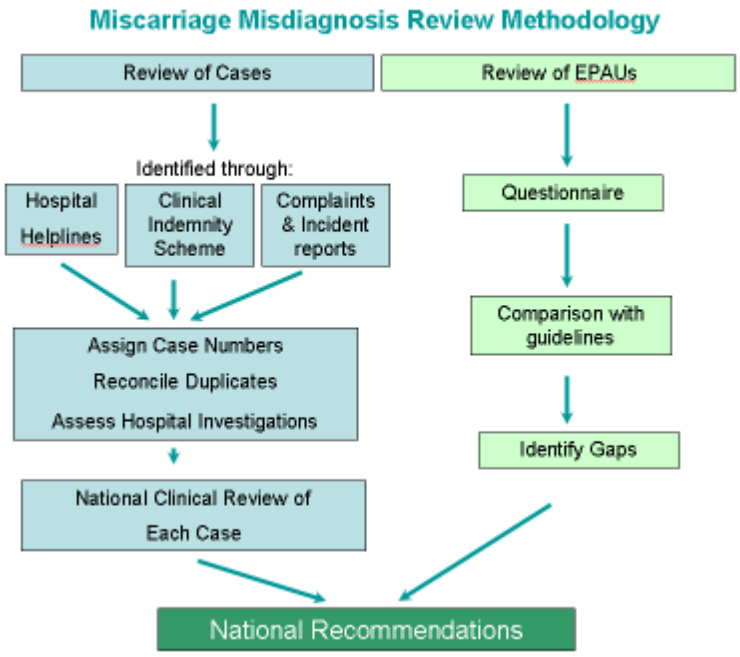


Fig 2.1 Review Methodology Diagram

### 2.1 Identification of Cases

The review team requested information from hospitals on cases where drug or surgical treatment was recommended when the diagnosis of miscarriage may have been made in error, via:

- The hospital help lines
- The hospitals' complaint and incident reporting systems
- The Clinical Indemnity Scheme (CIS)

All 19 public maternity sites in Ireland were asked to review their clinical records as part of this review. All private hospital sites in Ireland were also asked to review their clinical records as part of this review. Only one private hospital currently provides maternity services in Ireland.

| **HSE Region & Maternity Sites** | |
|---|---|
| **Dublin North East** | **West** |
| Rotunda Hospital | Galway University Hospital |
| Cavan General Hospital | Letterkenny General Hospital |
| Our Lady of Lourdes, Drogheda | Portiuncula General Hospital |
| | Mid-Western Regional Hospital |
| | Mayo General Hospital |
| | Sligo General Hospital |
| **Dublin Mid-Leinster** | **South** |
| National Maternity Hospital | Cork University Maternity Hospital (Erinville & St. Finbarr's) |
| Midlands Regional Hospital Portlaoise | Kerry General Hospital |
| Midlands Regional Mullingar | South Tipperary General Hospital |
| Coombe Women's Hospital | St. Luke's, Kilkenny |
| | Waterford Regional Hospital |
| | Wexford General Hospital |

| **Private Hospitals per Region** | |
|---|---|
| **Dublin North East** | **West** |
| Bon Secours Hospital, Glasnevin | Bon Secours, Galway |
| Mater Private Hospital, Dublin | St. Joseph's Sligo |
| | Barrington's Hospital, Limerick |
| **Dublin Mid-Leinster** | **South** |
| Mount Carmel Hospital | Bon Secours Hospital, Cork |
| St. Francis Private Hospital, Mullingar | Bon Secours Hospital, Kerry |
| Hermitage Clinic, Palmerstown | Aut Even Hospital, Kilkenny |
| Beacon Hospital, Sandyford | Shankhill Hospital, Cork |
| Blackrock Clinic | Whitfield Clinic, Waterford |
| St. Vincent's Private Hospital | |

Hospitals set up dedicated helplines immediately following media reports of cases on June 9th 2010. Over the subsequent weeks, a total of 409 calls were made to these hospital helplines.

Hospitals were given specific instructions by the clinical review team on how to assess the cases of the service users who made contact, and to identify those cases which should be referred to the review.

This involved a review of all callers' clinical records, of existing relevant hospital files relating to complaints, incidents or reports to the Clinical Indemnity Scheme. Hospitals used these sources to identify any cases that met the review case definition, that is, any cases where, in the last 5 years, drug or surgical treatment was recommended when the diagnosis of miscarriage has been made in error, and where subsequent information demonstrated that the pregnancy was viable.

**2.2. Referral of Cases to the Review Team**

The clinical review team agreed a preliminary questionnaire (Questionnaire 1, Appendix B) which was completed by the hospitals in respect of any such cases. This questionnaire allowed all the relevant information about the case to be collected and forwarded for review, maintaining anonymity and preserving the privacy of the service user. This questionnaire was completed by a Consultant Obstetrician at each maternity site.

In order to ensure that principles of good governance were applied, each questionnaire was co-signed by the Clinical Director for each hospital and the Hospital Manager/Chief Executive Officer. One questionnaire was completed for each potential case of miscarriage misdiagnosis. The purpose of the brief case questionnaire was to establish the overall numbers of potential cases of miscarriage misdiagnosis and to provide:

- An overview of case history (e.g. year of potential misdiagnosis)
- The number and type of individuals who had reviewed the case file to determine if it met the criteria for inclusion
- The prompt for review of the file (e.g. as a result of a call to the hospital helpline, previous complaint or previously reported incident etc.)
- The status of any investigation into the incident/complaint or ongoing legal processes

A second questionnaire (Questionnaire 2, Appendix B) was also completed by each hospital, giving details of existing policies, guidelines and standards, infrastructure and resources that were in place within the hospitals and which were relevant to this review. This questionnaire was completed by the Hospital Manager/Chief Executive Officer. The purpose of the second questionnaire was to determine the level to which each site complied with standards related to the management of early pregnancy.

Questionnaire 2 gathered details on:

- Policies, procedures and guidelines on early pregnancy and diagnosis of miscarriage currently in place at each site
- Staffing and training details for Early Pregnancy Assessment Units at each site
- Diagnostic and investigation equipment/facilities at each site
- Numbers, and type of staff trained in ultrasound at each site
- Type of supports currently available for women who experience a misdiagnosis of miscarriage
- Numbers of procedures/interventions per year over the preceding 5 year period

A third questionnaire (Questionnaire 3, Appendix B) was issued to all hospitals by the Incident Management Team. This required that each hospital follow a robust and clear process for examining the records of all women who made contact with the hospital expressing a concern that their case met the definition of the review. In order to provide assurance to the service users involved, and to the HSE, each Hospital Manager/CEO and Clinical Director was asked to verify that medical records were examined in a systematic and transparent manner.

The questionnaire sought details from each site on:

- How cases were assessed, what process was followed
- Who was responsible for assessment or examination of cases
- How each service user was responded to and any outcome(s) e.g. complaints, counselling offered
- Who signed off and verified this process

The Incident Management Team requested the information in Questionnaire 3 in order to facilitate an audit of the process for screening the cases for possible inclusion in the review related to women who contacted the helpline.

A fourth questionnaire (Questionnaire 4, Appendix B) was issued to all sites that had identified potential cases of miscarriage misdiagnosis through Questionnaire 1. The clinical review team designed the questionnaire to collect all clinical and other relevant information, based on their expert input and on the findings of similar reviews of cases of miscarriage misdiagnosis conducted internationally.

Clinical case notes and other hospital files were used by Consultant Obstetricians and Hospital Managers to complete Questionnaire 4. Data items that were requested included:

- clinical information/case history;
- details of any scans (including number, level of staff that conducted the scan etc.);
- details of other medical interventions (such as administration of drugs);
- details of any surgery; pregnancy and outcome;
- supports offered to the service user and
- detailed information on the early pregnancy assessment service at the time of the misdiagnosis.

A detailed chronology of events was constructed in each case. As in previous questionnaires, all responses were anonymised.

Questionnaire 4 also gathered information on the clinical governance and incident management systems that were in place at the time of the miscarriage misdiagnosis. Hospitals were asked to forward servicing and maintenance histories for ultrasound scanning machines used at the time of the case, copies of formal scan reports, copies of scan images and copies of any hCG blood test results.

**2.3 Cases known to Clinical Indemnity Scheme (CIS)**

The Clinical Indemnity Scheme (CIS) was established in 2002, and has responsibility for managing clinical negligence claims and associated risks within the Irish public healthcare system. Under the scheme, which is managed by the State Claims Agency (SCA), the State assumes full responsibility for the indemnification and management of all clinical negligence claims, including those which are birth-related.

At the request of the review team, the CIS provided details on cases that had become known to them through the STARSWeb national healthcare incident reporting system. Typically, hospitals notify the CIS when an adverse event has occurred or where a possible adverse event is identified through the complaints process.

The CIS provided information to the clinical review team for the purposes of reconciling cases with those that may have come through the helpline, hospital complaints or incident management systems. Information provided included: Location of incident; service user's date of birth; service user's age in years; Hospital Record Number.

The CIS provided the review team with details of twelve cases which became known to them through the STARSWeb system. The following is a breakdown of the 12 CIS cases, and how the responses were reconciled:

| Case Detail | Outcome |
|---|---|
| Case 1 | Currently in legal proceedings, therefore information was not made available to the Clinical Review Team |
| Case 2 | Reconciled with a previous case notified to the clinical review team through a maternity hospital |
| Case 3 | Case took place entirely in the community i.e. at primary care level, therefore it was not within the terms of reference of this review |
| Case 4 | Met terms of reference and is included in overall review of the 32 cases |
| Cases 5 – 12 | The remaining eight cases were studied by the review team and were deemed closed as there was no evidence of a miscarriage misdiagnosis. |

### 2.4 Returns from Private Hospitals & Dublin Academic Teaching Hospitals

Correspondence was also issued to all private hospitals and all 5 Dublin Academic Teaching Hospitals, (DATHs), requesting that they formally notify the clinical review team of any incidents of miscarriage misdiagnosis occurring since 18th June 2005. A copy of the correspondence issued jointly by Dr. Tony Holohan, Chief Medical Officer, DOHC, and Dr. Barry White, National Director of Quality & Clinical Care, HSE was enclosed.

A total of sixteen letters were issued to private hospitals, and one case was returned for consideration by the review team. A total of five communications were issued to the Dublin Academic Teaching Hospital's (DATHs); all hospitals responded and there were no cases returned for consideration to the clinical review team.

### 2.5 Hospital Systems Analysis Investigations

In addition to the national clinical review, which would identify trends and examine cases to aggregate the contributory factors, each individual hospital was required to carry out a detailed systems analysis investigation of the care provided to the individual women in these cases.

These individual investigations included the input of the service user involved and are part of the routine and quality response from a hospital to any incident. Hospitals have conducted and will continue to conduct their individual investigations independent of this national review and its publication. However, the National Miscarriage Misdiagnosis Review set out a range of requirements for hospitals in relation to the quality of those investigations.

The clinical review team requested that hospitals which recorded a case of miscarriage misdiagnosis that fell within the terms of reference for the review would submit any available draft systems analysis investigation reports to the clinical review team. This would be considered as part of the overall review process as

a) a systems analysis investigation should assist in the identification of national long term and systemic recommendations to address the causes of such incidents and

b) they provided evidence that the hospitals had conducted a satisfactory investigation of cases (using systems analysis) to determine the causes and the response to the cases, and had made recommendations as required.

### 2.6 Clinical Review of Cases

Having gathered information using all the processes outlined above, the clinical review team met to consider each case in detail.

Further information and clarification was requested in a number of cases. Each item of clinical care and decision making was assessed separately and the team considered whether there was evidence of clinical error, mechanical failure or inadequacy, or failure of support systems.

A database was developed to allow comparison of findings and identify patterns of practice that led to the possible misdiagnosis of miscarriage. The full clinical review findings are presented in Section 4 of this report.

The findings from each hospital's individual systems analysis investigation, together with the findings from the national review of cases, were used to develop a series of recommendations for improvement in services. Comments and Recommendations are presented in Section 5 of this report.

## Section 3

## Hospital Systems Analysis Investigations

The review methodology outlined in Section 2 describes how cases were assessed and referred to the review. In all, 32 cases were referred to the review team for consideration, and 24 cases were deemed to meet the terms of reference for the review. This is described in more detail in Section 4 of this report.

Part of the terms of reference for this national review outlined the need for hospitals to ensure that a systems analysis investigation was carried out in respect of each of the 24 cases included in the national review. The clinical review team carried out an examination of each hospital's investigation and their reports, as part of its analysis of the cases included in the review. The purpose of this was to assess the quality of the investigations carried out in each hospital and provide assurance to the women and families involved.

The review team received investigation reports from hospitals in respect of 21 of the 24 cases included in the review. In the three remaining cases, hospital investigation reports were not available or were not possible to complete due to incomplete records. These three cases occurred outside the remit of the enquiry (i.e. more than 5 years earlier) but were included in the overall review at the request of patients.

The investigation reports submitted to the Review Team were reviewed to establish:

1 General compliance with systems analysis methodology; and within the structure(s) of reports.
2 Identification of trends among the contributory factors identified in the reports.
3 Quality and safety improvement strategies that should be considered as improvements to national obstetric and gynaecological services.

Details of the methodology for this analysis are provided in Appendix C, along with general information on systems analysis investigation practice. The reports received were broadly similar in length and detail. While some variances were identified in relation to the application of a systems/root cause analysis methodology; there was evidence of a general standardisation and uniformity of approach and presentation in the reports received.

### 3.3 Compliance with systems analysis methodology:

The clinical review team considered all of the systems analysis reports that were submitted as part of this review. There was evidence of variable compliance with the principles of systems analysis methodology. While the majority were fully compliant, in some, the chronology sections of the reports were lacking in detail and other elements required by standard systems analysis methodology were not included. The clinical review team noted that the report sections that showed most evidence of variable compliance with standard systems analysis methodology were those sections of the reports describing Care Delivery Problems and Contributory Factors.

Care delivery problems are defined as problems that arise in the process of care; these care delivery problems are usually caused by the actions or omissions of staff members. However, although a care delivery problem may be caused by what a staff member does or does not do; it is accepted that there are usually systems causes (which are often not immediately obvious) which contributed to what the staff member did or did not do in the given set of circumstances. In order to prevent the same problem from presenting again in a different set of circumstances, the systems causes that contributed to what the staff member did or did not do must be corrected, in so far as this is possible.

For example, a systems analysis investigation may identify the Care Delivery Problem related to a specific incident as a *'Deviation from an agreed protocol'.* Further analysis may identify that the factors that contributed to the staff member deviating from the protocol were:

a) The staff member was new and inexperienced and was not aware of the protocol.
b)The protocol was informally communicated to staff i.e. it was not written and formalised.
c) The staff member had never encountered this situation previously and did not recognise that this was the protocol to be implemented in this circumstance etc.

The action plan developed as part of the systems analysis of this incident would focus on trying to eliminate or address these contributory factors.

**3.4 Care Delivery Problems (CDPs) Identified**
Thirteen of the investigation reports reviewed by the clinical review team described care delivery problems as part of the systems analysis carried out. The reports in which no care delivery problems were identified cited contributory factors, which confirmed that the staff members who carried out those investigations recognised that a problem had arisen in the process of care, although the nature of the problem had not been specifically described.

Where a care delivery problem was not explicitly described, there was also evidence that consideration had been given to the full range of systems causes that might have contributed to the events/incident that occurred.

Experienced systems analysis reviewers have confirmed that the most difficult aspect of conducting a full systems analysis review is in the correct and appropriate identification of the care delivery problems. This may account for the absence of a documented care delivery problem in some of the reports reviewed.

Based on the specific care delivery problems identified in many of the individual reports reviewed by the clinical review team, it was possible to identify aggregated themes and trends across the reports. The themes identified from the care delivery problems described in these systems analysis reports were:

- Themes related to the availability, access and use of specific equipment.
- Themes related to the availability and implementation of clinical guidelines for the management of all aspects of early pregnancy.
- Themes related to access to appropriate specialised facilities and appropriately trained and competent clinical specialists.

**3.5 Contributory Factors Identified**
Most of the reports reviewed analysed the factors that had contributed to the development of the care delivery problems identified. The contributory factors were generally clearly and comprehensively explained. However in some reports the link between the care delivery problems and the contributory factors were less defined.

In a small number of the reports it was highlighted that the incident had occurred over five years previously, which imposed limitations on the level of analysis that could be undertaken, and therefore it was not always possible to identify the factors that might have contributed to the problems in the care delivered. The clinical review team noted that in these reports it was highlighted that during the intervening period a number of positive changes had been made to the way that services were being delivered since the date of the incident.

All of the reports reviewed used a Contributory Factor Framework (i.e. a systematic method of grouping the contributory factors); most reports used the framework outlined in systems analysis methodology.

The contributory factors identified from a review of the reports fell into the 7 Factor Types described in a standard systems analysis methodology i.e.:

- Service User Factors
- Task (and Technology) Factors
- Individual Factors
- Team Factors
- Work Environment Factors
- Organisational /Management Factors
- Institutional Factors

The contributory factors most commonly cited across most of the reports were related to:

- The lack of experience and specific training of some of the clinicians who undertook the initial assessment and ultrasound scan.
- The number of previous miscarriages or other complications related to pregnancy that the woman had experienced.
- The clinical parameters used in the assessment of ultrasound images obtained.
- Staffing levels and skill-mix within ultrasound services.
- The increased number of women referred to the Early Pregnancy Assessment Unit and the associated impact on limited resources i.e. by increasing lists.
- The age or quality of ultrasound scanners.
- The quality of information/communication with the woman at the time of her assessment.

**3.6 Conclusions and Themes in Hospital Systems Analysis Reports**

Recommendations were provided in almost all of the reports. There was evidence in the majority of reports reviewed that the recommendations made related directly to the care delivery problem identified; in some reports this linkage was less obvious.

Most of the recommendations made as part of the systems analysis investigations related to the following themes:

Policies, procedures and guidelines:
Some hospital reports referenced the need to develop policies, procedures and guidelines for the performance of early pregnancy ultrasound which should include
a) specific reference to the training, accreditation and experience that staff members undertaking early pregnancy ultrasound should possess;
b) clinical parameters to be assessed in early pregnancy ultrasound and
c) the referral criteria for early pregnancy ultrasound.
Some also mentioned the need for policies, procedures and guidelines for suspected complications of early pregnancy or failing early pregnancy and guidelines related to the communication of appropriate, clear and comprehensive information to service users.

Clinical governance arrangements:
Some of the reports called for an audit of compliance with revised guidelines, and for systems analysis of errors identified to become routine. Others noted the need for a review of governance arrangements in place and for consistent adherence to risk management processes e.g. incident reporting.

Work environment
Some reports referenced the need for enhancement of the quality of ultrasound reports and development of a standardised formal report for early pregnancy ultrasound examinations. A review of facilities and equipment available in Early Pregnancy Assessment Units to ensure that equipment is fit for purpose was mentioned, as was the need for ultrasound machines to be included in external, validated quality assurance programmes. They also noted the need for a review of the skill-mix and ratio(s) of staff providing cover to Early Pregnancy Assessment Units.

Training and accreditation
Some reports recommended the development of a quality-assured, accredited training programme in early pregnancy ultrasound at a national level (and at local level in the interim) for trainees in obstetrics and gynaecology. They also called for a register of personnel who are adequately trained, accredited and experienced in early pregnancy ultrasound.

Those reports where there were no recommendations related to incidents that had occurred outside of the time-frame specified for the review (more than five years earlier).

In those cases, the reviewers who undertook the systems analysis were
a) unable to establish good quality information related to the incident
or
b) found that the environment within which the incident had occurred had changed and developed significantly during the intervening time in line with acceptable practice for the delivery of obstetric services.

**Hospital Investigations – Action Plans**
Action plans outlining how the hospitals planned to implement and monitor the recommendations contained in the investigation reports were evident in the majority of the reports reviewed. In some of the reports these action plans were extremely detailed and outlined the clinician/manager responsible to oversee implementation of each recommendation; other reports stated that the implementation of recommendations would be overseen by the governance structures in place at the hospital.

Although there was evidence of variation in relation to how systems analysis investigation methodology was applied by different hospitals, overall the clinical review team were reassured to note that when the contributory factors and recommendations identified in each of the systems analysis investigation reports were aggregated, they supported the findings and recommendations made by the clinical review team following consideration of the clinical details of the referred cases.

**Section 4**

**Findings from the Clinical Review of Cases**

**4.1 Cases Returned**

By the end of October 2010, 409 calls had been received by 19 public maternity hospital helplines. 136 callers were reassured on calling that their concerns were unfounded and did not require review within the hospital.

273 case files were reviewed by hospitals and of these, 33 cases that may have met the case definition for the review were referred to the Clinical Review Team. Of these 33, one case was found to be a duplicate return (from the hospital and from the CIS), bringing the overall total to 32. Details of referrals are provided in the Table 4.1 below

**Table 4.1 Breakdown of Numbers of cases inside/outside the five year timeframe for 32 cases referred to Clinical Review Team.**

| Cases reviewed within 5 year timeframe (from 18th June 2005) | Year | Cases reviewed outside of 5 year timeframe | Year |
|---|---|---|---|
| 4 | 2010 | 1 | 2005 |
| 8 | 2009 | 3 | 2004 |
| 3 | 2008 | 2 | 2000 |
| 1 | 2007 | 1 | 1996 |
| 5 | 2006 | 1 | 1998 |
| 1 | 2005 | 1 | 1995 |
| | | 1 | 1987 |
| **Total 22** | | **Total 10** | |
| **Overall Total Cases Referred to the Review: 32** | | | |

The clinical review team met seven times to examine and discuss the cases. Further information and clarification was obtained where necessary. Each stage of the clinical care delivered and decision-making was assessed and the team considered whether there was evidence of clinical error, mechanical failure or inadequacy, or failure of support systems. Not all of the 32 cases considered had evidence of failings in any of the abovementioned categories. Some had correct clinical management and appropriate imaging and support.

Of the 32 cases forwarded for consideration by the Clinical Review Team:

**Eight cases were deemed as closed by the Review Team as they did not meet the terms of reference for review.** This included:

- Three cases that were outside the timeframe for the review and where there was insufficient information available to the clinical review team to determine if a miscarriage misdiagnosis occurred
- Four cases in which there was no evidence of miscarriage misdiagnosis found and the clinical management was appropriate
- One case did not meet with the terms of reference of the review as it occurred entirely in a primary care setting.

**24 cases were confirmed as meeting the terms of reference for this review. Eighteen of these cases occurred within the five year period June 2005 – 2010.**

A further case which was referred to the Review Team through the Clinical Indemnity Scheme is currently going through legal proceedings and information was not made available to the team for review and inclusion in their findings.

### 4.2 Findings from analysis of the clinical questionnaires

## Introduction

The tables and text on the following pages outline the main findings made by the clinical review team in their examination of the 24 case questionnaires submitted for review under the terms of reference.

## Background Information

Women whose cases were assessed by the review team presented to their hospital for assessment across a broad range of months, week days, and time of day. 42% of cases (n=10) first presented to their hospital through the Emergency Department, 38% (n=9) to an Early Pregnancy Assessment Unit and the remainder (n=5) to a Gynaecology department.

In 58% of cases reviewed, women first presented to their hospital at 7 weeks gestation or less (n=14). The breakdown by weeks of gestation at initial presentation is presented in Table 4.2 below.

Table 4.2 Completed Weeks Gestation at Initial Presentation to Hospital

| Completed Weeks Gestation at Initial Presentation to Hospital | % of Cases | Count |
|---|---|---|
| 7 weeks or less | 58% | 14 |
| 8 weeks and over | 38% | 9 |
| Missing | 4% | 1 |
| Total | 100% | 24 |

## Level of Staff Making Primary Diagnosis

The primary diagnosis of miscarriage was made by Registrar level doctors in 54% of cases (n=13), Consultant level doctors in 25% of cases (n=6), and by Senior House Officers in 21% of cases (n=5).

## Analysis of Case Details and First Scan Conducted

The first scan was conducted by a registrar level doctor in 42% of cases (n=10), a midwife sonographer in 25% of cases (n=6), a senior house officer doctor in 21% of cases (n=5), a consultant in 8% of cases (n=2) and by a radiographer in 4% (n=1) of cases.

In 25% of cases (n=6) the scanning machine used at the first scan was older than five years.

First scan ultrasound images were not recorded in 21% of cases (n=5) and it was not known in two cases if ultrasound scan images were recorded or not.

A formal report of the findings of the first scan was not generated in 25% of cases reviewed (n=6) and not recorded on questionnaire four in two cases.

A transabdominal ultrasound was used in 50% of the first ultrasound scans (n=12). A transvaginal ultrasound was used in 54% of the cases reviewed (n=13). As shown in table 4.3 below in 6 cases a transabdominal scan was conducted at 7 completed weeks gestation or less (age of gestation was unknown for one case where a transabdominal scan was performed). In 38% of cases (n=9), a transvaginal scan was conducted at 7 completed weeks gestation or less.

Table 4.3 **Type and Timing of First Ultrasound Scans Conducted**

| **(n=24)*** | | **When was First Ultrasound Scan Conducted** | |
|---|---|---|---|
| **Type of First Ultrasound Scan Conducted** | | **Before 7 completed weeks gestation** | **After 8 weeks gestation** |
| Transabdominal Scan** | Count | 6 | 5 |
| | % | **25%** | **21%** |
| Transvaginal Scan | Count | 9 | 4 |
| | % | **38%** | **17%** |

* Please note the data in this table is based on the analysis of 24 cases. The total number of scan types is greater than 24 – as in one case a woman had both a transabdominal and a transvaginal scan. The total number of women that had their first scan before 7 completed weeks gestation was 14 (58%).
** Gestational age in weeks was unknown for one case where it was known that a transabdominal scan was conducted at 1st scan.

## Analysis of Case Details and Second Scan Conducted

The second ultrasound scan was conducted by a Registrar level doctor in 38% of cases (n=9), a Midwife sonographer in 25% of cases (n=6), a Consultant in 13% of cases (n=3) a Senior House Officer doctor in 4% of cases (n=1), and by a Radiographer in 4% (n=1) of cases. The level of individual who conducted the second scan was not recorded in 4 cases reviewed.

In 21% of cases (n=5) the scanning machine used at the second scan was older than five years. The age of the machine used in the second scan was not known in 38% of cases (n=9). Images from the second scan were not recorded in 21% of cases (n=5) and it was not known in 4 cases if scan images were recorded or not. A formal report of the findings of the second scan was not generated in 38% of cases reviewed (n=9) and unknown in 4 cases.

A transabdominal ultrasound was conducted in 38% of the second scans (n=9) reviewed. A transvaginal ultrasound was performed in 67% of the second scans reviewed (n=16). As presented in Table 4.4 below, in five cases a transabdominal ultrasound was conducted at 7 weeks gestation or less. A transvaginal ultrasound was conducted at 7 completed weeks gestation or less in nine cases examined by the review team.

Table 4.4 **Type and Timing of Second Ultrasound Scans Conducted**

| **(n=24)*** | | **When was Second Ultrasound Scan Conducted** | |
|---|---|---|---|
| **Type of Second Ultrasound Scan Conducted** | | **Before 7 completed weeks gestation** | **After 8 weeks gestation** |
| Transabdominal Scan | Count | 5 | 4 |
| | % | **21%** | **17%** |
| Transvaginal Scan | Count | 9 | 7 |
| | % | **38%** | **29%** |

- Please note the data in this table is based on the analysis of 24 cases. The total number of scan types is greater than 24 – as in one case a woman had both a transabdominal and a transvaginal scan. The total number of women that had their first scan before 7 completed weeks gestation was 14 (58%).

In 38% of cases (n=9) the diagnosis of miscarriage was corrected on the 2nd scan conducted. In 3 cases the second confirmatory scan was conducted the morning of a planned/booked ERPC. In 3 cases the 2nd scan was conducted at the woman's request following a previous discussion of options including surgical and medical options. In one case the second scan was conducted after Misoprostol had been prescribed and in one case the second scan was conducted after an ERPC procedure had been conducted. In fifteen of the cases reviewed, the second ultrasound did not show any change in the diagnosis.

**Table 4.5 When Correction of Diagnosis was Made**

| Correction of Diagnosis Made | % of Cases | Count |
|---|---|---|
| Second scan | 38% | 9 |
| Third scan | 50% | 12 |
| Fourth scan | 4% | 1 |
| Fifth scan | 4% | 1 |
| Sixth scan | 4% | 1 |
| Total | 100% | 24 |

## Clinical Risk Factors

Sixty seven percent of the women (n=16) had previously given birth. Over half of the women 54% had previously had a miscarriage (n=13). Twenty-nine percent of the women (n=7) had had three or more previous miscarriages. No history of a previous still birth was recorded in any of the cases.

In 25% of cases reviewed (n=6) there were clinical indications of a suspected ectopic or molar pregnancy.

## Recommendation of Drug or Surgical Treatment

The terms of reference for this review stated that cases would be included 'where drug or surgical treatment was recommended following a diagnosis of miscarriage, and where subsequent information demonstrated that the pregnancy was viable'.

Within this review treatments recommended by clinicians included advising, scheduling or performing a surgical procedure such as an ERPC / D&C and/or prescription of medication to induce evacuation of the womb or a laparoscopy to rule out suspected ectopic pregnancy.

In 58% of cases (n=14) the 1st ultrasound scan conducted was inconclusive and a second scan was then undertaken. Medical or surgical intervention was recommended following a second scan in 11 cases and after a 3rd or more scan in two cases examined. Due to an incomplete hospital record, information was not available on one case to determine when the decision to recommend further action was taken.

**Table 4.6 Timing of drug or surgical treatment recommendation**

| Drug or surgical treatment recommended based on ultrasound results | Percentage of Review Cases (i.e. out of 24) | Number of Cases |
|---|---|---|
| Following first scan | 42% | 10 |
| Following second scan | 46% | 11 |
| Following a third or more scan | 8% | 2 |
| Unknown | 4% | 1 |
| Total | 100% | 24 |

When the details surrounding the 13 cases where further treatment was recommended or discussed following 2 or more scans were further examined, the review team found that in 9 of those 13 cases the ultrasound that led to drug/surgical treatment (as described above) was conducted 9 days or less after the initial scan. In the remaining four cases the ultrasound images and/or report that led to a decision for further action (i.e. medical or surgical treatment) took place 10-14 days after the initial presentation.

The decision to advise, schedule or perform a surgical procedure or prescribe medical treatment was made by consultants (25%, n=6), registrars (54%, n=13) and senior house officers (21%, n=5).

## Clinical Recommendation for Medical Management

In 33% of cases (n=8) medication (such as Misoprostol or Methotrexate) was prescribed to induce evacuation of the womb or provide treatment for a suspected ectopic pregnancy following the primary diagnosis of miscarriage or ectopic pregnancy.

**Table 4.7 Outcome of Clinical Recommendation for Medical Management**

| Outcome of Clinical Recommendation for Medical Management | Percentage of Cases Reviewed (i.e. out of 24) | Number of Cases |
|---|---|---|
| Taken as directed | 17% | 5 |
| Prescribed, but woman chose not to take it | 13% | 3 |
| Total | 33% | 8 |

As presented in Table 4.7 above, in five of the eight cases, women took the drugs prescribed as directed. Three of the women were prescribed a drug, but chose not to take it.

## Clinical Recommendation for Surgical Treatment

In 75% of the twenty-four cases reviewed (n=18) a surgical procedure such as an ERPC, D&C was either conducted, scheduled to be conducted (often with a confirmatory scan planned), or advised or discussed with the service user.

As shown in table 4.8 below, in 29% of cases reviewed an ERPC/D&C procedure was scheduled (n=7). In 21% of cases an ERPC or D&C was either advised or discussed by the clinician with the woman (n=5).

A surgical procedure known as an ERPC or D&C was carried out in six cases; three in women that were believed to have had an incomplete miscarriage, two in cases of suspected ectopic pregnancy and one in a suspected molar pregnancy. Of the six women that had surgical procedures conducted, there were four live births, and two miscarriages.

**Table 4.8 Outcome of Clinical Recommendation of Surgical Treatment**

| Outcome of Clinical Recommendation of Surgical Treatment | Percentage of Review Cases (i.e. out of 24) | Number of Cases |
|---|---|---|
| ERPC/D&C was booked/scheduled with service user - often with a plan to re-scan prior to the procedure | 29% | 7 |
| ERPC/D&C was advised/ discussed or offered to a service user - with a plan to re-scan before the procedure | 21% | 5 |
| ERPC or similar surgical procedure conducted | 25% | 6 |
| Total | 75% | 18 |

Table 4.9 below shows that surgical treatment was recommended or discussed by senior doctors, including Registrars (38%) and Consultants (17%), and junior doctors (21%).

**Table 4.9 Grade of Clinician that Recommended or Discussed a Surgical Treatment Option**

| Who Recommended or Discussed Surgical Treatment Option | Percentage of Review Cases (i.e. out of 24) | Number of Cases |
|---|---|---|
| Registrar | 38% | 9 |
| SHO | 21% | 5 |
| Consultant/Locum Consultant | 17% | 4 |
| Total | 76 | 18 |

## Confirmation of Ongoing Pregnancy

Table 4.10 below outlines the details of when the diagnosis of miscarriage was corrected in each case reviewed.

**Table 4.10 Confirmation of an Ongoing Pregnancy**

| When was Ongoing Pregnancy Confirmed | Percentage of Cases | Number of Cases |
|---|---|---|
| Routine ultrasound at scheduled follow-up appointment post medication prescription | 21% | 5 |
| Positive pregnancy test or ultrasound following a surgical procedure | 21% | 5 |
| Scheduled confirmatory scan on day of scheduled surgical procedure | 17% | 4 |
| GP or another hospital confirmed ongoing pregnancy | 17% | 4 |
| Service user requested a scan prior to drug or surgical procedure | 13% | 3 |
| Service user scanned at scheduled follow-up appointment following discussion of options or offer of drug or surgical treatment | 13% | 3 |
| Total | 100% | 24 |

## Pregnancy Outcome

In 92% of the cases reviewed, the women went on to have a live birth (n=22) and two women suffered a miscarriage.

## Training in Early Pregnancy Ultrasound

Several clinicians reported significant years of experience in conducting ultrasound in early pregnancy, but formal training in early pregnancy ultrasound was reported by only 3 (13%) of the clinicians who made initial diagnoses. In eleven cases the review team found there was no mandatory training in ultrasound at the time the case occurred. Whilst many of the doctors were affiliated to relevant organisations and one stated they had a certificate, no specific ultrasound qualifications were made known to the review team.

As per table 4.11 in 50% of cases examined (n=12), the hospital stated that there was no mandatory training in ultrasound at the time the case occurred.

**Table 4.11 Presence of mandatory training in ultrasound at time of each Incident**

| Was mandatory training in place at the time of each incident | Percentage | Number |
|---|---|---|
| No mandatory training in place at the time | 50% | 12 |
| No data available on this question | 33% | 8 |
| In-house instruction and training provided to registrar grades not already signed off as competent. Named consultant to supervise and provide support. | 4% | 1 |
| Midwives encouraged and funded to do higher diploma in diagnostic imaging. Senior House Officers receive in-house training. | 4% | 1 |
| Staff training for midwives and Senior House Officers (SHO). SHOs can't scan alone. Doctors have normal Obstetrics and Gynaecology training. | 4% | 1 |
| Yes there was a mandatory training in place at the time | 4% | 1 |
| Total | 100% | 24 |

## Early Pregnancy Assessment Unit

The review team recognised that an EPAU was more likely to have been in place at the time of cases that had occurred in the past five years. In eight out of the 24 cases reviewed, an EPAU was not in place when the case occurred.

The hospitals reported that EPAUs were staffed by Consultants or Registrars, Midwives or Staff Nurses and Ultrasonographers, with some clerical support also provided by maternity care assistants.

## Counselling and Support Provided When Ongoing Pregnancy was Confirmed

Within questionnaire four, hospitals were asked to provide details on what type of supports were offered to women when their ongoing pregnancy was confirmed. The findings indicate that there was no consistency to the types of supports offered to women. In addition, none of the hospitals offered external support options following each incident, although for two women hospitals subsequently offered links to external counselling services following the commencement of the national review.

One hospital/unit stated they provided literature and the telephone contact details of the Miscarriage Association of Ireland to the woman or couple.

A full breakdown of the types of supports provided following each incident is shown in Table 4.12 below. It should be noted that more than one type of support listed below was offered to women and therefore the total numbers in column two exceed the total number of cases. Women also received additional follow-up not included in Table 4.12 as part of the overall management of the national review.

Table 4.12 **Type of Support Offered Following the Incident**

| Type of Support Offered Following the Incident | Percentage | Number |
|---|---|---|
| Explanation by consultant | 33% | 8 |
| Referred for ongoing Antenatal/multidisciplinary Care | 33% | 8 |
| Ongoing reassurance scans offered | 25% | 6 |
| Reassurance/counselling/support by consultant | 21% | 5 |
| Offer of ongoing support/review | 13% | 3 |
| Midwifery lead mental health support/ Referral to liaison psychiatry service/Midwifery counsellor | 13% | 3 |
| Information on Cytotec exposure | 8% | 2 |
| Discharge to GP | 8% | 2 |
| Not recorded | 8% | 2 |
| Change to personnel involved in care/ Transfer of care to specialist for unrelated complications | 8% | 2 |

Within questionnaire two, each hospital manager was asked to specify the type of supports currently available for women who experience a misdiagnosis of miscarriage. The results of questionnaire two found that Clinical Midwife Specialists support or provide follow up for women who suffer miscarriage at their hospitals/units with referral to a GP liaison nurse or bereavement specialist in 40% of maternity hospitals/units.

## Section 5 Comments and Recommendations from the Clinical Review

### 5.1 Early Pregnancy Assessment Units (EPAUs)

**General Comment**

The function of an EPAU is to make an early, correct diagnosis of ongoing pregnancy or pregnancy loss (miscarriage or ectopic pregnancy), followed by timely, effective treatment in a caring and supportive environment. Eight hospitals involved in this review did not have an Early Pregnancy Assessment Unit (EPAU) service at the time of the misdiagnosis and staffing arrangements varied across the sites. Of these units, all but two now have an EPAU in place. Efficient case management must not compromise the ability of such units to correctly diagnose and appropriately care for and treat women in early pregnancy. Not all cases will allow a rapid diagnosis and in some a delay will be necessary before the location and viability of a pregnancy can be confirmed.

**Recommendation**

All maternity hospitals that provide emergency gynaecological care should have a dedicated early pregnancy assessment unit service.

#### 5.1.1 EPAU Facilities

**Comment**

Most hospitals have already established an EPAU although not all appear to be properly staffed or equipped, and some are not adequately housed.

**Recommendation**

The EPAU must have a suitable, dedicated space with rooms for ultrasonography, clinical assessment and investigation, counselling, and a waiting area. There should be daily sessions each morning (Monday to Friday), with sufficient capacity in terms of opening hours (of at least two hours per day) and staffing to manage local needs and provide early pregnancy ultrasound on the next working day following presentation with suspected miscarriage. There should be facilities for telephone contact with service users in the afternoon for at least one hour.

The EPAU should have facilities for “same-day” hCG testing. Ultrasound equipment is considered below. There should be an annual audit of outcomes and other key performance indicators built into the clinical effectiveness and quality systems of the EPAU. Guidelines for establishing an EPAU can be found at www.earlypregnancy.org.uk/guidelines.asp

#### 5.1.2 EPAU Staffing

**Comment**

An EPAU is more than a designated space. Adequate staffing with properly trained personnel is essential for safe working. The EPAU can provide training for clinicians and others who are not yet qualified to perform ultrasound in early pregnancy but these staff members should not be left to make a definitive diagnosis or initiate treatment.

**Recommendation**

Whenever open, the EPAU must be staffed by a multidisciplinary team (medical, radiographer or specialist midwife or nurse) who are properly trained and accredited to perform early pregnancy ultrasound.

A senior obstetrician will lead the EPAU team. There will be a daily “Consultant on call” rota with an immediately available Consultant available during the opening hours of the EPAU. The EPAU will not be staffed by trainee doctors who are not certified as competent in early pregnancy ultrasound.

### 5.2 Ultrasound

**Comment**

High quality transvaginal ultrasound scanning is essential for safe practice in the clinical management of early pregnancy complications. The review found that, in 2010, six units had machines that were over five years old. All had been well maintained with full service histories.

Not all hospitals were able to provide copies of images taken at ultrasound, and some clinicians who performed ultrasound scans did not provide a written report. The UK Royal College of Radiology has produced Standards for Ultrasound Equipment (2005) which suggests that all images obtained, and their reports, be archived in a digital format. This allows for quality assurance and audit and makes information readily available for the clinical management of individual service users.

**Recommendation**

All ultrasound examinations performed in the setting of early pregnancy complications must have a written report available within the clinical record that will allow appropriate management. The written report should clearly identify the findings of the ultrasound scan, the date and time and the name and grade of the operator performing the ultrasound scan.

There should be a capital equipment replacement programme and an annual programme of quality assurance and maintenance. A quality assurance programme should be developed in discussion with the medical physics department or service engineers for each piece of equipment.

Upgrading or replacement of the equipment is dependent on the type of equipment but it must remain fit for purpose. At 5 years there should be a critical assessment of image quality and risk assessment of the equipment. The ultrasound equipment must be of sufficiently high quality and high frame rate to provide transvaginal images of diagnostic quality and be able to define a fetal heart beat. The addition of Colour Doppler although not essential is desirable. The equipment should be supported by an image archive system, preferably digital. Thermal prints are not ideal media.

### 5.2.1 Ultrasound Operator.

**Comment**

Few of the clinicians who performed ultrasound scans in the review cases had formal qualifications in the technique, although some had many years experience in the management of early pregnancy problems. Demonstration of competence by means of certification of completion of training, with regular updates, is an essential requirement of modern practice. The Royal College of Obstetricians and Gynaecologists' (RCOG) Guideline on the Management of Early Pregnancy Loss, (2006) recommends that all clinicians working in an EPAU setting should be formally trained in the use of both transabdominal and transvaginal ultrasound.

**Recommendation**

All personnel regardless of professional background must hold a recognised certificate or equivalent, demonstrating not only theoretical knowledge but also competency to perform transvaginal scanning of suspected miscarriage independently in the clinical setting. All departments performing early pregnancy scans should hold a register of practitioners competent to scan in early pregnancy that is updated annually

### 5.2.2 Training in Early Pregnancy Ultrasound

**Comment**

There is no current national programme for training doctors, midwives and radiographers in ultrasound in early pregnancy. Since the inception of this review, University College Dublin and the Institute of Obstetricians and Gynaecologists have developed training programmes for clinicians, radiographers and midwives who have chosen to specialise in the area of ultrasound.

**Recommendation**

The HSE, in partnership with UCD School of Medicine and Medical Science (or other universities) and the Institute of Obstetricians and Gynaecologists, should implement training programmes in ultrasound in early pregnancy for obstetrician/gynaecologists midwives, sonographers, general practitioners and other health care professionals. The HSE should harmonise available training programmes to ensure that there is a common national approach to the management of early pregnancy.

All trainees in obstetrics and gynaecology must be able to demonstrate completion of training in early pregnancy ultrasound before they undertake any unsupervised ultrasound examinations of service users with suspected miscarriage or other problems in early pregnancy.

Applications for clinical appointments that are completed by trainees in obstetrics and gynaecology should include information on training in early pregnancy ultrasound, which can be scrutinised and validated at the time of appointment. This will assist in workforce planning and staffing of the EPAU.

### 5.2.3 Continuing Accreditation and Medical Education

**Comment**

The majority of ultrasound scans that led to misdiagnosis of miscarriage were performed by Registrar or Consultant level medical staff. Although new entrants to the specialty of Obstetrics and Gynaecology will be provided with formal training, it is equally important to ensure that more senior staff are competent and up-to-date in the performance of early pregnancy ultrasound.

**Recommendation**

All medical staff should maintain a personal log of cases which they have scanned, and their outcome. Any possible misdiagnoses will be investigated locally and the outcome of such cases should be included in the log. For Consultants, the log should be reviewed at the time of an annual appraisal.

All clinicians who perform ultrasound in early pregnancy should attend a course in obstetric ultrasound at least once every five years. Such attendances should be included in the log and validated at the appraisal.

### 5.2.4 Guidelines for Audit

**Comment**

From May 2011 all medical practitioners will be required to demonstrate that they spend at least one hour per month engaged in clinical audit to support evidence based practice.

**Recommendation**

Appendix D of this report recommends guidelines for clinical audit for use as part of overall clinical effectiveness structures and yearly clinical audit plans.

### 5.3 Clinical Management of Threatened Miscarriage

**Actions since the commencement of the Review**
We recommend that the HSE develop, disseminate and implement national guidelines for the management of early pregnancy complications. As of February 2011, such national guidelines have been developed by the HSE and are being implemented across all maternity sites. This rapid response is welcomed by the Review Team.

#### 5.3.1 Investigation in Early Pregnancy
**Comment**
The necessity for prompt action in cases of life threatening haemorrhage must take precedence over efforts to confirm a diagnosis of miscarriage. Such cases are rare, forming 1 – 2% of miscarriages.

Most women with threatened miscarriage will present in early pregnancy with pain and/ or bleeding which while distressing is not life threatening. 'Reassurance' scans can be helpful to women who are understandably anxious about fetal viability after previous miscarriage or other adverse pregnancy outcome. Ultrasound can provide rapid reassurance of viability of the pregnancy if a fetal heart beat can be identified within the uterine cavity. Confirmation of viability is likely to require transvaginal ultrasound in the first 6 – 8 weeks of pregnancy.

Whilst a positive demonstration of a heart beat provides reassurance, a negative finding in early pregnancy does not confirm miscarriage. The HSE National Clinical Guidelines on Ultrasound Diagnosis of Early Pregnancy Miscarriage (2010) provides detailed recommendations concerning safe diagnosis of miscarriage, which should be followed in all cases.

**Recommendation**
Before an ultrasound scan is performed in early pregnancy, particularly before eight weeks of gestation, the woman should be advised that a fetal heartbeat may not be visible and that a second scan may be needed later.

Ultrasound examination in early pregnancy is more accurate when performed transvaginally, and this should be the preferred technique provided that the woman agrees to vaginal ultrasound.

#### 5.3.2 Provision of a Second Ultrasound Scan
**Comment**
The hazards of the use of ultrasound to diagnose a miscarriage in very early pregnancy have been repeatedly highlighted since the introduction of the technique in the 1970s and there have been recent reports of misdiagnosis of miscarriage from the United Kingdom and Australia. The enquiry reviewed several cases in which a single ultrasound scan in very early pregnancy was followed by a plan for surgical evacuation of the uterus or prescription of Misoprostol. Such interventions are unwarranted unless the diagnosis of miscarriage is certain.

Both the service users and staff must have confidence that all reasonable steps were taken to confirm the diagnosis. Hence a second ultrasound examination should be seen as a confirmation of the original diagnosis and not as a criticism of the skills and training of the initial operator.

**Recommendation**
A second ultrasound examination should be performed in cases where

- the initial examination is performed "out of hours",
- the initial examination is performed by a trainee doctor

A second ultrasound examination should be offered as an option to women in cases where

- the initial examination is performed by a single handed practitioner (e.g. a clinician, a midwife or sonographer working alone in an EPAU).

Any service user who requests a second ultrasound examination before action is taken should be provided with this service. No intervention (medical or surgical) should occur until the second ultrasound is performed and the result is known.

**5.3.3 Clinical intervention following diagnosis**
**Comment**
There is rarely a need for urgent medical intervention in cases of miscarriage. **Delay may be the best policy if the pregnancy is below eight weeks gestation and the clinical picture is stable without excessive bleeding or pain.**

Repeated examinations may cause frustration to women who reasonably expect a rapid diagnosis, but this delay is preferable to misdiagnosis. Serum hCG measurement can be a useful adjunct to ultrasound in difficult cases, particularly those where the uterus is very retroverted or a woman has a high body mass. The review included several cases in which surgery or Misoprostol were recommended after a single ultrasound examination in very early pregnancy and in which the fetus was subsequently shown to be viable.

**Recommendation**
Prescription of Misoprostol should only occur after formal agreement to treatment from a named senior Obstetrician, recorded in the case notes. Surgical evacuation of the uterus for miscarriage should only be performed after formal agreement to treatment has been given by a named Senior Obstetrician and recorded in the case notes.

If there is no contraindication, and a woman prefers to delay a medical or surgical procedure in order to allow time to pass before later confirmation of the diagnosis with ultrasound +/- hCG testing, then this wish should be respected.

---

**5.4. Pregnancy of unknown location/ suspected ectopic pregnancy**

**Comment**
In the case of treatment of suspected ectopic pregnancies or pregnancies of unknown location, an ongoing early intrauterine pregnancy must be considered and excluded. Criteria for exclusion of an intrauterine pregnancy must be agreed locally, depending on the assay used for hCG by the local laboratory.

An early ectopic pregnancy can often be successfully treated by systemic injection of Methotrexate, avoiding need for surgery. However, Methotrexate could also end a viable pregnancy and should be used with caution. Surgical treatment of ectopic pregnancy will usually use a laparoscopic approach.

If an ectopic pregnancy is not seen then the differential diagnosis is of a very early ectopic pregnancy, complete or incomplete miscarriage or a very early viable pregnancy. Instrumentation of the uterus or use of uterine curettage/ biopsy to confirm miscarriage should only be carried out if clinically indicated and if there is certainty that a viable pregnancy has been ruled out. This may require a second procedure some days later after monitoring of serial hCG measurements.

**Recommendation**
All cases of pregnancy of unknown location or suspected ectopic pregnancy must be discussed with a Senior Obstetrician before intervention in the form of diagnostic laparoscopy or administration of Methotrexate is undertaken.

Written annotation must be made in the case notes that a named Senior Obstetrician has agreed that a viable intrauterine pregnancy has been excluded before Methotrexate is administered. **In a case of negative laparoscopy for ectopic pregnancy, no intrauterine procedure should take place unless approved by a named Senior Obstetrician.**

---

**5.5 Communication, counselling and support**

**Comment**
The types of supports provided for women included in this review post-miscarriage varied across the country. Only one hospital/unit stated they provided literature and the telephone contact details of the Miscarriage Association of Ireland to the woman or couple. Clinical Midwife Specialists support or provide follow up for women who suffered miscarriage at their hospitals/units with referral to a GP liaison nurse or bereavement specialist in 40% of hospitals/units. It is important that some type of recognised support or counselling is offered to women suffering miscarriage. Clinical Nurse or Midwife Specialists in this area will have a recognised qualification at Higher Diploma Level to provide this specialised service. Clinical Midwife Specialists in bereavement and counselling are an under-utilised resource who can provide invaluable support for the women in their care.

**Recommendations**
**5.5.1** Each woman must be afforded ample time to consider and understand her diagnosis. She should be encouraged to ask questions. The distress caused by this information should be appreciated by the information giver. The clinician should be available to the woman to address any issues around the diagnosis and answer any questions. Information about the diagnosis should be given in a suitable environment where the woman can be supported by her husband/partner or relative. Relevant information leaflets should be made available to the woman to take away and read at home.
**5.5.2** It is preferable that the woman is accompanied when she is returning home from the hospital. Contact details should be provided for a named liaison person within the hospital for follow up support and counselling and a list of support groups should also be made available for the woman.
**5.5.3** It is recognised that the uncertainties of the outcome in very early pregnancy, possibly necessitating repeated ultrasound scans and blood tests, may lead to substantial anxiety and distress for the woman. Medical, nursing and ultrasonography staff should be trained in counselling skills, support techniques and other issues around problems in early pregnancy.
**5.5.4** If a woman has experienced early pregnancy loss, this information should be communicated to the General Practitioner as soon as possible, in order to ensure good continuity of care after discharge.
**5.5.5** Each unit should develop a local guideline for supporting women who have suffered an adverse incident in their hospital related to miscarriage.

**Additional Recommendations**

**5.6. Systems Analysis Investigations**
It is the policy of the HSE that all incidents causing harm shall be identified, reported, communicated and investigated. Hospitals should have enhanced capacity to conduct systems analysis investigations of incidents such as misdiagnosis of miscarriage.

**5.7 Communication after a clinical error**
The Medical Council in their 2009 guidance document; 'Guide to Professional Conduct and Ethics for Medical Practitioners' state that 'Service users and their families are entitled to honest, open and prompt communication with them about adverse events that may have caused them harm'. The Guidance goes on to state that in relation to communicating with a service user following an adverse event that the medical practitioner should:

- Acknowledge that the event happened
- Explain how it happened
- Apologise, if appropriate and
- Give assurance as to how lessons have been learned to minimise the chance of this ever happening again in the future.

**5.8 Management of Complaints**
Access to independent advocacy and a hospital appointed dedicated service user liaison person should be provided as part of a complaints structure. The service user liaison person should be at a senior level and should be the principal point of contact with the woman. The woman should be made aware of the progress of her complaint/concerns.

**GLOSSARY**

| | |
|---|---|
| Biopsy | A procedure to take a small sample of tissue from some part of the body for examination. |
| Dilation and curettage (D&C) | A surgical operation which opens the entrance of the womb in order to remove tissue from the lining of the womb. |
| Doppler | A non-invasive method for measuring the flow of blood using ultrasound scanning. |
| Ectopic pregnancy | A pregnancy where a fertilised egg implants outside the womb (usually in one of fallopian tubes). |
| Early miscarriage | When a woman loses her pregnancy in the first three months. |
| Early Pregnancy Assessment Unit | A clinic that specialises in problems in early pregnancy. It is a place where a woman receives medical care, counselling and treatment in early pregnancy. |
| ERPC | Evacuation of the retained products of conception, a procedure carried out after a miscarriage has occurred, to remove any remaining tissues left in the uterus. |
| Human chorionic gonadotrophin (hCG) | A hormone which appears in a woman's blood or urine if she is pregnant. |
| Laparoscopy | A procedure in which a surgeon uses a scope inserted through a small incision below the tummy button (called a laparoscope) to look at or operate on part of the abdomen or pelvis. |
| Molar pregnancy | A rare condition in pregnancy in which the placenta does not form properly, leading to a collection of tissue within the womb which requires evacuation |
| Transabdominal scan | An ultrasound scan in which the scan probe is moved across the abdomen. |
| Transvaginal scan | An ultrasound scan in which the scanning probe is placed inside the vagina. |
| Ultrasound | High frequency sound waves used to provide images of the body, tissues and internal organs. |

**APPENDIX A**



10th June 2010

Dear RDO

As you are aware, concerns have emerged regarding the diagnosis of miscarriage in early pregnancy. You will understand that it is necessary that steps are taken to protect women from any possible risks in this regard. We are aware that in many maternity units, local guidelines are in place for the management of women with early pregnancy loss.

It is, nevertheless, acknowledged that further improvements need to be implemented in standardizing clinical practices, staff training and hospital facilities. In this regard, an obstetric programme has been established to standardise care for early pregnancy loss and other aspects of obstetric care. This programme will be led by Prof Michael Turner of the Coombe Women's and Infants' University Hospital. As part of this work, a guidance document for the management of early pregnancy loss will be developed in conjunction with the Institute of Obstetricians and Gynaecologists.

As an interim response, it is recommended that the decision to use a pharmacological agent (e.g. Cytotec) or to perform an evacuation of the retained products of conception (ERPC) in women who have had a miscarriage diagnosed must be approved by a consultant obstetrician. If the consultant considers it necessary, an ultrasound examination by a suitably trained sonographer should be carried out.

We thank you for your immediate attention to this matter.
Please confirm compliance with the above recommendation.

Private hospitals should communicate with Dr Tony Holohan, Chief Medical Officer, Department of Health and Children and HSE/HSE funded agencies via the Regional Directors of Operation and the Integrated Services Directorate in the Health Service Executive.

Yours sincerely

Dr Tony Holohan
Chief Medical Officer
Department of Health & Children
Hawkins House, Dublin 2

Dr Barry White
National Director of Quality &
Clinical Care, HSE
Dr Steevens' Hospital, Dublin 8

# APPENDIX B

# REVIEW QUESTIONNAIRES TO HOSPITALS (Questionnaires 1-4)

**REVIEW OF MISCARRIAGE MISDIAGNOSIS**
**CASE QUESTIONNAIRE 1 – Maternity Hospitals**

To be completed for each case of miscarriage misdiagnosis by a consultant obstetrician

**Case questionnaire: background & instructions**

- Incidents of miscarriage misdiagnosis will be referred to the review team from a number of sources. The purpose of this questionnaire is to provide the team with an overview of cases included in the review and to identify duplicate cases.
- The review team will not be privy to the identity of any case referred as part of this process.
- Where free text is required, **PLEASE USE BLOCK CAPITALS**
- All Information provided is strictly confidential to this review.
- Please ensure all sections are completed and relevant accompanying documents (e.g. anonymised investigation reports) are returned to the review team.
- Each case questionnaire must also be co-signed by the hospital manager/CEO & the hospital clinical director
- Where information is not available, please outline a brief reason why under section 4 (additional information).

**Section 1: Identification of cases**

**Q.1 Please circle the number to the right of the hospital where the miscarriage misdiagnosis occurred.**
*For example if the incident occurred at Cavan General, you would circle the number 1.*

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cavan General Hospital | **1** | Letterkenny General Hospital | **6** | Mid-Western Regional Hospital, Limerick | **11** | Sligo General Hospital | **16** |
| Coombe Womens Hospital | **2** | Mayo General Hospital | **7** | National Maternity Hospital | **12** | South Tipperary General Hospital | **17** |
| Cork University Hospital | **3** | Merlin Park University Hospital | **8** | Our Lady of Lourdes, Drogheda | **13** | St. Lukes General Hospital, Kilkenny | **18** |
| Galway University Hospital | **4** | Midland Regional Hospital Mullingar | **9** | Portiuncula Hospital | **14** | Waterford Regional Hospital | **19** |
| Kerry General Hospital | **5** | Midland Regional, Portlaoise | **10** | Rotunda Hospital | **15** | Wexford General Hospital | **20** |

**Q2.**
**In your opinion does this case fulfil the definition criteria below?**

"drug or surgical treatment was recommended when the diagnosis of miscarriage had been made in error, and where subsequent information demonstrated that the pregnancy was viable."

*(please circle the number opposite your intended response, for example to respond yes to this question, you would circle the number 1)*

| | |
|---|---|
| **Yes** | 1 |
| **No** | 2 |

**Q3.**
**What professionals (including you) have reviewed this patients file and determined that it meets the definition criteria for inclusion in this review?** *Yes = 1, No = 2*
*(please circle all that apply)*

| | **Yes** | **No** |
|---|---|---|
| NCHD/ SHO | 1 | 2 |
| Registrar | 1 | 2 |
| Specialist Registrar | 1 | 2 |
| Consultant Obstetrician/Gynaecologist | 1 | 2 |
| Clinical Director | 1 | 2 |
| Clinical Nurse/Midwife Specialist | 1 | 2 |
| Director of midwifery | 1 | 2 |
| Risk/quality manager | 1 | 2 |
| Other *(please write below)* | 1 | 2 |

**Section 2: General Patient Information/Case History**

**Q4.**

**What prompted this patient's chart to be reviewed and its subsequent inclusion in the review of miscarriage misdiagnosis?** *(please circle)*

| | |
|---|---|
| Call to hospital helpline | 1 |
| Complaints process | 2 |
| Reported Incident | 3 |
| If other, please write below | 4 |

**Q5.Patients Medical Record Number**
*(please write)*

**Q6. Patients age in years at time of incident**
*(please write)*

| | |
|---|---|
| | |

**Q7.**

**Year of misdiagnosis**

| | | | |
|---|---|---|---|
| | | | |

**Q8.**

**Patients Date of Birth** (please write)

/ /

**Q9.Patients BMI at time of incident, if known.**

| | | | |
|---|---|---|---|
| | | . | |

**Q10. Method of referral to hospital**
*(please circle)*

| **Self** | **GP** | **Other** |
|---|---|---|
| 1 | 2 | 3 |

If other please write

**Section 3: Investigation of Miscarriage Misdiagnosis**

**Q.11 a) Has an investigation into this incident occurred in your hospital?** *(please circle)*

| | | |
|---|---|---|
| **Yes** | 1 | *If yes, go to Q12* |
| **No** | 2 | *If no, go to Q14* |

**Q. 12 Have changes or recommendations been implemented as a result of this investigation?**

| | |
|---|---|
| **Yes** | 1 |
| **No** | 2 |

If yes, please give brief details

**Q13. Has an anonymised investigation report been sent to the review team?** *(please circle)*

| | |
|---|---|
| **Yes** | 1 |
| **No** | 2 |

*! If yes,* please forward anonymised investigation reports including recommendations to review team through the hospital manager and local RDO office

**Q.14 Has the Clinical Indemnity Scheme (CIS) been notified of this incident? (Starsweb)**

| | |
|---|---|
| **Yes** | 1 |
| **No** | 2 |

**Q. 15 Are you aware of any legal proceedings that are related to this incident?** *(please circle)*

| | |
|---|---|
| **Yes** | 1 |
| **No** | 2 |

*If yes,* please write brief details

**Section 4: Additional Information**

Please provide any additional information or comments that you may wish to bring to the attention of the review team. Such comments can be written within the section below or attached, as a separate piece, to this questionnaire.

Signature 1_____ Date / /
**(Consultant Obstetrician)**

Signature 2_____ Date / /
**Hospital/Service Clinical Director (or equivalent)**

Signature 3_____ Date / /
**Hospital Operational Manager (or equivalent)**

Please forward completed forms with three signatures for the attention of the relevant Regional Director of Operations (RDO), HSE, **Friday, 9th of July, 2010.**

Please ensure that, where available, relevant investigation reports are attached to the questionnaire or details are provided on the status of an investigation.

**Thank you. The Miscarriage Misdiagnosis Incident Review Team.**

**Review of Miscarriage Misdiagnosis Incident**
**QUESTIONNAIRE 2: Hospital Manager/CEO Questionnaire**
To be completed by Hospital Manager/CEO & forwarded to the Regional Director of Operations (RDO)

**Section 1 General Information**

**Q.1 Please circle the number to the right of your Hospital.**
**For example for Cavan General, you would circle the number 1.**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cavan General | **1** | Letterkenny General | **6** | Mid-Western Regional, Limerick | **11** | Sligo General Hospital | 16 |
| Coombe Womens | **2** | Mayo General | **7** | National Maternity Hospital | **12** | South Tipp. General | 17 |
| Cork University | **3** | Merlin Park University | **8** | Our Lady of Lourdes, Drogheda | **13** | St. Lukes General | 18 |
| Galway University | **4** | Midland Regional Mullingar | **9** | Portiuncula Hospital | **14** | Waterford Regional | 19 |
| Kerry General | **5** | Midland Regional, Portlaoise | **10** | Rotunda Hospital | **15** | Wexford General | 20 |

**Section 2 Policies, Procedures & Guidelines on Diagnosis of Miscarriage**

**Q2 Are the following type of guidelines/procedures on miscarriage diagnosis in place for local clinicians to follow?**

*(please circle)*
*1 = yes*
*2= no*

| **Type of Miscarriage Diagnosis Guidance /Procedures Followed** | **Yes** | **No** |
|---|---|---|
| Guidelines prior to recommending Evacuation of Retained Products of Conception (ERPC) & medication prescribed in advance of and ERPC procedure (e.g. Cytotec/misprostol) | 1 | 2 |
| Guidelines for the management of suspected ectopic pregnancy | 1 | 2 |
| Guidelines for the management of intrauterine pregnancy of uncertain viability | 1 | 2 |
| Guidelines for the management of pregnancy of unknown location | 1 | 2 |
| Royal College of Obstetricians and Gynaecologists (RCOG) guidance | 1 | 2 |
| Letter from Chief Medical Officer, DoHC and HSE to Hospitals June 10 2010 | 1 | 2 |
| Guidelines for Expectant Management of Patients | 1 | 2 |
| Other guidelines related to diagnosis of miscarriage, please write brief details below | 1 | 2 |

*! P*lease forward copies of any local guidelines and procedures relating to the diagnosis of miscarriage to the review team through the RDO.

**Section 3 Staffing & Training Within the Early Pregnancy Assessment Unit (EPAU)**

**Q3.**
**Does your hospital have an Early Pregnancy Unit (EPAU)?**
*(please circle)*

| | |
|---|---|
| **Yes** | 1 |
| **No** | 2 |

If no, please give reason why?

**Q4.**

**Who is the <u>clinical supervisor</u> of the EPAU?**
*(please circle)*

| | |
|---|---|
| Senior House Officer/NCHD | 1 |
| Registrar | 2 |
| Senior Registrar | 3 |
| Consultant Obstetrician/Gynaecologist | 4 |
| If other, please write | 5 |
| | |

**Q5.**
**Please write the number of staff in each category below working in the EPAU?**

| **Staff Type** | **Full-time** *(please write number)* | **Part-time** *(please write number)* |
|---|---|---|
| Senior House Officer/NCHD | | |
| Registrar | | |
| Senior Registrar | | |
| Consultant Obstetrician/Gynaecologist | | |
| Midwife | | |
| General Nurse | | |
| Radiographer | | |

*Please provide details of any additional clinicians working in the EPAU*

**Q6. What number of staff in each category (below) are trained in <u>transabdominal</u> ultrasound (TAS)?**
*(please circle)*

| **Sonagraphers** | **Full-time** (please write number) | **Part-time** (please write number) |
|---|---|---|
| Senior House Officer/NCHD | | |
| Registrar | | |
| Senior Registrar | | |
| Consultant Obstetrician/Gynaecologist | | |
| Midwife | | |
| General Nurse | | |
| Radiographer | | |
| *If other, please write clinician type & number* | | |
| *! P*lease forward any details on training provided to sonagraphers to the review team through the RDO. | | |

**Q7.**
**What number of staff in each category (below) are trained in transvaginal ultrasound (TVS)?**
*(please circle)*

| **Sonagraphers** | **Full-time** (please write number) | **Part-time** (please write number) |
|---|---|---|
| Senior House Officer/NCHD | | |
| Registrar | | |
| Senior Registrar | | |
| Consultant Obstetrician/Gynaecologist | | |
| Midwife | | |
| General Nurse | | |
| Radiographer | | |
| *If other, please write clinician type & number* | | |

*! P*lease forward any details on training provided to sonagraphers to the review team through the RDO.

**Section 4 – Diagnosis & Investigation Equipment/Facilities**

**Q8.**
**What makes & models of scanning equipment are used within the EPAU?**
*(please write)*

| **Make** | **Model** | **Number Available** |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

| **Q. 9** **Do clinicians have access to the following tests?** | *(please circle)* *1 = yes* *2= no* | |
|---|---|---|
| **Test** | **Yes** | **No** |
| Selective serum human chorionic gonadotrophin (hCG) | 1 | 2 |
| Rhesus antibody testing | 1 | 2 |
| Progesterone estimation | 1 | 2 |

**Section 5 – Support & Follow-up**
**Q.7. What type of support & follow-up is currently offered in your hospital for patients who have had a diagnosis of miscarriage?**
*1 = yes, 2= no (please circle all that apply)*

| **Clinician/Professional Support/Follow-up for Patients** | **Yes** | **No** |
|---|---|---|
| Consultant Obstetrician/Gynaecologist support/follow-up | 1 | 2 |
| Clinical Nurse/Midwife Specialist support/follow-up | 1 | 2 |
| Bereavement specialist/GP liaison nurse | 1 | 2 |
| Chaplain | 1 | 2 |
| Onsite counselling | 1 | 2 |
| Offsite counselling | 1 | 2 |
| Follow-up details included in discharge letter | 1 | 2 |
| Public health nurse support/follow-up | 1 | 2 |
| GP support/follow-up | 1 | 2 |
| If other, please write below | 1 | 2 |

**Section 6 – HIPE Report Requests**
**VERSION 3 Friday, 2nd of July, 2010**

| **Q.8 Please return the following four report requests as a separate attachment to be compiled by the Hospital In-Patient Enquiry (HIPE) data manager/coordinator at your site.** | | |
|---|---|---|
| **No** | **HIPE Report Request** | **ICD-10 Codes/Query** |
| 1 | • The number of mothers who delivered in your maternity unit between Jan 1st 2005 – December 31st 2009. | • All secondary diagnoses Z37, count report and organise by discharge year. |
| 2 | • The number of Evacuation of Retained Products of Conception (ERPC) procedures performed in the hospital Jan 1st 2005 – December 31st 2009. | • From **Jan 2005 to Dec 2008** Principal Procedure Block 1267, 1256, count report and organise by discharge year.. • |
| 3 | • Type of pregnancy with abortive outcome<br>• The number per year (as above)<br>• Total number for 2005-2009 inclusive | • Diagnosis blocks 000, 001, 002, 003<br>• Different totals per hospital |
| 4 | • The number of women given Cytotec (for miscarriage purposes only) between Jan 1st 2005 – December 31st 2009. | • Code 90462-00<br>• Different totals per hospital |

**Section 6 – Additional Information**
Please provide any additional details or comments you would like to bring to the attention of the miscarriage misdiagnosis incident review team. Comments can be written in the section below or attached along with the HIPE reports (as per section 5 on previous page).

**This form and the reports attached have been compiled by:**

_____ Date / /
**Hospital Manager/CEO (or equivalent)**

Please forward completed forms with signature of Hospital manager/CEO for the attention of the relevant Regional Director of Operations (RDO), HSE, **Friday, 9th of July, 2010. Thank you. The Miscarriage Misdiagnosis Incident Review Team.**

**Review of Miscarriage Misdiagnosis Incident**
**QUESTIONNAIRE 3 VERIFICATION QUESTIONNAIRE**

- **The purpose of this questionnaire is to provide assurance, to patients and to the HSE, to verify that all patient files were examined in a systematic and transparent manner.**
- To be completed by Hospital Manager/CEO & forwarded to the Regional Director of Operations

**Section 1 General Information**

**Q.1 Please circle the number to the right of your Hospital.**
**For example for Cavan General, you would circle the number 1.**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cavan General | **1** | Letterkenny General | **6** | Mid-Western Regional, Limerick | **11** | Sligo General Hospital | 16 |
| Coombe Womens | **2** | Mayo General | **7** | National Maternity Hospital | **12** | South Tipp. General | 17 |
| Cork University | **3** | Merlin Park University | **8** | Our Lady of Lourdes, Drogheda | **13** | St. Lukes General | 18 |
| Galway University | **4** | Midland Regional Mullingar | **9** | Portiuncula Hospital | **14** | Waterford Regional | 19 |
| Kerry General | **5** | Midland Regional, Portlaoise | **10** | Rotunda Hospital | **15** | Wexford General | 20 |

**Section 2 Miscarriage Misdiagnosis Hospital Response Team**

**Q2. What clinicians/professionals were included in your hospital's response team for miscarriage misdiagnosis?**
*(please circle all that apply) Yes = 1, No = 2*

| | **Yes** | **No** |
|---|---|---|
| Senior Hospital Manager/CEO | 1 | 2 |
| Hospital Clinical Director | 1 | 2 |
| Consultant Obstetrician/Gynaecologist | 1 | 2 |
| Clinical Nurse/Midwife Specialist | 1 | 2 |
| Director of midwifery | 1 | 2 |
| Quality & Safety Manager/Patient Liaison | 1 | 2 |
| Risk Manager/Advisor | 1 | 2 |
| Complaints Officer | 1 | 2 |
| Medical Social Worker | 1 | 2 |
| Bereavement Specialist/GP Liaison Nurse | 1 | 2 |
| Chaplain | 1 | 2 |
| Medical Records Officer | 1 | 2 |
| Administrative Support | 1 | 2 |
| Other *(please write below)* | 1 | 2 |
| | | |

**Section 3 Process for Assessing Cases for inclusion in the review**

**Q3. How many case files were examined due to calls to helplines/complaints system**
*(please write number)*

**Q4. How many cases have been forwarded to the miscarriage miscarriage diagnosis review team?**
*(please write number)*

**Q5.**

| **What clinicians/professionals examined cases and determined if a misdiagnosis of miscarriage was made?** | **Yes** | **No** |
|---|---|---|
| Senior Hospital Manager/CEO | 1 | 2 |
| Hospital Clinical Director | 1 | 2 |
| Consultant Obstetrician/Gynaecologist | 1 | 2 |
| Clinical Nurse/Midwife Specialist | 1 | 2 |
| Director of midwifery | 1 | 2 |
| Quality & Safety Manager/Patient Liaison | 1 | 2 |
| Risk Manager/Advisor | 1 | 2 |
| Complaints Officer | 1 | 2 |
| Medical Records Officer | 1 | 2 |
| Administrative Support | 1 | 2 |
| Other *(please write below)* | 1 | 2 |
| | | |

**Q6. What patient files were reviewed as a results of calls to helplines etc?** *(please circle)*
*1 = yes*
*2= no*

| | Yes | No |
|---|---|---|
| Queried miscarriage cases that occurred within the last 5 years | 1 | 2 |
| Queried miscarriage cases that occurred outside the last 5 years | 1 | 2 |

**Q7. What results were examined within case files to determine if a diagnosis of miscarriage was incorrectly made?** *(please circle)*
*1 = yes*
*2= no*
*3= not available*

| Results | Yes | No | Not available |
|---|---|---|---|
| Transvaginal ultrasound results | 1 | 2 | 3 |
| Transobdominal ultrasound results | 1 | 2 | 3 |
| Selective serum human chorionic gonadotrophin (hCG) results | 1 | 2 | 3 |
| Rhesus antibody test results | 1 | 2 | 3 |
| Progesterone estimation results | 1 | 2 | 3 |
| Other, please write details | 1 | 2 | N/A |

***! Please forward any supporting documents related to the examination of files***

**Section 3 Process for Assessing Cases for inclusion in the review contd.**

**Q8. What was the internal process followed where it was not clear from the evidence within the case file if a case should be referred to the review team or not (please write brief details, or attach supporting documents)**

**Q9. Where there was insufficient evidence to determine if a misdiagnosis was made, were such cases referred to the review team?** *(please circle)*

| | |
|---|---|
| **Yes** | 1 |
| **No** | 2 |

**Section 4 Response, Support & Follow-up Provided to Callers to Helplines**

**Q7. What type of support & follow-up was offered to patients who made calls to the hospital helpines or came through the complaints process, but did not meet the definition of a diagnosis of miscarriage?** *(please circle all that apply) 1 = yes, 2= no*

| Clinician/Professional Support/Follow-up for Patients | Yes | No |
|---|---|---|
| Consultant Obstetrician/Gynaecologist support/follow-up | 1 | 2 |
| Clinical Nurse/Midwife Specialist support/follow-up | 1 | 2 |
| Bereavement specialist/GP liaison nurse | 1 | 2 |
| Chaplain | 1 | 2 |
| Onsite counselling | 1 | 2 |
| Offsite counselling | 1 | 2 |
| GP support/follow-up | 1 | 2 |
| If other, please write below | 1 | 2 |

**Section 4 – Additional Information**
Please provide any additional details or comments you would like to bring to the attention of the miscarriage misdiagnosis incident review team. Comments can be written in the section below or attached as a separate piece.

**This form and any reports attached has been compiled by:**

_____ Date / /
**Hospital Manager/CEO (or equivalent)**

Please forward completed forms with signature of Hospital manager/CEO for the attention of the relevant Regional Director of Operations (RDO), HSE **Friday, 9th of July, 2010.**

**Thank you. The Miscarriage Misdiagnosis Incident Review Team.**

**REVIEW OF MISCARRIAGE MISDIAGNOSIS**
**CASE QUESTIONNAIRE 4**

**CLINICAL REVIEW OF MISCARRIAGE MISDIAGNOSIS: DETAILED CASE QUESTIONNAIRE (4)**

| Review Identifier | MRN/Patients Record Number | DOB | Year of Misdiagnosis |
|---|---|---|---|

- To be completed by a consultant obstetrician
- Co-signed by local operational manager & clinical director (or their equivalents)
- Where free text is required, **PLEASE TYPE RESPONSES OR USE BLOCK CAPITALS**
- All Information provided is strictly confidential to this review.
- Please ensure all sections are completed.
- No patient or staff (job titles should be used) identifiers to be included either within this questionnaire or as part of attachments
- All questions in this questionnaire relate to the **year of the misdiagnosis** incident (not current practices etc.) and will be reviewed in this context

**Section 1: General Patient Information/Case History**

**Q1 Please write day, week & time of presentation**

| Day (mon, tues etc.) | Time (00.00hrs) | Month |
|---|---|---|
| | | |

**Q4. How many weeks gestation from start of last menstrual period had elapsed when a misdiagnosis of miscarriage was made?**
*(please write no. of weeks)*

| | |
|---|---|
| | |

**Q2. Number of previous Live births to patient**
*(please circle number)*

| 0 | 1 | 2 | 3 | 4 | 5 | Other |
|---|---|---|---|---|---|---|
| | 6 | 7 | 8 | 9 | 10 | |
| | | | | | Not known | 99 |

**Q5. Number of previous Miscarriages to patient**
*(please circle number)*

| 0 | 1 | 2 | 3 | 4 | 5 | Other |
|---|---|---|---|---|---|---|
| | 6 | 7 | 8 | 9 | 10 | |
| | | | | | Not known | 99 |

**Q7. Number of previous Still births to patient**
*(please circle number)*

| 0 | 1 | 2 | 3 | 4 | 5 | Other |
|---|---|---|---|---|---|---|
| | 6 | 7 | 8 | 9 | 10 | |
| | | | | | Not known | 99 |

**Q3. What department did the patient present to?**
*(please circle)*

| | |
|---|---|
| EPAU | 1 |
| Emergency Department | 2 |
| Gynaecology Dept. | 3 |
| If other please write | 4 |

**Q6. What department was the misdiagnosis made in?**
*(please circle)*

| | |
|---|---|
| EPAU | 1 |
| ED | 2 |
| Gynaecology Dept. | 3 |
| If other please write | 4 |

**SECTION 1: GENERAL PATIENT INFORMATION/CASE HISTORY CONTINUED**

**Q8. What level of clinician made the misdiagnosis of miscarriage?**
*(please circle)*

| | |
|---|---|
| NCHD/SHO | 1 |
| Registrar | 2 |
| Specialist Registrar | 3 |
| Consultant | 4 |
| If other please write | |

**Q9 Did this clinician have formal training in miscarriage misdiagnosis? If so, please give details**

**Q10. Was an internal examination performed?**

| Day | Time (00.00hrs) | Month |
|---|---|---|
| | | |

**SECTION 2: DETAILS OF PATIENTS 1ST SCAN/ULTRASOUND**

**Q.11 Why was 1st scan performed?**
*(please circle)*

| | |
|---|---|
| Clinically Indicated | 1 |
| Performed at Patients Request | 2 |

If other, please write

**Q.12. What scans were performed on patient?**
*(please circle all that apply)*

| | |
|---|---|
| Transabdominal | 1 |
| Transvaginal | 2 |
| If other, please write | 3 |

**Q.13 What symptoms did patient present at 1st scan?**
*(please circle all that apply)*

| | |
|---|---|
| Bleeding PV | 1 |
| Pains. | 2 |
| None | 3 |

**If others please write**

**Q.14. Who performed this scan?**
***Grade of Individual***

***Years Post Qualification***
*Experience of working in an Early pregnancy Unit*

**Q14a When was the scan performed? (please write)**

| Day | Time (00.00hrs) | Month |
|---|---|---|
| | | |

**Q15. What was the make, model & year of purchase of scanning equipment used for the 1st scan?**
*(please write)*
**Make**
**Model**
Year Purchased

| | | | |
|---|---|---|---|
| | | | |

**PLEASE ATTACH MAINTENANCE HISTORY/SERVICE DETAILS**

**Q16 Was a formal report generated for the 1st scan?**

| | | |
|---|---|---|
| Yes | 1 | **IF YES, PLEASE ATTACH SCAN REPORT TO THIS QUESTIONNAIRE** |
| No | 2 | |

**Q17 Were scan images recorded?**

| | | |
|---|---|---|
| Yes | 1 | **! IF YES, PLEASE ATTACH SCAN IMAGES REPORT TO THIS QUESTIONNAIRE** |
| No | 2 | |

**Q18 Was this scan carried out according to Royal College of Obstetricians and Gynaecologists / Royal College of Radiologists guidelines for performing ultrasound in early pregnancy?**

| | |
|---|---|
| Yes | 1 |
| No | 2 |

**Q18aWere the results of the scan, blood and urine tests discussed with a Consultant Obstetrician**

| | |
|---|---|
| Yes | 1 |
| No | 2 |

**SECTION 3: DETAILS OF PATIENTS 2ND SCAN/ULTRASOUND**

**Q19 Was a 2nd scan performed?**

**Q19a If yes to Q20, Why was a 2nd scan performed?** *(please circle)*

| | |
|---|---|
| Clinically Indicated | 1 |
| Performed at Patients Request | 2 |
| If other, please write | |

**Q.20. What scans were performed on patient?** *(please circle all that apply)*

| | |
|---|---|
| Transabdominal | 1 |
| Transvaginal | 2 |
| If other, please write | 3 |

**Q.21. What symptoms did patient present at 2nd scan?** *(please circle all that apply)*

| | |
|---|---|
| Bleeding PV | 1 |
| Pains. | 2 |
| None | 3 |

**Q.22. Who performed this 2nd scan?**
***Grade of Individual***

***Years Post Qualification***
*i.e. experience in performing ultrasound scans in early pregnancy*

**Q22a When was the scan performed? (please write)**

| Day | Time (00.00hrs) | Month |
|---|---|---|
| | | |

**Q23. What was the make, model & year of purchase of scanning equipment was used at 2nd scan?** *(please write)*

**Make**
**Model**

Year Purchased

| | | | |
|---|---|---|---|
| | | | |

**PLEASE ATTACH MAINTENANCE HISTORY/SERVICE DETAILS**

**Q24 Was a formal report generated?**

| | | |
|---|---|---|
| Yes | 1 | **IF YES, PLEASE ATTACH SCAN REPORT TO THIS RETURN** |
| No | 2 | |

**Q25 Were 2nd scan images recorded?**

| | | |
|---|---|---|
| Yes | 1 | **IF YES, PLEASE ATTACH SCAN IMAGES REPORT TO THIS RETURN** |
| No | 2 | |

**Q26 Was this 2nd scan carried out according to RCOG guidelines?**

| | |
|---|---|
| Yes | 1 |
| No | 2 |

**SECTION 4: DISCUSSION OF 1ST OR 2ND SCAN RESULTS WITH PATIENT**

**Q27. Were the results of the 1ST AND/OR 2ND SCANS discussed with the patient? If so, please outline the content of this discussion, including the advice given to the patient.**

**Section 5 : Other Medical Interventions**

**Q28. Was patient prescribed Misoprostol (Cytotec©) or a similar drug? (***please circle)*

| | |
|---|---|
| **Yes** | 1 |
| **No** | 2 |

**28a What department was this prescribed in?**

**Q28b When was this prescribed? (please write)**

| Day | Time (00.00hrs) | Month |
|---|---|---|
| | | |

**Q29. If Misoprostol (Cytotec©) was prescribed, who prescribed it?** *(please write)*

***Q29 a Grade of Individual***

***Q29 b Years Post Qualification***

**Q30. If Misoprostol (Cytotec©) was prescribed, please indicate the outcome?** *(please circle)*

| | |
|---|---|
| Cytotec© prescribed & taken | 1 |
| Cytotec© prescribed, but not taken | 2 |
| If other, please write: | 3 |

**Q31 . Was ERPC advised?** *(please circle)*

| | |
|---|---|
| **Yes** | 1 |
| **No** | 2 |

**31a What department was this advised in?**

**Q31b When was this advised? (please write)**

| Day | Time (00.00hrs) | Month |
|---|---|---|
| | | |

**Q32. If ERPC was advised, whom advised it?** *(please write)*

***Q32 a Grade of Individual***

***Q32 b Years Post Qualification***

**Q33. If ERPC was advised, please indicate the outcome?** *(please circle)*

| | |
|---|---|
| EPRC conducted | 1 |
| EPRC not conducted | 2 |
| If other, *please write* | 3 |

**Q34Did this patient have a urinary HCG blood test?**
*(please circle)*

| | |
|---|---|
| Yes | 1 |
| No | 2 |

**If yes,**

| What department | Time (00.00hrs) | Day of week | Month |
|---|---|---|---|
| | | | |

**Q35. Was same day reporting of HCG blood tests available at your hospital at the time of this miscarriage misdiagnosis?** *(please circle)*

| | |
|---|---|
| Yes | 1 |
| No | 2 |

**When were results available?**

**Q36. If given, what was the result of the Beta HCG blood test?** *(please circle)*

| | |
|---|---|
| 5 units | 1 |
| 10 units | 2 |
| 25 units | 3 |
| Not known | 4 |
| If other, please write | 5 |

**PLEASE ATTACH ANY HCG BLOOD TEST RESULTS IF AVAILABLE (WITH NAMES REDACTED)**

**Section 6: Pregnancy & Outcome**

**Q.37 Was a baby delivered?**

| | |
|---|---|
| **Yes** | 1 |
| **No** | 2 |

**Q38. What was the gestation (in weeks) at delivery?** *(please write no. of weeks)*

| | |
|---|---|
| | |

**Q39. Were there pregnancy Complications?**

*(please circle)*

| | |
|---|---|
| **Yes** | 1 |
| **No** | 2 |

If yes please give brief details

**Q.40. If a pregnancy continued what was the birth weight?** *(please circle)*

| | |
|---|---|
| < 500g | 1 |
| 501g – 1500g | 2 |
| | |
| 1501g – 2499g | 3 |
| ≥ 2500g | 4 |

**Q41. Were there congenital Malformations/abnormalities?** *(please circle)*

| | |
|---|---|
| **Yes** | 1 |
| **No** | 2 |

**If yes, please give brief details**

**Section 7: Supports provided to this patient following a misdiagnosis of miscarriage**

**Q.42. What type of supports were offered within your hospital at the time of the discovery of the miscarriage misdiagnosis?** *(please write)*

**Q43. What type of support was offered to this patient?** *(please write)*

**Section 8 Background Information for the OBGYN Department at the Time of the Misdiagnosis of Miscarriage**

Please provide the following details for your service at the time of this Misdiagnosis of Miscarriage

| Q 44 | Item | Details |
|---|---|---|
| **1** | Number of attendees to the OBGYN department in **YEAR** | |
| | Number of scans done per year in OBGYN department in **YEAR** | |
| **3** | Number of scans done per year in EPAU department (if EPAU was in place in **YEAR** | |
| **3** | Numbers of miscarriages per year in **YEAR** | |
| **4** | Number of queried miscarriages per year | |
| **5** | Was there an EPAU in place in your hospital in **YEAR** If yes, please give details. | |
| **5a** | Was there an EPAU in place in your hospital in **YEAR** If yes, please give details.<br>Opening Times<br>Staffing Levels | |
| **5b** | Accreditation & Training Provided to Staff in EPAU at time of miscarriage misdiagnosis incident | |
| **5c** | How do patients access the Unit i.e. self referral, GP referral | |
| **5d** | Has the Early Pregnancy Unit access to a trained sonographer? | |
| **5e** | Has the Unit access to the use of Transabdominal and Transvaginal ultrasound | |
| **5f** | Are formal reports of ultrasound in line with the proposal of the Joint Working Party of the Royal College of Radiologist and the Royal College of Obstetricians and Gynaecologist | |
| **5g** | Are ultrasounds carried out in line with the British Medical Ultrasound Society recommendations? | |
| **5h** | Has the EPAS developed diagnostic and therapeutic algorithms of care? If yes please give details | |
| **5I** | What standard blood and urine tests are carried out on Patients who attend the EPAU | |
| **5J** | Is the EPAU located in a dedicated area i.e. is it located in OPD , on a Maternity Ward or a stand alone unit | |
| **5K** | What mandatory training is provided to ensure that staff are competent to carry out their role safely in the EPAU | |
| **5L** | Is there a register that is continuously maintained of the personnel considered to be adequately trained and experienced in obstetric ultrasound | |
| **5M** | Is an ultrasound performed on women who area suspected of early pregnancy loss within 24 hours of admission | |
| **5N** | Are results of Serum HCG available to clinicians within 24 hours of being taken | |
| **5O** | Are women with confirmed missed or incomplete miscarriage offered a choice of surgical, medical and expectant management options | |

| Section 9: Clinical Governance & Incident Reporting<br>Arrangements in Place at time of Miscarriage Misdiagnosis in YEAR<br>Please Provide the following details for your service at the time of this miscarriage misdiagnosis in YEAR | | |
|---|---|---|
| **Q 46** | **Item** | **Details** |
| **1** | Was formal incident reporting in place in your hospital in **YEAR**? | |
| **2** | Were any incidents of miscarriage misdiagnosis reported by your hospital in **YEAR**? | |
| **3** | Who would have signed off the management of incidents of miscarriage misdiagnosis in **YEAR**? | |
| **4** | Was your department auditing your practice against RCOG guidelines on the management of early pregnancy loss in **YEAR**? | |
| **5** | Does your department currently audit your practice against RCOG guidelines on the management of early pregnancy loss? (please write details) | |

**Section 10: Check List of Attachments**

**Please ensure that all attachments/additional information requested by the review team are included with this questionnaire.**

**** to ensure patient confidentiality patient names should be redacted on all attachments supplied to the clinical review team****

| No | Item | Please Tick |
|---|---|---|
| **1** | Service History of Machine Used for 1st Scan | |
| **2** | Service History of Machine Used for 2nd Scan | |
| **3** | Copies of any formal scan reports – with names redacted | |
| **4** | Copies of any scan images – with names redacted | |
| **5** | HCG Blood Test Results | |

**Section 11 Required Signatures**

Signature 1_____ Date / /
**(Consultant Obstetrician)**

Signature 2_____ Date / /
**Hospital/Service Clinical Director (or equivalent)**

Signature 3_____ Date / /
**Hospital Operational Manager (or equivalent)**

Please forward completed forms with three signatures for the attention of the relevant Regional Director of Operations (RDO), HSE.

PLEASE RETURN THIS QUESTIONNAIRE NO LATER THAN **WEDNESDAY THE 25TH OF AUGUST 2010**

**Thank you. Professor William Ledger, Chair, on behalf of the Miscarriage Misdiagnosis Clinical Review Team.**

**APPENDIX C**

**SYSTEMS ANALYSIS**

A systems analysis investigation is a structured investigation that aims to identify the systems cause(s) of an incident or complaint and the actions necessary to eliminate the recurrence of the incident or complaint or where this is not possible to reduce the likelihood of recurrence of such an incident or complaint as far as possible.

Healthcare services carry out incident investigations using systems analysis to find out what happened, how it happened, why it happened, what the organisation can learn from the incident and what changes the organisation should make to prevent it happening again.

A Systems Analysis investigation looks at all aspects surrounding the incident or complaint including:

- The service user involved e.g. was their medical condition complex/unusual?
- The ward and environment.
- The reliability of equipment used.
- Staffing numbers.
- The reliability of the policies and procedures in place.
- Whether the organisation had adequately supported staff through appropriate education and training.

Systems Analysis investigations help to identify those factors in healthcare systems that contributed to the incident or complaint. They should identify systems problems/deficiencies, prioritise resources, ensure that lessons are learned, improve safety and by doing this to improve the quality of services.

A key element in the development of a robust governance structure in any organisation is the ability of that organisation to learn from adverse incidents, near misses and complaints.

It is generally accepted that systems or root cause analysis is the most effective tool for the investigation of incidents, near misses and complaints occurring in healthcare.

Taylor-Adams et al., (2006) describe systems analysis as the process used to ensure a comprehensive and thoughtful investigation of an incident, going beyond the more usual identification of fault and blame. They are clear that the approach does not supplant clinical expertise or deny the importance of the reflections of individual clinicians on an incident. Rather the aim is to utilise clinical experience and expertise to the fullest extent. The approach assists the reflective investigation because:

- While it is sometimes straightforward to identify a particular action or omission as the immediate cause of an incident, closer analysis usually reveals a series of events leading up to an adverse outcome. The identification of an obvious departure from good practice is usually only the first step of an investigation
- A structured and systematic approach means that the ground to be covered in any investigation is, to a significant event, already mapped out.
- If a consistent approach to investigation is used, members of staff who are interviewed will find the process less threatening than traditional unstructured approaches
- The methods used are designed to promote a greater climate of openness and to move away from finger pointing and the routine assignation and blame (Taylor et al., 2006)

The HSE's Toolkit of Documentation to Support the Health Service Executive Incident Management (2009) states that the HSE has adopted systems analysis as the method for investigating incidents 'as it is an accepted method of the effective identification of the systems causes of incidents' and because the methodology is 'designed to promote a greater climate of openness and (a) move away from individual blame towards systemic analysis which assists in identifying solutions that are long term and not just a 'quick fix'.'

On the basis that systems analysis investigations undertaken should assist in the identification of long term and systemic recommendations to address issues identified during investigation(s) of incidents in healthcare organisations; the Miscarriage Misdiagnosis Review Team requested that those hospitals that had recorded incidents of miscarriage misdiagnosis that fell within the Terms of Reference for the review submitted their investigation reports to the Review Team to be considered as part of the overall review process.

**METHODOLOGY FOR REVIEW OF HOSPITAL SYSTEMS ANALYSIS REPORTS**

Each of the hospital systems analysis investigation reports were read and assessed to determine the overall consistency with systems analysis methodology. In order to determine the level of consistency in report writing, structure and content, each of the reports was assessed against the recommendations contained in the Toolkit of Documentation to support HSE Incident Management (March 2009) i.e. HSE Guidance for Systems Analysis Investigation Reports.

The Toolkit document recommends that systems analysis reports should contain the following elements:

- Title Page
- Table of Contents
- Background – concise summary of
- Circumstances surrounding incident
- Purpose of the investigation
- Scope of the investigation
- Investigation Team
- Investigation Review Method
- Sources of Information
- Chronology or Sequence of Events
- Aftermath of Incident
- Contributory Factors / Issues Highlighted
- Care Delivery Problems identified
- Analysis of Findings
- Recommendations
- Action Plans
- Appendices
- Terms of Reference
- Names of contributors / team members etc

(Ref: Toolkit of Documentation to Support HSE Incident Management, March 2009.)

Note: This list of contents was used as 'guidance' only as the clinical review team recognised that hospitals might have their own template reports for recording the information collated during the investigation of the incident(s).

- The Contributory Factors identified in each of the reports were examined to identify patterns and trends
- The recommendations for systems improvements highlighted as a result of the investigation(s) conducted were examined to identify patterns and trends

Systems analysis investigation generally utilises the following classification framework to identify those factors which contributed to the development of the Care Delivery Problem(s) (CDPs) which resulted in the eventual adverse outcome experienced by the service user/service user. Care Delivery Problems are defined as problems that arise in the process of care, usually through actions or omissions by employees. Several Care Delivery Problems can be involved in one incident.

CDPs have two essential features:

- care deviated beyond safe limits of practice
- the deviation had at least a potential direct or indirect effect on the eventual adverse outcome for the service user

**Contributory Factors Framework:**

- Service user/Service User Factors - complexity and seriousness of service user/service user condition; language and communication; personality and social factors; psychological, existing mental health condition, stress.

- Task and Technology Factors - task design and clarity of structure; availability and use of protocols, policies, standards; protocols, standards, policies etc. are relevant, unambiguous, correct and realistic; availability and accuracy of test results and decision-making aids.

- Individual (Staff) Factors - knowledge and skills; competence – education, training, supervision; physical, psychological and mental health illness.

- Team Factors - verbal communication; written communication; supervision and seeking help; team structure e.g. leadership, congruence, consistency etc.

- Work Environmental Factors - staffing levels and skills mix; workload and shift patterns; administrative and managerial support; physical and cognitive environment; design, availability and maintenance of equipment.

- Organisational and Management Factors - organisational structure; financial resources and constraints; policy, standards and goals; quality and safety culture and priorities.

- Institutional Context Factors - economic and regulatory context; national Health Service Executive; links with external organisations.

## APPENDIX D - GUIDELINES FOR CLINICAL AUDIT

1. All trainees who perform early pregnancy ultrasound should provide evidence of completion of relevant training and maintain a logbook of cases performed by them.

2. All non-training grade doctors should provide an up-to-date log of early pregnancy ultrasound scans and evidence of completion of relevant training with attendance at an ultrasound course within the last five years.

3. All hospitals that provide care to women in early pregnancy should have a dedicated EPAU which meets the quality standards detailed in this report

4. All ultrasound machines should have a full service history and evidence of a quality assessment if over 5 years old.

5. Cases in which medical or surgical intervention for management of miscarriage has been undertaken, in which diagnosis has been made with ultrasound below eight weeks gestation, should have been approved by a Senior Obstetrician

6. Prescription of Misoprostol should be approved by a Senior Obstetrician

7. Surgical evacuation of the uterus for miscarriage should have been approved by a Senior Obstetrician

8. Laparoscopy for investigation of suspected ectopic pregnancy should not usually involve instrumentation of the uterus.

**APPENDIX E**

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