

FINAL REPORT

Investigation of Incident 50278 from time of patient's self referral to hospital on the 21st of October 2012 to the patient's death on the 28th of October, 2012.

Investigation Commencement and Completion Dates
--

Details of this investigation including the terms of reference overseen by an Independent External Chair were agreed on Monday 19 th of November, 2012.
--

Investigation Completed 7 th of June 2013
--

JUNE 2013

Contents

	Page
Foreword	4
Acknowledgement	7
Glossary of Terms	8
Executive Summary	11
Methodology	19
Section 1 Background to the Investigation	21
Section 2 Chronology of Events	22
Section 3 Aftermath of Incident	54
Section 4 Key Causal Factors, contributory factors, incidental factors and linked recommendations.	55
References	82
Appendix A: Summary Outline of the legal position in Ireland with respect to the regulation of the termination of pregnancy and, in particular, as regards the protection of the right to life of the pregnant woman and of the unborn.	85
Appendix B: Terms of Reference	97
Appendix C :Interim recommendations conveyed to hospital	99
Appendix D: Sources of Information Reviewed by the Investigation Team	101
Appendix E: Framework of Contributory Factors	103
Appendix F: Patient Observation Scores (<i>transposed by the investigation team onto the modified obstetric early warning score chart not in use at the time for pregnant women on the gynaecology ward</i>)	104

Foreword

This investigation undertook to provide a methodical, accurate and impartial report on the events which took place between the 21st of October and the 28th of October, 2012 relating to this tragic maternal death which had a devastating affect on the patient's husband and her family. The staff who cared for this patient were also deeply saddened by the patient's tragic and untimely death. The investigation team established that this was the first direct maternal death¹ to have occurred at the hospital in 16 years. 51,440 births were recorded at the hospital from the time in 1996 when the last direct maternal death occurred - to December 2012.

We set out to be thorough in our approach and to establish if any aspect of the care this patient received may have contributed to this maternal death and if so, to identify the key causal and contributory factors. We also set out to make any necessary recommendations for hospital and national level, to address any contributory factors or causes identified so as to prevent future harm arising from these causes and to improve the safety of services for future service users.

A post-mortem examination was performed on the 30th of October, 2012. The cause of death established by the Coroner's Inquest in this case in April, 2013 was:

- “1(a) Fulminant septic shock from E. coli bacteremia.*
- 1(b) Ascending genital tract sepsis.*
- 1(c) Miscarriage at 17 weeks gestation associated with chorioamnionitis.*
- (2) There were no co-morbidities”.*

Sepsis is a common cause of death in the general population. In the United States, sepsis contributes to more than 200, 000 deaths per year. Sepsis is also the most common cause of maternal mortality identified in the UK Centre for Maternal and Child Enquiry (CMACE) 2006-2008 report (2011).

Sepsis is a systemic illness that complicates severe infection which is caused by the invasion and multiplication of microbes in normally sterile sites in the body. Sepsis causes a systemic inflammatory response with evidence or suspicion (pending the results of tests) of an underlying infection. When accompanied by evidence of organ/tissue hypoperfusion or dysfunction, sepsis becomes severe sepsis. When severe sepsis is accompanied by hypotension (low blood pressure) despite adequate fluid resuscitation, a patient is considered to have septic shock. Progression from sepsis to severe sepsis to septic shock can occur within hours and correlates with increasing mortality. Early diagnosis and management is essential to reduce the mortality rate.

Sepsis is difficult to diagnose in pregnancy due to the associated natural physiological changes and this calls for efficient assessment and monitoring of the patient by the clinical team to enable them to promptly recognise and respond to the signs of infection and clinical deterioration.

¹ A maternal death is defined within the UK Confidential Enquiry as: “Deaths of women while pregnant or within 42 days of the end of the pregnancy from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes”. Maternal deaths are subdivided into four further groups, including direct maternal deaths. Direct maternal deaths are those that result from obstetric complications of the pregnant state (pregnancy, labour and puerperium), from interventions, omissions, incorrect treatment or from a chain of events resulting from any of the above (classification 8 of the ninth revision of the International Classification of Diseases, Injuries and Causes of Death).

Our investigation established that hospital guidance assumes four-hour monitoring of patient observations for patients with premature rupture of membranes. However, in this case monitoring of the patient who had prolonged rupture of membranes was less frequent (See Appendix F). There was inadequate assessment and monitoring that would have enabled the clinical team to recognise and respond to the signs that the patient's condition was deteriorating due to infection, together with non adherence to guidelines for the prompt and effective management of sepsis, severe sepsis and septic shock when it was suspected or diagnosed. The modified Obstetric Early Warning Score (mOEWS) observation chart was not in use in some hospitals at the time of this incident for pregnant women on gynaecology wards.

We considered that the patient's condition involved prolonged rupture of membranes, which is associated with increasing risk of infection with the progress of time. In this case, the patient's condition was rare and serious. There was a lack of recognition of the gravity of the situation and of the increasing risk to the mother which led to passive approaches and delays in aggressive treatment.

This appears to have been either due to the way the law was interpreted in dealing with the case or the lack of appreciation of the increasing risk to the mother and the earlier need for delivery of the fetus.

When the patient and her husband enquired about the possibility of having a termination, this was not offered or considered possible by the clinical team until the afternoon of the 24th of October due to their assessment of the legal context in which their clinical professional judgement was to be exercised. The Irish constitution Article 40.3.3 (as inserted by the eight amendment in 1983) states that: *'the state acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right'* (See Appendix A for a summary outline of the legal position in Ireland with respect to the regulation of the termination of pregnancy and, in particular, as regards the protection of the right to life of the pregnant woman and of the unborn).

From the time of her admission, up to the morning of the 24th of October - the clinical management plan for the patient centred on the approach to "await events" and to monitor the fetal heart in case an accelerated delivery might be possible once the fetal heart stopped. Awaiting events is clinically appropriate provided it is not a risk to the mother or the fetus.

Appropriate monitoring and evaluation of the changing clinical presentation with appropriate clinical investigations would likely have led to reconsideration of the need to expedite delivery. Monitoring and adherence to guidelines for the prompt and effective management of sepsis would likely have helped to prevent rapid deterioration of the patient.

Delaying adequate treatment including expediting delivery in a clinical situation where there is prolonged rupture of the membranes and increasing risk to the mother can, on occasion, be fatal.

The investigation team is aware that clinical circumstances can and have arisen in Ireland where a termination of pregnancy is an appropriate and necessary clinical step in the medical treatment and care of a patient. In this regard the investigation team notes the evidence which was given to the Oireachtas Joint Committee on Health and Children to discuss the implementation of the Government decision following the publication of the

expert group report on matters relating to the case A, B and C v. Ireland on the 8th of January, 2013.²

We strongly recommend and advise the clinical professional community, health and social care regulators and the Oireachtas to consider the law including any necessary constitutional change and related administrative, legal and clinical guidelines in relation to the management of inevitable miscarriage in the early second trimester of a pregnancy including with prolonged rupture of membranes and where the risk to the mother increases with time from the time that membranes are ruptured including the risk of infection and thereby reduce risk of harm up to and including death. These guidelines should include good practice guidelines in relation to expediting delivery for clinical reasons. We recommend the use of the mOEWS, or a nationally agreed equivalent, for such patients, along with mandatory induction and continuous education of staff on the recognition, monitoring and management of infection, sepsis, severe sepsis and septic shock. We emphasise that early warning score charts cannot replace professional clinical judgement and the importance of considering the entire clinical context. mOEWS are useful to assist and focus multidisciplinary care teams on potential derangement of physiology and act to alert, not diagnose.

We are hopeful that prompt consideration and early implementation of the recommendations of this investigation will go some way to enhance the safety of Irish maternity services for women in the future and reduce the risk of harm up to and including death.

In the course of the preparation of the report, we have noted the intention of the HSE to offer an apology to the late patient's family. We would like to extend our sympathies to the family.

**Sir Sabaratnam Arulkumaran,
Professor Emeritus of Obstetrics and Gynaecology,
St. George's University of London,
External Independent Chairperson
JUNE 2013**

² Source

(<http://oireachtasdebates.oireachtas.ie/Debates%20Authoring/DebatesWebPack.nsf/committeetakes/HEJ2013010800002?opendocument>)

Acknowledgement

It was evident at interviews with employees who cared for this patient that they were deeply saddened and shocked by the patient's tragic and untimely death. Some interviewees had experienced verbal abuse and / or had received abusive correspondence from the public in the aftermath of this event. The investigation team is aware that the hospital put in place supports and services to support employees through this difficult time. The investigation team believes that the hospital cooperated fully with this investigation and we thank them for their contribution to the process, and recognise that it was made in extremely sad and difficult circumstances.

Glossary of Terms

(O)EWS	(Obstetric) Early Warning Score
ARDS	Acute Respiratory Distress Syndrome.
BMI	Body Mass Index
BP	Blood Pressure
BST	Basic Specialist Trainee
C&S	Culture and Sensitivity
Cerclage	Stitch around the cervix in an attempt to close it and keep it closed to prevent miscarriage or preterm delivery.
Chorioamnionitis	Chorioamnionitis is a condition that can affect pregnant women. In this condition, bacteria infects the chorion and amnion (the membranes that surround the fetus) and the amniotic fluid (in which the fetus floats). This can lead to infections in both the mother and fetus.
CMM	Clinical Midwife Manager
CNM	Clinical Nurse Manager
Coliform(s)	Coliform(s) is a term often applied to a broad group of Gram negative bacilli before they are fully identified to species level by the Microbiology laboratory.
CRP	C-Reactive Protein, a measure of inflammation
<i>E. coli</i>	<i>E. coli (Escherichia coli)</i> is one of several types of Gram negative bacilli bacteria that normally inhabit the intestine of humans. Some strains of <i>E. coli</i> are capable of causing disease under certain conditions.
ECG	Electrocardiogram
EEG	Electroencephalogram
ESBL	Extended-Spectrum Beta-Lactamases ESBL-producing bacteria are bacteria that produce enzymes that may break down commonly used antibiotics.
FH	Fetal Heart
Gram negative bacilli	Gram negative bacilli are a type of bacteria. The name is derived from a type of staining called Gram staining where these particular bacteria do not retain the stain. This is characteristic of bacteria having a cell wall surface more complex in chemical composition than the gram-positive bacteria.
H1N1	Swine influenza virus
HDU	High Dependency Unit

HR	Heart rate
HSE	Health Service Executive
ICU	Intensive Care Unit
ISBAR	Identify, Situation, Background, Assessment, Recommendation.
Mané	The next morning
Maternal Death	A maternal death is defined within the UK Confidential Enquiry as 'Deaths of women while pregnant or within 42 days of the end of the pregnancy* from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes'. Maternal deaths are sub-divided into four further groups, including direct maternal deaths. Direct maternal deaths are those that result from obstetric complications of the pregnant state (pregnancy, labour and puerperium), from interventions, omissions, incorrect treatment or from a chain of events resulting from any of the above (classification 8 of the ninth revision of the International Classification of Diseases, Injuries and Causes of Death).
MOET	Managing Obstetric Emergencies and Trauma
NIMT	National Incident Management Team
Nocte	At night
O&G	Obstetrics and Gynaecology
O/E	On examination
P	Pulse
PPROM	Preterm Pre-labour Rupture of Membranes
QPSD	Quality & Patient Safety Directorate
R	Registrar
RCOG	Royal College of Obstetricians and Gynaecologists
RM	Registered Midwife
SBAR	Situation, Background, Assessment, Recommendation.
SHO	Senior House Officer
Sonicaid	Hand held ultrasound monitor that is used to detect fetal heart rate
SpR	Specialist Registrar
STAT	Medication given immediately as a single dose

T	Temperature
Vx	Vertex

Executive Summary

Introduction

This investigation was commissioned by the Clinical Director at the Hospital where this tragic maternal death occurred on the 28th of October 2012.

The terms of reference for this investigation are within appendix B of this report. The investigation team considered and accepted the terms of reference for this investigation.

Aim

The terms of reference led the investigation team to form the view that this investigation was to establish the circumstances as to what happened, and whether any aspects of the care of this patient contributed to the untimely and unexpected death of this 31 year old mother following a miscarriage at 17 weeks of gestation. In particular the investigation team sought to focus on a chronology of events leading to this patient's admission to the Intensive Care Unit from the Gynaecology Ward on the 24th of October, 2012. Where aspects of care were considered to have contributed, a further aim was to identify the underlying causes of these so that such causes can be addressed to improve the care given to mothers experiencing miscarriage in maternity hospitals.

Purpose

The purpose of this investigation was to:

- Establish the factual circumstances leading up to the incident³
- Identify any key causal factors that may have occurred
- Identify the contributory factors that may have caused the key causal factors
- Recommend, where necessary, actions that seek to address the contributory factors so that the risk of future harm arising from these factors is eliminated or if this is not possible, is reduced as far as is reasonably practicable.

The investigation was supported by the HSE National Incident Management Team (NIMT). The role of the NIMT is to support and build the capability of local areas to manage and investigate incidents satisfactorily. The NIMT has responsibility for overseeing incident

³ An incident is defined by the HSE Guidelines for Systems Analysis Investigation of Incidents and Complaints (2012) as "An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. (Adapted from WHO (2009) and DoH (2010), HSE Quality and Risk Taxonomy (2009)).

Incidents include **adverse events** which result in harm; and **near-misses** which could have resulted in harm, but did not cause harm, either by chance or timely intervention.

Incidents can be clinical or non-clinical and include incidents associated with harm to:

- our patients, service users, staff and visitors
- the attainment of HSE objectives
- HSE ICT systems
- data security e.g. data protection breaches
- the environment

Incidents include complaints which are associated with harm and as such these complaints are service user reported incidents."

management within the HSE and has authority to directly manage certain serious incidents and to support and quality-assure the management of incidents in line with agreed criteria and international best practice.⁴

Members of the investigation team included:

This investigation team was chaired by a Professor Emeritus of Obstetrics and Gynaecology, St. George's Hospital, University of London who is also President of the International Federation of Obstetrics and Gynaecology and comprised a number of experts in the relevant disciplines; including intensive care, infectious diseases, midwifery, obstetrics and gynaecology, patient representation, and investigation methods.

- Sir Sabaratnam Arulkumaran, Professor Emeritus of Obstetrics and Gynaecology, St. George's Hospital, University of London & President of the International Federation of Obstetrics and Gynaecology (Chairperson)
- Ms Cora McCaughan, National Incident Management Team, HSE Quality and Patient Safety Directorate (Deputy Chairperson)
- Ms. Cathriona Molloy, Service User Advocate, Patient Focus
- Dr. Brian Marsh, Consultant in Intensive Care Medicine, Mater Misericordiae University Hospital, Dublin.
- Ms. Geraldine Keohane, Director of Midwifery, Cork University Hospital
- Professor James Walker, Consultant Obstetrician and Gynaecologist, University of Leeds.
- Prof. Mary Horgan, Consultant in Infectious Diseases, Cork University Hospital and Professor in the School of Medicine, University College Cork.

Ms. Deirdre Coyne, Research Officer, National Incident Management Team, HSE Quality and Patient Safety Directorate, fulfilled the role of Investigation Co-ordinator.

The investigation team sought to complete its work in as timely a manner as was possible.

Under the terms of reference the investigation team was required in the event that any immediate safety concerns arose during the investigation process, that the safety concerns would be conveyed to the commissioner of the investigation as soon as possible. Interim safety recommendations were conveyed to the Commissioner on the 30th of November 2012. At this time, the hospital commenced implementation of these interim safety recommendations. See interim recommendations conveyed to the hospital on 30th of November 2012 in appendix C.

⁴ Examples of patient safety incidents/investigations directly managed by the NIMT include the Review of X-rays in the North East (2008); the Miscarriage Misdiagnosis Review (Published April 2011); The link between H1N1 and Narcolepsy; the Investigation into the incident associated with the transportation of a young patient for transplantation surgery at Kings College Hospital London (Published August 2011); and the DePuy Hip Recall.

Key Causal Factors

Key causal factors are defined by the HSE Guidelines for Systems Analysis Investigation of Incidents and Complaints (HSE, November 2012⁵) as issues that arise during the process of delivering and managing health services that are considered by the investigation team to have had an effect on the eventual adverse outcome. This investigation identified the following 3 key causal factors:

Key Causal Factor 1:

Inadequate assessment and monitoring that would have enabled the clinical team to recognise and respond to the signs that the patient's condition was deteriorating due to infection associated with a failure to devise and follow a plan of care for this patient that was satisfactorily cognisant of the facts that:

- the most likely cause of the patient's inevitable miscarriage was infection and
- the risk of infection and sepsis increased with time following admission and especially following the spontaneous rupture of the patient's membranes.

Key Causal Factor 2:

Failure to offer all management options to a patient experiencing inevitable miscarriage of an early second trimester pregnancy where the risk to the mother increased with time from the time that membranes were ruptured.

Key Causal Factor 3:

Non adherence to clinical guidelines related to the prompt and effective management of sepsis, severe sepsis and septic shock when it was diagnosed.

⁵ Systems analysis is a method of investigating patient safety incidents, based on the "London Protocol" (2004) which involves collection of data from the literature, relevant records, interviews with those involved in delivering care where the incident occurred, and analysis of this data to establish the chronology of events that led up to the incident, and to identify the key causal factors that are considered to have had an effect on the eventual adverse outcome, the contributory factors, and recommended control actions to address the contributory factors to prevent future harm arising as far as is reasonably practicable. The systems analysis method acts as an aid to conducting serious patient safety incident investigations. At the time of the incident with which this investigation is concerned the version of the guidelines for systems analysis investigations were the version in the *"Toolkit of Documentation to Support the Health Services Executive Incident Management"* (HSE 2009). Prior to the decision to establish this investigation team a process of administrative review of these guidelines, in consultation with external systems safety and patient safety experts, service users and staff was concluding. The updated Systems Analysis Guidelines were concluded and adopted on the 18th of November 2012 during the early stages of this investigation and prior to establishing this investigation team. HSE Guidelines of "Systems Analysis Investigation of Incidents and Complaints" (HSE, November 2012) can be downloaded at http://www.hse.ie/eng/about/Who/qualityandpatientsafety/Quality_and_Patient_Safety_Documents/QPSDGL5211.pdf

Recommendations:

The investigation team has made recommendations to address the factors that the investigation team identified as contributing to the key causal factors related to this incident.

The Clinical Director at the hospital where this incident occurred and who is the commissioner of this investigation and senior management at the hospital are responsible for the planning and implementation of the recommendations at that hospital.

At December, 2012, following the initial part of their investigation, the investigation chairperson Sir Arulkumaran and the investigation team members discussed proposed draft recommendations (in isolation of the draft investigation report) with representatives of:

- The Institute of Obstetricians and Gynaecologists
- The Obstetrics and Gynaecology Clinical Care Programme
- The Neonatal Mortality Group The National Perinatal Epidemiology Centre

The HSE established a national implementation steering group in March 2013 to co-ordinate and oversee the implementation of any recommendations made by the investigation team.

In March 2013 the investigation team circulated revised draft recommendations (in isolation of the draft investigation report) of the second draft report for review and feedback to representatives of:

- The National Clinical Programme for Anaesthesia
- The National Clinical Programme for Critical Care
- The National Early Warning Score Project
- The National Office for Nursing and Midwifery Services.
- The Neonatal Mortality Group The National Perinatal Epidemiology Centre
- The Obstetrics and Gynaecology Clinical Care Programme
- The Quality and Patient Safety Directorate

Each representative was asked to review the second draft recommendations and provide feedback to the investigation team in relation to whether the recommendations were appropriate from their organisation's perspective. Specifically, representatives were asked:

- Whether the national recommendations of the second draft report were sufficiently specific, measurable, achievable, and time bound? If not, representatives were asked for their comments to enhance the recommendations
- To provide information about the status of the implementation of any of the recommendations related to their area of responsibility including details of work due to commence, work ongoing and what recommendations were completed.

The investigation team recommends with regard to **recommendation 4b** that the stakeholders would include but would not necessarily be limited to the following:

- An Bord Altranais
- Service User Representatives
- The College of Anaesthetists of Ireland (CAI)
- The Department of Health
- The Institute of Obstetricians and Gynaecologists
- The Medical Council
- The National Clinical Effectiveness Committee
- The National Clinical Programme for Anaesthesia
- The National Clinical Programme for Critical Care

- The National Early Warning Score Project
- The National Office for Nursing and Midwifery Service Director.
- The Neonatal Mortality Group The National Perinatal Epidemiology Centre
- The Obstetrics and Gynaecology Clinical Care Programme
- The Quality and Patient Safety Directorate
- The Joint Faculty of Intensive Care Medicine of Ireland
- The Irish Forum of Postgraduate Medical Training Bodies

Recommendation 1:

Prompt introduction – followed by audit of compliance with - an appropriate Maternity Early Warning Scoring Systems Chart for patients receiving care for pregnancy complications on gynaecology wards. The Maternity Early Warning Scoring System Chart should define a coupled process of monitoring with activation of an escalating nursing, medical and multi-disciplinary response.⁶

Recommendation 2:

Mandatory induction and education of all clinical staff working in obstetrics and gynaecology on the early recognition, monitoring and management of infection, sepsis, severe sepsis, and septic shock in accordance with appropriate clinical guidelines including guidelines for the Management of Suspected Sepsis and Sepsis in Obstetric Care and Antimicrobial Guidelines, and as per the Royal College of Obstetrics and Gynaecology Green-top guidelines on Bacterial sepsis (Green-top Guidelines No 64a April 2010) and as per the chapter on sepsis from the Centre for Maternal and Child Enquiries (CEMACE) ‘ Saving Mothers’ report 2006 - 2008. This induction of staff must highlight the need for early and appropriate involvement of the multidisciplinary team to include an anaesthetist, intensive care specialist, microbiologist, infectious diseases specialist, and other relevant specialists in cases of sepsis or suspected sepsis. This induction should be provided on an appropriately regular basis to address the training needs of nursing /midwifery and medical staff where they change and rotate frequently. There should be regular updating of:

- a) induction programmes and
- b) ongoing and continuing professional education programmes.

⁶ The review team was aware at the time of preparation of this investigation report that twelve of the nineteen maternity units in the country were using a (modified) Obstetric Early Warning Score. The review team is aware that all HSE hospitals providing acute obstetric care have commenced planning and implementation of the Irish Maternity Early Warning System (I-MEWS) that has been developed by the Clinical Care Programme in Obstetrics and Gynaecology. The I-MEWS should be implemented in association with a multidisciplinary educational programme and its use should be audited in all maternity units. The National Early Warning Score (NEWS) will be applied for gynaecological patients and the I-MEWS will be applied for pregnant women and in the immediate postpartum period. A final design of the I-MEWS has been agreed and a training programme has been arranged. It is planned to roll out the I-MEWS during March 2013 and to pilot it for the month of April 2013. After the month of April it is planned to audit its practice for 12 months and to assess whether the sensitivity of the triggers need to be adjusted upwards or downwards. I-MEWS is a tool to assist midwifery staff in the course of their daily clinical practice to identify any deviation from normal and seek early medical advice and treatment from the Obstetrician and/or the Anaesthetist.

Recommendation 3:

The HSE should develop, disseminate and implement national guidelines on infection and pregnancy. The HSE should also develop multidisciplinary educational programmes to improve the quality of care in pregnancies complicated by infection.

Specifically, there is a need for the development, implementation and audit of compliance with guidelines on the management of infection in pregnancy, suspected sepsis and sepsis in cases of inevitable miscarriage of an early second trimester pregnancy including where there is prolonged rupture of membranes and where the risk to the mother increases with time from the time that membranes were ruptured. These guidelines should emphasise the:

- Need to focus appropriate attention on the early detection and management of infection and the prevention and management of sepsis, including vigilant monitoring of the time that has elapsed since the rupture of the membranes and consideration of appropriate antibiotic therapy and management or removal of the source of infection.
- Need for appropriate and early involvement of the multidisciplinary team to include a microbiologist anaesthetist, intensive care specialist, infections diseases specialist and other relevant specialists in cases of sepsis or suspected sepsis.
- Need for clarity about who is responsible for following up, reviewing and acting upon the results of tests ordered.
- Clear pathways for most efficient access to blood gas and lactate testing (preferably at point of care), along with appropriate training.

Recommendation 4a

Develop, implement and audit compliance with guidelines on the management of early second trimester inevitable miscarriage that are cognisant of the possible rapid deterioration of the patient from sepsis to severe sepsis to septic shock which could be within a few hours. These guidelines must also be cognisant of the high mortality rate (up to 60%) associated with this. These guidelines should include but may not necessarily be limited to the following:

- Appropriate monitoring for efficient detection of infection and sepsis as per appropriate clinical guidelines for the Management of Suspected Sepsis and Sepsis in Obstetric Care; and Antimicrobial Guidelines
- Appropriate management that recognises the fact that the risk to the mother increases with time from the time the membranes are ruptured.
- Clarity about who is responsible for following up, reviewing and acting upon the results of tests ordered.
- Clear pathways for most efficient access to blood gas and lactate testing (preferably at point of care), along with appropriate training.

Recommendation 4b.

There is immediate and urgent requirement for a clear statement of the legal context in which clinical professional judgement can be exercised in the best medical welfare interests of patients. There is a parallel immediate requirement for clear and precise national clinical guidelines to meaningfully assist the clinical professionals who have the responsibility, often in circumstance of rapid deterioration or emergency, as to how to exercise their clinical professional judgement in a particular case. We recommend that the clinical professional community, health and social care regulators, and the Oireachtas consider the law including any necessary constitutional change and related administrative, legal and clinical guidelines in relation to the management of inevitable miscarriage in the early second trimester of a pregnancy including with prolonged rupture of membranes and where the risk to the mother increases with time from the time that membranes were ruptured including the risk of infection. These guidelines should include good practice guidelines in relation to expediting delivery for clinical reasons including medical and surgical termination based on available expertise and feasibility consistent with the law.

We recognise that such guidelines must be consistent with applicable law and that the guidance so urged may require legal change.

Recommendation 5

The HSE should implement and audit compliance with improved communication practices between all disciplines and grades of staff, and implement improvements in the handover for acutely ill patients including between staff shifts. Adoption of appropriate definitive communication tools to assist clear and focussed communication of information in relation to the deterioration of a woman's condition, and/or consultation, and/or handover to a higher level of care, such as ISBAR ⁷ (HSE Acute Medicine Programme, 2013) which is a modification of SBAR as recommended within 'Improving patient handover – RCOG Good Practice No 12' (Dec 2010) is recommended.

Recommendation 6

Development, implementation and audit of compliance of guidelines in line with the Royal College of Obstetricians and Gynaecologists Guidelines on the *"Responsibility of the consultant on call"* (RCOG Good Practice No. 8 - March 2009).

These guidelines should clarify the need to call in senior medical staff including consultants if indicated due to difficulty coping with case load or to consult on a suspected serious case. These guidelines should reflect that a midwife/nurse should be able to summon this help from a senior nurse midwifery manager or the Director of Nursing on duty including call the consultant directly as appropriate and as needed.

⁷ ISBAR stands for Identify, Situation, Background, Assessment, Recommendation.

Recommendation to address incidental factor 1

The review team recommends consideration of a national quality assurance programme for obstetrics and gynaecology as an initial step to maintain confidence amongst patients/service users, staff, the public, administrators and regulators and to put into place safe systems before a catastrophe happens. Monthly work loads, clinical outcomes and adverse incidents should be monitored by using a dashboard to include green, amber and red signals to warn of the possibility of impending problems (Ref; Maternity Dashboard: Clinical Performance and Governance Score Card – RCOG Good Practice No. 7 Jan 2008).

Recommendation to address incidental factor 2

Ensure that the psychological impact of inevitable miscarriage is appropriately considered and that a member of staff is available to offer immediate support and information at diagnosis. Members of staff should also advise of the availability of counselling services for women and partners at diagnosis. Care given, including counselling and support, should be documented. The availability of counselling services for women, partners and families who have suffered any incident or bereavement in childbirth should be reviewed, considered and developed as appropriate at each maternity site.

Recommendation to address incidental factor 3

Implement the *HSE Standards and Recommended Practices for Healthcare Records Management V3.0 (May 2011)* and make arrangements for an audit of compliance with this standard (and any subsequent standard) within a six-month timeframe and yearly thereafter.

Methodology

Overview of the Methodology

This investigation was set up pursuant to the provisions of Section 7 of the Health Act, 2004 as amended and followed the HSE Guidelines for Systems Analysis Investigation of Incidents and Complaints (QPSD November 2012⁸). It was conducted in a non-confrontational manner that was cognisant of the rights of all involved to privacy and confidentiality; dignity and respect; due process; and natural and constitutional justice. Systems analysis is a methodical investigation which involves collection of data from the literature, records, interviews with those involved and analysis of this data to establish the chronology of events that lead up to the incident, identifying key causal factors that had an effect on the eventual adverse outcome, the contributory factors and recommendations to address these and to prevent future harm arising as far as is reasonably practicable.

Sources of Information Reviewed by the Investigation Team

The investigation team did not have access to the post mortem results and therefore did not have information about the actual cause of death in this case.

The investigation team visited the obstetrics ward, the labour ward, theatre area and Intensive Care Area where the patient was cared for.

The sources of information reviewed by the investigation team to determine the chronology of events are listed in appendix D.

There are a number of occasions where entries were made in the medical records at a time later than the time that the entry relates to. This is referred to within the chronology section of this investigation report.

Following a review of the healthcare records a total of 26 interviews with key staff involved in the care of this patient were conducted by the investigation team. Initial interviews in person were conducted on the 20th and 21st of November. Additional interviews and second interviews with some staff members were also conducted on 10th - 12th of December. Staff interviewed included:

- Consultant Obstetricians and Gynaecologists
- General Midwifery Staff
- Clinical Midwife Managers 1 and 2
- Senior House Officer (Medical)
- Specialist Registrar (Obstetrics and Gynaecology)
- Consultant Microbiologists
- Consultant in Infectious Diseases with experience in Microbiology
- Consultants in Anaesthesia and Intensive Care Medicine
- Night Sister on duty on the 23rd/24th of October
- Assistant Director of Midwifery/Nursing
- Assistant Director of Nursing for Intensive Care

⁸. HSE Guidelines for A copy of "Systems Analysis Investigation of Incidents and Complaints" (HSE, November 2012 can be downloaded at http://www.hse.ie/eng/about/Who/qualityandpatientsafety/Quality_and_Patient_Safety_Documents/QP_SDGL5211.pdf

In advance of interview, staff were provided with the terms of reference for the investigation and were informed of their entitlement to be accompanied to interview. Prior to interview, staff were also informed of the process for the preparation of the draft report whereby they would have an opportunity to review and comment on/check the factual accuracy of the draft report.

At the suggestion of the Chairperson, the investigation team adopted lines of investigation based on their analysis of the medical records and copies of local, national and international guidance documentation. Analysis of the medical notes provided a draft chronology of events for the investigation team to explore at interview with key staff involved in care of the patient. In particular the investigation team sought to establish the chronology of events and the clinical management of the patient leading to the transfer from the Gynaecology Ward to the Intensive Care Unit in the context of the clinical management of an early second trimester miscarriage, and in the context of the diagnosis and management of sepsis and associated timelines.

All interviews were conducted in person and were an opportunity for the investigation team to seek to confirm the chronology of events compiled following the team's analysis of the medical records and relevant policy and guidance documentation.

The interviews were also an opportunity for staff to provide any information relating to the rationale for the clinical management of the patient and to give information about the clinical care provided that may not have been included in the healthcare records. Where possible, the investigation team asked open ended questions, with staff encouraged to recall their version of the clinical management of the patient including what aspects of care could, with hindsight, be improved should a similar circumstance reoccur.

The investigating team reviewed the medical records, conducted interviews with staff involved and reviewed the local, national and international guidelines (See Appendix D) in an attempt to answer the questions raised by the terms of reference.

The investigation team felt it was important that the patient's husband's account of events be considered as part of the investigation and report. The husband of the patient did not wish to meet with the investigation team chairperson or other members to discuss his account of events, and the investigation team respected the patient's husband's wishes not to be involved in the information gathering process of this investigation.

However, prior to completion of this report and in the aftermath of the verdict of the Coroners' Court members of the investigation team met the legal representative of the deceased's husband and a family friend and considered observations made on their behalf.

The investigation team also reviewed all relevant hospital guidelines, (Irish) National Policy and Guidance Documents, and International/European Policy and Guidance Documents.

In January, 2013, the Health Information and Quality Authority (HIQA) required the HSE pursuant to Section 70 and Section 73 of the Health Act 2007 as amended (the "Act") to provide HIQA with a copy of "Report (draft or otherwise) of the Clinical Review..." and the HSE complied with this request.

Section 1: Background to this Investigation

On the 21st of October 2012 a 31-year woman in her first pregnancy self referred to the gynaecology ward (accompanied by her husband) at 17 weeks of her pregnancy complaining of lower backache radiating to the lower pelvic region for the previous 12 hours.

Clinical examination indicated bulging membranes and no cervix to be felt. In the medical records the diagnosis noted was that of “an inevitable/impending pregnancy loss”. The patient was admitted to the hospital for management of inevitable miscarriage on the 21st of October 2012.

The patient’s membranes spontaneously ruptured at 00.30hrs on the 22nd of October. Her condition deteriorated on the 24th of October and a diagnosis of sepsis secondary to chorioamnionitis was made. She was admitted to the High Dependency Unit (HDU) from the Gynaecology ward at 16.45 hrs on the 24th of October. The patient was post miscarriage at 17 weeks when admitted to the HDU. On admission the patient was noted to be drowsy, but rousable.

During that night there was a clinical deterioration with an increasing oxygen requirement, vasopressor requirement, and worsening metabolic status. The patient was therefore transferred to the Intensive Care Unit (ICU) at 03:00 hrs on October 25th and was intubated and mechanically ventilated at 03:30 hrs on the 25th of October.

The patient’s condition further deteriorated despite appropriate management in the ICU and she sadly passed away at 01.09 hrs on Sunday, the 28th of October 2012.

Section 2: Chronology of Events⁹

Pre-admission

The patient was a 31 year old in her first pregnancy.

On the 17th August 2012, she was referred by her General Practitioner to the Antenatal Clinic for care.

The referral letter completed by the patient's General Practitioner indicates that this was the patient's first pregnancy and that her expected date of delivery was 30th March 2013. No risk factors or past medical problems were noted.

On the 11th of September her antenatal bloods were carried out and results noted on the 21st of September 2012 by the patient's General Practitioner. It was confirmed that the patient's blood group was B Rhesus negative. The result of other blood tests indicated that antibody to HIV and the surface antigen to Hepatitis B were not detected (indicating no evidence of infection with either of these viruses), antibody to *T. pallidum* was not detected and the antibody to rubella virus was not detected (indicating susceptibility to infection with rubella virus).

On 11th of October 2012, the patient attended for her first routine antenatal visit at 15 weeks and 5 days. It was noted that this was an unplanned pregnancy and she was certain of her dates. Past surgical history of Tonsillectomy/adenoids and rubella non-immune. Medications during this pregnancy; folic acid.

At this visit, the patient had a number of assessments carried out which included; a physical examination of her heart and lungs and an examination of her urine. The findings of these examinations were normal. Her height was 1.54 m and she weighed 58.6 Kg giving her a BMI of 24.7. An ultrasound assessment of the fetal size confirmed that the fetal growth was correct for the gestational dates. (15 weeks and 5 days).

The patient's blood pressure at this booking appointment was recorded as 102/65mm Hg.

Records state that the patient wished to breastfeed and advice was given and delivery plans discussed. Because of her ethnic background and family history, a Glucose Tolerance Test was arranged. It was noted at this time that the patient was complaining of back pain and it is documented that a referral to the physiotherapy service was to be arranged. A fetal anomaly scan was booked.

It appears that the patient was scheduled to attend her next antenatal clinic on 3rd of December 2012 when she would have been 23 weeks gestation.

⁹ Italics used throughout the chronology of events section indicate direct quotes from interviews with staff and information as written within the patient record by staff members.

Sunday 21st of October 2012: 09.35HRS

The patient and her husband attended the Gynaecology ward where she was assessed by Staff midwife 1. It was noted that she was 31 years old and 17 weeks pregnant with her first child.

The documentation completed by Staff Midwife 1 states that the woman had self-referred to the hospital with a twelve hour history of intermittent lower backache which radiated to the lower pelvic region anteriorly. There had been no vaginal loss (*i.e. no per vaginal bleeding or leaking liquor which might indicate that she may miscarry*) but she indicated that she had been experiencing frequency of micturition (*i.e. passing urine more often than usual*) but no dysuria (*i.e. - pain or burning sensation on passing urine*). It is documented that the woman had a history of a sacral disc problem for the previous nine months.

The documentation of the patient's clinical observations at this time indicated that her observations were recorded as follows:

- Temperature 36.8 degrees Celsius
- Pulse rate 82 per minute
- Blood pressure 113/73 mmHg.

A urinalysis (*i.e. examination of the urine for sugar, protein, white cells and nitrites using a dipstick colour indicator*) was carried out at this time and was normal, suggesting no active infection in the urine.

At interview CNM (Clinical Nurse Manager) B stated that the patient and her husband asked to have the heartbeat of their child monitored.

Sunday 21st of October 2012: 11.15HRS

At interview CNM B recalled bringing the patient to the review room on the gynaecology ward to measure the fetal heart rate as no couch had been available earlier.

CNM B has documented that an assessment of the fetal heart was carried out with a sonicaid and that the fetal heart was heard. CNM B recalled that she "*got it (the fetal heart) easily*". Following this the patient was reassured.

At interview, SHO (Senior House Officer) 1 confirmed that (s)he was also present when the fetal heart was heard.

This noting of the fetal heart rate was added to the case records after 11:15 hrs when it was listened to.

Sunday 21st of October 2012: Time not recorded

The patient was assessed by a senior house officer (SHO) doctor.

The documentation completed in relation to this assessment by SHO 1 indicates that the woman was a 31 year old and was 17 weeks pregnant with her first child and that she had self-referred to the hospital with a history of lower backache radiating to her lower pelvic region. It is documented that the patient had a background history of lower back pain. SHO 1 has documented that the patient was complaining of increasing urinary frequency without dysuria (*i.e. pain or burning sensation*). It is also documented that the patient had no PV loss

noted (i.e. no per vaginal bleeding or leaking liquor which might indicate that she may miscarry) and that she had no symptoms of nausea or vomiting.

The documentation of the physical examination carried out as part of the patient's assessment indicates that her abdomen was soft and not tender and that the fetal heart was heard at this time. The patient was noted to have tenderness of her back on palpation (pressing with hand) with a normal neurological examination and straight leg test (i.e. raising the leg did not show there was any nerve irritation which would have limited this movement).

The documented impression of the reviewing doctor (SHO 1) was that the patient was suffering from low back pain, the cause of which was being queried to be symphysis pubis dysfunction (i.e. separation of pubic symphyseal bones leading to radiated pain). At interview SHO 1 stated that this queried diagnosis was made as the patient had reported that she had a history of back problems, that the pain radiated from the lower region, pain worsened when walking and that the patient had tenderness on palpation.

SHO 1 recalled at interview that a speculum examination was considered, but not deemed appropriate at that stage.

The documented plan of treatment at this time was that the patient was to be commenced on medication to manage her pain and that she was to be referred for physiotherapy. SHO 1 has noted that the patient was currently attending a physiotherapy clinic for the complaint of lower back pain. At interview SHO 1 recalled advising the patient to take paracetamol, but did not prescribe paracetamol (or note it on the medication chart) as it is available over the counter.

There is no documentation that the patient was given pain relief or any follow-up.

SHO 1 recalled at interview that the patient *"felt reassured, but I told her that if she had any concerns to come back to us, and she did"*.

Sunday 21st of October 2012: 15.30HRS (Approx)

The patient re-attended the gynaecology ward and was assessed by Staff Midwife 2. CNM B stated at interview that (s)he was also present with Staff Midwife 2 when the patient and her husband returned to the ward at 15.30 hrs.

Staff Midwife 2 recalled at interview that the patient was *"upset and crying"* when she and her husband returned to the ward.

Sunday 21st of October 2012: 15.30HRS

The documentation completed by Staff Midwife 2 at 15.30 hours in relation to this assessment was that the patient had indicated that she had returned to the hospital as she had *"felt something coming down"* and stated that she had *"pushed a leg back in."* Documentation stated that there had been no PV (per vagina) loss (i.e. blood or fluid).

Staff Midwife 2 stated that *"I immediately thought that she would miscarry and I brought her to the review room for an examination"*.

At interview Staff Midwife 2 stated that with the patient's permission (s)he conducted an external vaginal examination *"just what I could see myself externally"*. Staff Midwife 2 has

documented that no fetal parts were visible and the documented plan was that the patient was to be reviewed by the Senior House Officer on duty. CNM B stated at interview that (s)he and the Staff Nurse/Midwife “also got the SpR to see her”.

Sunday 21st of October 2012: Time not recorded

The patient was reviewed by SHO (Senior House Officer) 1. The documentation of that assessment indicates that the patient had a history of lower back pain and that she had noticed a sensation of something “coming down” that afternoon. It is documented that the patient was still experiencing lower back pain at this time and that she indicated that she had not experienced any PV (per vaginal) loss.

She was seen by the same SHO (Senior House Officer) 1 that saw her previously. SHO 1 recalled at interview that the patient was anxious and had reported not being able to urinate when she had returned home.

The SHO confirmed that the woman still was experiencing backache and as part of this assessment the SHO carried out a Speculum examination. The documented findings of this assessment indicate that the gestational sac was visible on speculum examination. SHO 1 recalled at interview seeing bulging membranes and therefore decided to remove the speculum as (s)he was worried they might rupture. SHO 1 recalled explaining to the patient that s(he) would discuss with the other doctor (the Obstetrics and Gynaecology (O&G) registrar on duty) and would come back to the patient. SHO 1 recalled at interview that the speculum was “not cloudy to my knowledge”.¹⁰

It is documented that the woman’s case was discussed with the O&G SpR on duty.

Sunday 21st of October 2012: This entry was timed as at 14.20HRS within the medical record¹¹

The patient was reviewed by O&G SpR (Specialist Registrar) 1. O&G SpR 1 started their documentation with ATSP (asked to see patient). At interview SHO 1 confirmed that (s)he was also present when the patient was reviewed by O&G SpR 1.

The documentation completed in relation to this assessment indicates that the patient had been experiencing back pain for the previous twenty four hours and that she had indicated to O&G SpR (Specialist Registrar) 1 that this pain was different to the back pain which she had been experiencing previously during her pregnancy. She had described the pain that she was currently experiencing as “unbearable”.¹² It is documented that the patient was distressed at this time.

In addition it is documented that the patient was experiencing crampy abdominal pains and that she had no per vagina loss at this time and that she had no history of any treatment to her cervix (i.e. treatment that could lead to weakness of the cervix and an early miscarriage).

¹⁰This refers to the fact that fluid seen through the bulging membranes was not cloudy, suggesting there was little possibility of infective material. At times this is referred to as amniotic fluid sludge on ultrasound examination.

¹¹ The 14.20hrs entry was entered in the medical record after the records timed at 15.30 hours on 21.10.12.

¹² Pain, particularly severe pain may be a symptom of intrauterine sepsis or the process of miscarriage and should alert a clinician to look for uterine tenderness and if necessary, additional investigations.

As part of this assessment, O&G SpR (Specialist Registrar) 1 carried out an examination with a speculum and a gentle vaginal examination (i.e. to assess the state of the cervix).

The documented findings of the speculum examination indicated bulging membranes (i.e. the water bag around the baby was bulging) and the vaginal examination indicated that the membranes were almost at the introitus (i.e. at the entrance of the vagina) and that the cervix was not felt.¹³

O&G SpR 1 recalled at interview:

“that the woman was very uncomfortable on examination and a thorough examination could not be performed. The state and dilatation of the cervix could not be assessed. I did not know whether the cervix was widely dilated or not”.

The documented impression of the reviewing doctor was that a pregnancy loss was inevitable/impending and that it was considered that a rescue cerclage was not appropriate in this case (i.e. it was too late to stitch the cervix in an attempt to close it to prevent her from miscarrying).

O&G SpR 1 recalled at interview that the patient was actively having pain and that *“it was probably a matter of hours before miscarriage”*. The management option considered by O&G SpR 1 and discussed with the patient was *“conservative management, wait and see what would happen naturally”* and that *“no other forms of management were discussed”*. O&G SpR (Specialist Registrar) 1 documented that these findings were discussed with the patient and her partner.

O&G SpR 1 recalled at interview discussing with the patient and her husband that the pregnancy was not viable. O&G SpR 1 did not recall a discussion including options to speed up the process of inevitable miscarriage. O&G SpR 1 recalled leaving review room as *“the couple wanted time alone”*.

The documented plan of treatment at this time was to admit and *“await events”*. The patient was to have intravenous access sited and bloods drawn for full blood count and group and hold (in case blood transfusion will be required). Analgesia was to be administered.

SpR 1 recalled at interview requesting a **full blood count** to establish a baseline because of the risk of bleeding at the time of miscarriage and that there were no concerns of infection at that time. Bloods were taken by SHO 1.¹⁴

O&G Consultant 1 recalled at interview that no ultrasound was carried out by the Specialist Registrar on the 21st of October, and that this was likely to be because the probe (normally used for scanning) was broken and the image is not good on the portable scanner.

¹³ This could mean that the cervix was effaced and dilated and hence not felt, or simply it was not felt due to examination difficulty.

¹⁴ SpR 1 recalled expecting that (in line with hospital practice) routine monitoring of blood pressure, temperature and pulse rate would be carried out at four-hour intervals on the gynaecology ward. SpR 1 also recalled that *“on admission I could find no clinical evidence of infection”* the patient's main complaint had been pain and there had been no vaginal discharge. At interview, SpR 1 stated that in general the person that takes a routine blood test would follow the result, but as a general rule it is the responsibility of the senior person on call as well to make sure this is done. Staff Nurse/Midwife 2 stated at interview that it is not the nurses' responsibility to follow-up on blood results.

Sunday 21st of October 2012: (Untimed. Between 15.00HRS and 17.00HRS Approx)

Staff Midwife 2 who had seen the patient earlier in the day documented that the patient had been admitted at 17 weeks gestation with a history of abdominal pain. Staff Midwife 2 documented that the patient had been reviewed by SHO (Senior House Officer) 1 and O&G Specialist Registrar 1 and that a speculum examination had been carried out and the findings indicated the presence of bulging membranes almost to the introitus and that the cervix was not felt. The documented diagnosis for handover to the night staff was of an inevitable/impending pregnancy loss and that the fetal heart was heard using a sonicaid in the presence of the Senior House Officer.

To give the patient privacy the nursing staff arranged for the patient to be admitted to a single room in the gynaecology ward (Women experiencing miscarriage are generally not treated on wards with other obstetric patients).

Sunday 21st of October 2012: 16.50HRS

Staff Midwife 2 stated that the patient *“was very upset, she was crying, and I would have been very sympathetic and they knew I was there to help in any way, I said ‘if there’s anything I can do please ask me’...her distress was more noticeable when I went down to the room, I offered pethidine for pain and she accepted”*.

Staff Midwife 2 documented (in the note written at a time between 15.00hrs and 17.00hrs) that the patient was administered analgesia - pethidine 75mgs and an antiemetic - Stemetil 12.5mgs at 16.50 hrs. Staff Nurse/Midwife 2 stated at interview that whilst the patient was in pain, she did not have the appearance of a sick woman and the level of pain she was experiencing was usual for patients experiencing inevitable pregnancy loss.

The note written sometime later but related to this time completed by Staff Midwife 2 between 15.00hrs and 17.00hrs also stated that a call bell was given (to call for help if required and if the pain worsened). Staff Midwife 2 also recalled at interview that they brought the patient a commode and that (s)he told them they were free to contact them at any time.

Staff Midwife 2 documented that the husband was present with the patient when admitted. It was noted that both were very upset. The patient was to be allowed a normal diet. It was noted that the patient’s blood group was B negative and that she would require Anti D post delivery to prevent the possibility of Rhesus immunisation.

At interview Staff Midwife 2 stated that hi(s)her practice is that (s)he would have checked the patient intermittently and that (s)he also considered that the patient and her husband needed some time alone.

Sunday 21st of October 2012: 17.10HRS

Staff Midwife 2 took the patients observations at approx. 17.00 hrs.

From the chart observations at 17.00 hrs were:

- Temperature 36.5 degrees Celsius
- Pulse rate 90/min

→ Blood Pressure 115/75 mmHg

Sunday 21st of October 2012: 18.33HRS

Blood sent for full blood count (taken at 14.20 hrs as above) was received in the laboratory at 18.33 hrs.¹⁵

The white cell count on the sample received was $16.9 \times 10^9 / L$ (normal range in second trimester pregnancy is $6.2 - 14.8 \times 10^9 / L$),¹⁶ and the neutrophil count was $13.8 \times 10^9 / L$ (normal range in second trimester pregnancy is between $3.8 - 12.3 \times 10^9 / L$).

Sunday 21st of October 2012: 21.00HRS (Approx)

On the 21st of October Staff Nurse/Midwife 2 did not go off duty until 21.30 hrs. Staff Midwife 2 stated that a delivery trolley had been set up in the event of miscarriage.

Staff Midwife 2 recalled setting up a folding bed for the patient's partner and explained that the room might have to be re-arranged should the delivery trolley be required in the event of delivery. Staff Midwife 2 also recalled the patient's husband thanking the Staff Midwife.

Sunday 21st of October 2012: 21.00HRS

Staff Midwife 3 (night staff) stated that (s)he visited the patient's room at 21.00 hrs. Staff Midwife 3 documented in an untimed ward round report that (s)he recalled completing at approximately 21.00 hrs that the patient was admitted with a history of abdominal pain at 17 weeks. She had been seen by the registrar and, on speculum examination, bulging membranes could be seen at the introitus and no cervix was felt. The impression was that of an inevitable/impending miscarriage and that cervical suture was not appropriate. The fetal heart had been heard with sonicaid. Also documented in the notes was that the findings had been discussed with patient and husband.

An IV cannula was sited in the left hand and bloods had been taken for full blood count and group and hold (in case blood transfusion will be required). Vital signs were stable early nocte. No per vagina (PV) loss. Declined analgesia and denies pain at present. The patient's husband was noted as staying in the room with his wife overnight.

Sunday 21st of October 2012: 22.00HRS

Staff Midwife 3 recorded observations at 22.00 hrs as follows:

- Temperature 36.6 degrees Celsius
- Blood pressure 100/60 mmHg
- Pulse rate was 89 per minute
- Pain score was nil

¹⁵ The investigation team established that on an average haematology results would be available to staff two hours from the time of receiving the blood.

¹⁶ Source, Bain 2006

Monday 22nd of October 2012: 00.30HRS (Approx)

Staff Midwife 3 recalled that the patient rang the call-bell. Staff Midwife 3 went into the (single) room and into the bathroom. Staff Midwife 4 was also present.

Staff Midwife 3 documented that following a visit to the bathroom, the patient had **vomited “++”** (interpreted as significant amount of vomitus) and that she had a **spontaneous rupture of membranes (SROM)** at this time (this means that the bag of membranes around the baby had burst and the fluid or liquor has leaked out). Staff Midwife 3 recalled at interview that the patients *“pyjamas were wet and there was a pool of clear liquor (fluid from the pregnancy sac around the baby) around her feet”*. This implies that the membranes have ruptured and the fluid has leaked out and that there was a copious amount of amniotic fluid at the patients’ feet. Staff Midwife 4 recalled that there was *“no odour”*.

It is documented that the patient had been escorted back to bed and that she had indicated that she was feeling better and that she had no complaints of pain at this time. Both nurses recalled at interview that they escorted the patient back to bed. It was noted that the patient was not fasting and there is no indication that the medical staff were informed of the events.

Monday 22nd of October 2012: 02.30HRS (Approx)

Staff Midwife 3 stated at interview the she checked the patient and her husband and they were both asleep. This is not documented in the notes.

Monday 22nd of October 2012: 03.30HRS

Staff Midwife 3 has documented that the patient was continuing to experience a pinkish per vagina loss in moderate amounts and that she was **anxious “++”**, and unable to sleep and had been advised to rest. Staff Midwife 3 recalled that it was her/his impression that the patient *“felt it was the first stage of what was going to happen”*.

Monday 22nd of October 2012: 06.00HRS

Staff Midwife 4 documented that the patient used the commode and that the patient had passed some clots vaginally on the commode but the continued loss was minimal. Patient was nauseated but had declined an antiemetic. In addition the patient had indicated that she was not experiencing any pain at this time. The patient was advised to fast from now, intravenous (IV) fluids commenced (as per the chart).

Monday 22nd of October 2012: 06.05HRS

Staff Midwife 4 recorded observations at 06.05 hrs as follows:

- Temperature 37 degrees Celsius
- Pulse rate 94 per minute
- Blood pressure 108/65 mmHg
- Oxygen saturations 99% on room air.
- Pain Score was *“No Pain”*

Monday 22nd of October 2012: 06.30HRS

It is charted that the patient was commenced on intravenous fluids (1 litre) and was advised that she would be fasting from this time onwards.¹⁷ Staff Midwife 4 recalled commencing the intravenous (IV) fluids with a view to asking a doctor to review.

Monday 22nd of October 2012: 08.20HRS

The patient was reviewed by O&G Consultant 1 as part of the Obstetrics and Gynaecology Team morning ward round.

The documentation completed by the consultant in relation to this assessment indicates that the patient had been admitted with a history of back pain at 17 weeks gestation and that a speculum examination carried out following admission had indicated bulging membranes almost down to the introitus. It is documented that the patient had experienced a spontaneous rupture of membranes that morning and that she was currently experiencing some vaginal bleeding similar to a (menstruation) period and she had indicated that the pain had eased at that time.

The consultant stated at interview that (s)he discussed the risk of infection and sepsis with the patient "*hence the need for a regular heart check (of the fetus)*". No specific instructions were given "*routine clinical observations, more frequent if abnormal was current practice...the policy has changed, we used to do full blood count, now we monitor on clinical grounds, rather than blood tests*". The consultant would expect routine observations to be carried out every four hours.

The consultant was aware of the dilation of the cervix as SpR 1 had documented the previous day that the membranes were almost at the introitus (i.e. at the entrance of the vagina) and that the cervix was not felt (i.e. the cervix was effaced and dilated and hence not felt). The consultant stated that (s)he informed the patient that "*the likelihood was that she would deliver, but that it was difficult to give a timeline for this. It was unlikely she would continue on to a time of fetal viability*".

O&G SpR 1 stated at interview that the patient "*was very uncomfortable on examination and a thorough examination could not be performed*". Hence the state and dilatation of the cervix could not be assessed (i.e. the medical staff could not tell whether the cervix was widely dilated or not).

The documented plan of treatment following this review was that the patient was to have an ultrasound scan carried out to check for the presence of a fetal heart and to "*await events*".

Monday 22nd of October 2012: 08.30HRS

The patient's observations were recorded as follows:

- Temperature 36.6 degrees Celsius
- Pulse rate 92 per minute
- Blood pressure 102/59 mmHg

¹⁷ Fasting would have been advised as a precaution since it was believed that miscarriage was imminent and a general anaesthetic may be needed for removal of placenta in case it was retained.

- Oxygen saturations 98% on room air
- Pain Score was noted as "...easier at present"

Monday 22nd of October 2012: 11.00HRS

Staff Midwife 1 documented that the patient had returned to the ward following her scan.

The documented report of the findings of this scan indicated that the scan had been carried out to assess the fetus in the second trimester.

The findings of the scan were as follows;

"Fetal Measurements (plotted in relation to the normal mean and 5th to 95th centile). Heart action present. Presentation cephalic. Diagnosis: cardiac pulsations present."
(This result suggests a normally grown and alive fetus).

Staff Midwife 1 documented that the woman was no longer fasting and she had passed some large clots and was experiencing moderate vaginal bleeding. She was not complaining of any pain at this time and vital signs were stable. She was not experiencing any symptoms of nausea or vomiting.

Staff Midwife 1 documented that the results of the patient's scan were discussed with the clinical team caring for the patient, and that no new changes had been made to the patient's treatment plan at this time.

Monday 22nd of October 2012: 15.25HRS

The patient's observations chart noted her observations as follows:

- Temperature 36.8 degrees Celsius
- Pulse rate 98 per minute
- Blood pressure 92/58 mmHg
- Oxygen Saturation 99% on room air

Monday 22nd of October 2012: 18.00HRS

The patient's observations chart noted the patients' observations as follows:

- Temperature 37.1 degrees Celsius
- Pulse rate **102** per minute
- Blood Pressure 98/62 mmHg

It is also noted that her bowels had opened and she had passed urine.

Monday 22nd of October 2012: 21.40HRS

Observational chart note the following:

- Temperature 37 degrees Celsius
- Pulse rate **102** per minute
- Blood pressure 110/62 mmHg

→ Oxygen saturations 97% on room air.

Monday 22nd of October 2012: 22.00HRS

The patient was administered the first dose of erythromycin 250mgs orally.

Staff Midwife 4 documented that the patient had been commenced on oral antibiotics (erythromycin 250 mgs orally every six hours at that time).

While the rationale for this has not been documented in the clinical records it has been confirmed by clinical staff involved in the investigation that the rationale for prescribing erythromycin in the patient's case was ruptured membranes. Staff Midwife 4 recalled discussing antibiotic cover with the Registrar on call on that night.

Staff Midwife 4 also stated that (s)he checked the patient again later in the night (unsure of time), and that the patient was awake.

Tuesday 23rd of October 2012: nocte Time documentation is written as approximated as before 06.00HRS

Staff Midwife 4 documented in an untimed handover note written for day staff that the patient was at 17 weeks gestation with a history of abdominal pain. On speculum bulging membranes were seen at the introitus and no cervix felt. Cervical suture was not appropriate.

Staff Midwife 4 documented that the patient had spontaneous rupture of membranes the previous night (22nd of October) and was also scanned the previous day and fetal heart was heard. The documented plan was to '*await events*'.

Staff Midwife 4 documented in the handover note for day shift staff that the patient's clinical observations were stable at this time and that she was not experiencing any per vagina loss and that the patient was not experiencing any pain at this time.

Tuesday 23rd of October 2012: 06.00HRS

In a continuation of the handover note timed at 06.00 hrs, Staff Midwife 4 documented that the patient had minimal per vagina loss on pad, the patient's temperature was normal and that there was no pain.

Chart observations at this time are noted as follows:

- Temperature 37 degrees Celsius
- Pulse rate 84 per minute
- Blood Pressure **95/52** mm Hg¹⁸

¹⁸ As per clinical notes, at the patient's first examination on 21.10.12 her blood pressure was 113/73mmHg. The patients blood pressure at booking on 11.10.12 was 102/65 mmHg.

Tuesday 23rd of October 2012: 08.20HRS

The patient was reviewed by the O&G Consultant 1 and O&G Registrar 2 as part of the morning ward round.

The documented findings of this particular clinical review (completed by O&G Registrar 2) indicate that the patient was 17 weeks gestation with a history of a premature rupture of membranes after having a protruding sac was noted.

It is documented that an ultrasound carried out the previous day had indicated the presence of a beating fetal heart. It is documented that the patient had a blood stained vaginal discharge and that she had no complaints of pain at this time.

The patient's observations as recorded in the notes were:

- Temperature 37.1 degrees Celsius
- Pulse rate 84 per minute

The documented plan of treatment at this time was that the patient was to remain on antibiotic therapy (erythromycin) and was to be administered Anti D.

In addition, the fetal heart was to be monitored by auscultation and consideration was to be given to carrying out a fetal ultrasound scan. It is documented that the possibility of cervical cerclage for any further pregnancy had been discussed with the patient.

O&G Consultant 1 stated that the patient and her husband were emotional and upset when told that a miscarriage was inevitable. The consultant stated that the patient and her husband enquired about the possibility of using medication to induce miscarriage as they indicated that they did not want a protracted waiting time when the outcome of miscarriage, was inevitable.

At interview, O&G Registrar doctor 2 stated that the plan was to check the fetal heart and that the patient had asked on the 23rd of October about termination.

O&G Consultant 1 stated that the patient and her husband were advised of Irish law in relation to this. At interview the consultant stated *"Under Irish law, if there's no evidence of risk to the life of the mother, our hands are tied so long as there's a fetal heart"*. The consultant stated that if risk to the mother was to increase a termination would have been possible, but that it would be based on actual risk and not a theoretical risk of infection *"we can't predict who is going to get an infection"*.

Tuesday 23rd of October 2012: 08.35HRS

The patient's clinical observations are recorded as follows:

- Temperature 36.4 degrees Celsius
- Pulse rate 92 per minute
- Blood pressure 100/64mmHg
- Oxygen saturations 99% on room air.

Tuesday 23rd of October 2012: 09.00HRS

It is documented that oral erythromycin was given (250mg). This was the second dose of this antibiotic.

Tuesday 23rd of October 2012: 12.00HRS

It is documented in the clinical records by Clinical Midwife Manager 1 that the fetal heart rate had been checked with a Doppler and that the patient had become upset and had indicated that she did not wish to have the fetal heart checked and that O&G Consultant 1 had been informed of this and had indicated that (s)he would review and discuss this issue with the patient the following day. The patient was noted to have no per vagina loss at this time.

The medical notes record that the patient was “anxious” for a bath and nursing staff advised against it.

Tuesday 23rd of October 2012: 14.45HRS

The patients’ clinical observations are documented as:

- Temperature 37 degrees Celsius
- Pulse rate **100** beats per minute
- Blood pressure 108/74mmHg
- Respiratory rate 18 per minute
- Oxygen saturations 97% on room air.

Tuesday 23rd of October 2012: 16.30HRS

The patient was administered erythromycin 250mgs orally. This was the third dose of this antibiotic.

Tuesday 23rd of October 2012: 19.00HRS

The patient’s clinical observations are documented as:

- Temperature 36.6 degrees Celsius
- Pulse rate **114** per minute
- Blood pressure 108/66mmHg
- Oxygen saturation 99% on room air.

Tuesday 23rd of October 2012: 19.30HRS

It is documented in the clinical records by Clinical Midwife Manager 1 that the patient was administered an injection of Anti D and that she was continued on oral antibiotics at this time (Erythromycin). As part of the process of the administration of Anti D, Clinical Midwife Manager 1 has indicated that (s)he gave the patient an information leaflet and the patient was given an opportunity to read it prior to the administration of the anti-D. No comments on the patient’s clinical condition were noted.

Tuesday 23rd of October 2012: 20.00HRS

The patient's clinical observations are documented as:

- Temperature 36.8 degrees Celsius
- Pulse rate **108** per minute
- Blood Pressure 106/68mmHg
- Oxygen saturations 99% on room air.

Tuesday 23rd of October 2012: 21.00HRS

Staff Midwife 4 recalled the ward round commencing at 21.00 hrs.

Nursing documentation summarised the clinical situation. The patient was currently on oral antibiotics and that she had been administered an injection of anti D the previous day. It was also documented that the patient had a minimal amount of brown per vagina loss and that she had no complaints of pain at this time. Nursing documentation stated that the patient had been complaining of "*weakness*" earlier in the night and that the patient's blood pressure was stable (as per observation chart parameters) and that the patient's pulse rate had ranged from 90-100 beats (regular) per minute since admission.

The patient's clinical observations were recorded by Staff Midwife 4 at 21.00 hrs as:

- Temperature 36.9 degrees Celsius
- Pulse rate **106** per minute
- Blood pressure **105/60** mmHg
- Respiratory rate **18** per minute
- Oxygen saturations 98% on room air.

Staff Midwife 4 stated at interview that the patient was no longer on IV fluids at that time (they had been stopped on Monday the 21st of October) and the patient was eating and drinking normally.

At a time between 21.00 hours and 22.00 hours Staff Midwife 4 stated that (s)he asked the senior house officer doctor (SHO 2) to see the patient because the patient had complained of weakness early nocté. A 'heart rate' of 96 to 100 since admission noted on the notes. The SHO 2 said that (s)he was busy early nocté but would see the patient later. Staff Midwife 4 also documented that SHO 2 had been contacted to review the patient and that this review was awaited as SHO 2 had a busy caseload at this time.

It is also documented that the patient's husband stayed in the hospital with his wife overnight.

Tuesday 23rd of October 2012: 22.00HRS

The patient was administered erythromycin 250 mgs orally. This was the fourth dose of this antibiotic.

At interview SHO 2 stated that (s)he had been contacted at approximately 22.00hrs by the nursing staff on the gynaecology ward with a request to review the patient's care and that it

had been reported to the senior house officer doctor by nursing staff at this time that the patient was feeling weak.

Wednesday 24th of October 2012: 01.00HRS

While it is not documented in the clinical records, SHO 2 stated at interview that as requested by the nursing staff at approximately 22.00 hrs, (s)he came to the ward to review the patient at 01.00 hrs when (s)he was less busy. However, the patient was asleep at this time. The senior house officer doctor was advised by Staff Midwife 4 that the patient's condition was stable. Staff Midwife 4 recalled "[the doctor] *came back to the ward at approximately 01.00 hrs. The patient was asleep and husband was asleep on the camp bed. She had settled to sleep so [the senior house officer doctor] didn't see her...and the fact she had settled I didn't disturb her and we left her to sleep*". On the basis of this, SHO 2 made a decision that (s)he would not wake the patient to review her care at this time.

Wednesday the 24th of October 2012: 04.15HRS

Staff Midwife 3 stated that (s)he answered the call bell to the patient's room.

It is documented in the clinical records by Staff Midwife 3 that the patient was complaining of feeling cold and shivery.¹⁹

The staff midwife's patient observations were:

- Temperature 37.7 degrees Celsius.
- No pulse or Blood Pressure recordings were taken at this time

The patient was administered 1 gram of Paracetamol orally to manage the patient's increased temperature.

At interview Staff Midwife 3 recalled:

*"Both the patient and her husband were cold and asked for extra blankets...as I covered her up **her teeth were chattering**²⁰, so I took her temperature, just her temperature, no blood pressure or heart rate. There were no signs she was septic to me...I didn't think she was unwell enough...she seemed to settle then...I knew she'd had a SRM²¹, but room was cold so I was thinking of everything...her mental status was fine, she was alert and communicating and she appeared to settle after being given the second blanket"*.

¹⁹ Rigors (i.e. shaking or shivering) is a sign of sepsis.

²⁰ Rigors indicated by teeth chattering suggests sepsis.

²¹ Spontaneous Rupture of Membranes (SRM)

Wednesday the 24th of October 2012: 04.20HRS

It is documented by Staff Midwife 3 that the patient had **vomited**²² up some water (but that she did not vomit up the tablets that she had been administered previously) and that both the patient and husband had been given an extra blanket as *“the radiator was stone cold”*.

Wednesday the 24th of October 2012: 05.00HRS

It is documented in the clinical record by Staff Midwife 3 that the patient’s temperature was rechecked at 05.00 hrs and the temperature was 37.5 degrees Celsius. There were no other clinical observations documented at this time.

Wednesday the 24th of October 2012: 06.30HRS

Staff Midwife 4 documented in the clinical records on nursing rounds that the patient was complaining of feeling weak with general body aches.

The patient’s observations were:

- Temperature **39.6** degrees Celsius.
- Pulse rate **160** per minute
- Blood pressure **94/55**mmHg,
- Respiratory rate 15 per minute
- Oxygen saturations **97%** on room air.

Staff Midwife 4 documented that the senior house officer doctor (the same doctor as earlier) was contacted immediately to review the patient. Staff Midwife 4 also called the other staff midwife on duty. The senior house officer doctor had already been called to the ward to deal with another ill patient and arrived (approximately ten minutes later) and went to see the patient concerned with this investigation first.

Wednesday the 24th of October 2012: 06.40HRS

The staff midwife who called the senior house officer to review the patient documented that the s(he) was present on the ward at 06.40 hrs. The staff midwife also documented that cold compresses were applied on the patient to reduce the elevated temperature and that Oxygen supplementation was started.²³

The other staff midwife on duty was also attending the patient at this time and s(he) recalled getting a tepid sponge and an ECG (Electrocardiography) machine (used to measure the maternal heart rate and electrical activity of the heart).

Wednesday the 24th of October 2012: 06.45HRS

²² Diarrhoea or vomiting - may indicate exotoxin production (early toxic shock) (as per RCOG Guideline 64a *Bacterial Sepsis in Pregnancy* (2012).

²³ Oxygen supplementation suggests that the patient was clinically unwell.

The patient was administered Paracetamol 1gram intravenously.

Her clinical observations are recorded as:

- Temperature was not recorded.
- Pulse rate **166** per minute,
- Blood pressure 130/72mmHG
- Respiratory rate 16 per minute
- Oxygen saturations **97%** on room air [*sic*]

Wednesday the 24th of October 2012: 07.00HRS

Nursing documentation stated that the patient was feeling slightly better and that her temperature was **37.9** degrees Celsius. An electrocardiograph (ECG) was carried out. The patient had **nausea and vomiting** and Stemetil 12.5 mgs was given.²⁴

A note related to this time – but written later by the senior house officer doctor timed 07.00 hrs summarised the clinical situation up to that point. This states that the patient was 17 weeks and three days in her first pregnancy and had been admitted to the hospital three days previously with a history of bulging membranes evident on speculum examination and that an ultrasound carried out on the 22nd October had indicated the presence of a fetal heartbeat with the fetus in a Cephalic presentation. There was a history of leaking of liquor of one day as suggested by a gush of clear fluid that had soaked her clothing with subsequent trickling.²⁵

The senior house officer doctor documented that the patient was then on oral antibiotic therapy with erythromycin 250mg, prescribed 6 hourly since October 22nd at 22.00 hrs and that she was now complaining of a **fever with palpitations**. The fever had been of gradual onset with a high-grade temperature of **39.6** degrees Celsius and associated **chills and rigors**. The patient indicated that she had been experiencing palpitations which were fast, regular and associated with general weakness. In addition she indicated to the doctor that she had no abdominal pain, urinary symptoms, symptoms of chest pain, shortness of breath, leg pain or swelling.

The patients' observations were:

- Temperature **39.6** degrees Celsius (despite paracetamol)
- Pulse rate **160** per minute
- Blood Pressure **100/60** mm/Hg

The electrocardiographs (ECG) recorded at 06.13 hrs and 06.14 hrs showed a sinus tachycardia (i.e. elevated heart rate) of **168** beats per minute, confirming this is a reactive tachycardia and probably not a primary cardiac event.

The documentation of the findings of the clinical assessment of the patient's chest indicates that it was clear with the presence of normal heart sound and no murmurs evident.

The documented findings of the clinical assessment of the patient's abdomen indicates symphyseal fundal height (SFH) of the uterus was 17/40 weeks in size.

²⁴ Nausea and vomiting in the clinical context is consistent with sepsis.

²⁵ The gush of clear fluid that soaked the patient's clothing had occurred on the 22.10.12 at 00.30hrs .

These clinical findings show that the patient had **tenderness”++”** (interpreted as significant amount of pain on examination) present **over the left iliac fossa and the right iliac fossa and suprapubic regions.**²⁶

It is also documented that a vaginal examination and a speculum examination had been carried out previously and the findings indicated the presence of a healthy cervix (i.e. no inflammation/infection of cervix) and there appeared to be ragged membranes at cervical os (at the neck of the uterus). In addition, a **foul smelling brownish discharge “++”** (interpreted as a significant amount) was now present and a HVS (high vaginal swab) was taken.

It is further documented that the patient had declined a fetal heart assessment by sonicaid the previous day.

The clinical impression following this review by the senior house officer doctor was that the patient was suffering from at least Chorioamnionitis²⁷ but probable sepsis.

The patient was commenced on oxygen therapy (40% via facemask) with blood samples taken for full blood count, SMAC (blood test sent to the biochemistry laboratory to test renal and liver function) serum lactate and blood cultures (ordered by the senior house officer doctor). This doctor stated at interview that (s)he ordered a serum lactate test as (s)he was worried about tissue hypoperfusion that may indicate severe sepsis.

The documented plan of treatment following this review was that the patient was to be administered paracetamol 1g intravenously to manage her temperature and was to be commenced on intravenous antibiotic therapy Augmentin (Coamoxiclav) 1.2g every eight hours) and intravenous fluid therapy (one litre of Hartmanns solution every eight hours).

O&G SpR 3 stated that the senior house officer (SHO) doctor contacted them by phone at approximately 07.00 HRS. SHO 2 recalled contacting O&G SpR 3 at approximately 07.15 hrs. O&G SpR 3 stated at interview that (s)he was busy in the labour ward when contacted, and that (s)he was unable to review the patient at 07.00 hrs. The specialist registrar doctor had not been aware of the patient prior to this phone call (as (s)he was on a team with a different consultant obstetrician and gynaecologist).

O&G SpR 3 agreed with SHO 2's plan to give intravenous antibiotics and paracetamol and to send bloods for full blood count (FBC), C-reactive protein (CRP) and blood cultures.

SHO 2 recalled:

“I discussed my findings and [SpR 3] didn't tell me to do anything extra. I gave the vital signs, pulse, temperature. I stated all the facts”

Following the senior house officer (SHO) doctor's phone conversation with O&G SpR 3 the plan of treatment was not to change the SHO's management and to organise further management of the patient through O&G Registrar 2 (who was also a member of the patient's team due to review the patient at 08.00 hrs).

²⁶ The patients documented pain and tenderness over the suprapubic region with the foul smelling brownish discharge is consistent with intrauterine infection.

²⁷ Chorioamnionitis is a condition that can affect pregnant women. In this condition, bacteria infects the chorion and amnion (the membranes that surround the fetus) and the amniotic fluid (in which the fetus floats). This can lead to infections in both the mother and fetus.

When asked specifically at interview SPR 3 did not recall the senior house officer giving details of the patient's heart rate (HR) or blood pressure (BP).

At interview, when asked about the management of the patient's pyrexia (fever) at that time, SpR 3 stated that it was his/her view that the management was adequate. When asked by the investigation team might the patient's management have been different if SpR 3 had been aware of the blood pressure and heart rate parameters SpR 3 stated that it may have been.

Wednesday the 24th of October 2012: 07.20HRS

It is documented that the patient had vomited a small amount of green bile and that she had been administered an antiemetic (Stemetil 12.5mgs) intramuscularly at 07.10 hrs.

The patient's clinical observations are recorded as follows:

- Pulse rate **164** per minute
- Blood pressure **100/60** mmHg,
- Respiratory rate **20** per minute
- Oxygen saturations 98% on 40% oxygen supplementation.

Wednesday the 24th of October 2012: 07.30HRS

The patient's clinical observations are documented as follows:

- Temperature **37.9** degrees Celsius,²⁸
- Pulse rate **154** per minute,
- Blood pressure **98/54** mmHg
- Oxygen saturations 99% on 40% oxygen.

Wednesday the 24th of October 2012: 07.50HRS

SHO 2 documented that the patient's clinical observations were re-checked and were as follows:

- Temperature **37.9** degrees Celsius.
- Pulse rate **140** per minute
- Blood pressure was **100/55** mmHg

Senior house officer doctor stated at interview that (s)he met O&G Registrar 2 on the ward corridor and discussed the patient's findings and management. O&G Registrar 2 was on O&G Consultant 1's team that were scheduled to conduct ward rounds at approximately 08.00hrs

Whilst it is not documented in the clinical records the senior house officer (SHO) doctor has stated that as part of their discussion with O&G Registrar 2 that (s)he queried if the patient should be commenced on a different antibiotic regime i.e. Flagyl (Metronidazole) and that (s)he was advised by O&G Registrar 2 that (s)he would come up to review the patient's case

²⁸ The patient's temperature was 37.9 degrees Celsius following IV paracetamol given at 06.45hrs.

shortly and that in the interim the patient was to be continued on Augmentin (Coamoxiclav). O&G Registrar 2 recalled the SHO doctor saying that the patient had a temperature spike.

On interview, the senior house officer doctor stated that the patient asked them about the findings of the ECG and that (s)he explained the findings and the proposed treatment plan to her and that (s)he remained with the patient until the obstetrics and gynaecology team came to see her at 08.25 hrs.

"[the patient] was talking to me, she asked me about the ECG, seemed to have some medical knowledge, she was aware. I explained my management to her and my findings. I stayed with her until the team came on."

Wednesday the 24th of October 2012: 08.25HRS

The patient was reviewed by the patient's consultant obstetrician/gynaecologist and their team at the start of ward rounds.

The documentation of the assessment in the clinical records completed by O&G Registrar 2 indicates that the patient who was 17 weeks gestation and had a history of premature rupture of membranes had been unwell that morning with symptoms of feeling cold, aches and pains and back pain.

The documentation of the patient's vital signs (as recorded in the case notes) as part of this ward round assessment indicates that the patient's temperature was **37.9** degrees Celsius following the administration of intravenous paracetamol at 06.45 hrs and that her pulse rate was **144** per minute and that she was on 40% Oxygen supplementation to support an Oxygen saturation of 98-99%. The patient's blood pressure was also documented on the observation chart as being **98/54** mmHg but this was not documented or commented on in the case notes.

The patient had an examination of her chest and abdomen carried out as part of this assessment. The clinical findings of this examination indicated that she had mild lower abdominal tenderness.

The documented clinical impression of the medical team following this review was that the patient had a diagnosis of chorioamnionitis and the documented plan of treatment at this time was that she was to continue on intravenous fluid therapy, was to commence a second antibiotic (Metronidazole 500 mgs eight hourly), the first dose of which was administered at 08.30 hrs, and to continue on intravenous Augmentin (Coamoxiclav) 1.2 gms eight hourly.

In addition a high vaginal swab was sent and a midstream specimen of urine (MSU) was to be sent to the laboratory for cultures to discover what infection was present. It was noted that the results of the patient's blood tests including blood cultures were awaited at this time (i.e. 08.25 hrs). The patient's consultant obstetrician/gynaecologist confirmed that the focus of the team at this time was to identify the source of infection and that they felt they could wait for the results to come back and if they did need to intervene it would be later that day following blood results.

During interview, the patient's consultant obstetrician/gynaecologist stated that (s)he advised the patient and her husband that if the source of infection could not be found, a termination of the pregnancy might have to be considered. The O&G Registrar doctor stated that the medical team discussed possible termination of the patient's pregnancy amongst the team and that the consultant had said that if the patient didn't improve, she may need to be

induced (on October 24th). This discussion between the Obstetrics and Gynaecology team is undocumented in the medical records.

The patient's consultant obstetrician/gynaecologist stated at interview that (s)he felt, based on the RCOG Guidelines On Bacterial Sepsis in Early Pregnancy (2012) that there was no sign of septic shock as the patient's blood pressure was normal.

The O&G Registrar doctor also stated at interview that the team had seen the patient's temperature had come down and antibiotics had just been given. The patient had received IV Augmentin (Coamoxiclav) and Paracetamol and "we were giving it time to work".

Wednesday the 24th of October 2012: 11.45HRS

A note related to this time but written later by midwifery/nursing staff documented that the patient was to be administered paracetamol on a regular basis and that she had been administered this at 06.45 hrs and 11.00 hrs.

It is documented at 11.45 hrs that the patient's per vagina (PV) blood loss remained unchanged at this time and that she had a tachycardia of 140 -160 per minute. In addition the fetal heart had been checked and was 148 beats per minute.

It is documented that the clinical team managing her care at 08.25 hrs considered a diagnosis of chorioamnionitis. The plan of treatment following this review was for the patient's vital signs and fetal heart rate to be monitored and that the patient was to be reviewed again by the team later with a view to arranging an induction of labour if there was no fetal heart present. It is documented by the same Staff Midwife at this time that intravenous fluid therapy was being administered at this time and that the result of a midstream specimen of urine (MSU) test was awaited.

Wednesday the 24th of October 2012: 12.00HRS

A later note related to this time by midwifery staff documented that the patient's blood pressure had decreased to **76/46 mm Hg** and that the rate of her intravenous fluid therapy regime had been increased so as to manage this and that she was subsequently transferred to a different room to facilitate more close monitoring of her clinical condition following the deterioration in her clinical observations (also noted in a retrospective note completed by the Clinical Midwife Manager (2). The patient's consultant obstetrician/gynaecologist stated that (s)he was not informed when the patient was moved to another room for closer monitoring.

The consultant recalled at interview checking the patient's blood results at midday "*There was certainly no MSU results (midstream specimen of urine) at [midday]. I was awaiting the MSU. I looked at her renal function and platelets were normal. The white cell count (reported as 1.7) raised less alarm bells in that context*".

The patient's white cell count was $1.7 \times 10^9/L$ on a sample reported in the laboratory at 08.29hrs. A normal range for a white cell count in a second trimester pregnancy is between $6.2 - 14.8 \times 10^9/L$ (Bain, 2006).²⁹

²⁹ A low white blood cell count or an elevated blood cell count outside the normal range for a person in a second trimester pregnancy suggests sepsis (as per RCOG Guideline 64a *Bacterial Sepsis in Pregnancy* (2012).

Wednesday the 24th of October 2012: 13.00 HRS

Staff Midwife 6 documented in a retrospective note that the patient's observations were as follows:

- Pulse rate **156** per minute
- Blood pressure **72/38** mmHg,

The patient was complaining of chest discomfort and an ECG had been recorded and the rate of the patient's intravenous fluids had been increased. The Staff Midwife also noted that the intern on call had been contacted to review the patient's care.

Wednesday the 24th of October 2012: 13.10 HRS (Approximately)

The patient's consultant obstetrician/gynaecologist stated that (s)he received a call to review the patient at 13.10 hrs. The consultant recalled going to the Gynaecology Theatre en route to the gynaecology ward to collect a scanner. Nursing staff reported that the patient was unwell i.e. had a high respiratory rate and was having difficulty in breathing.

Wednesday the 24th of October 2012: 13.20HRS

The Staff Midwife 6 documented in a note related to this time but written later that the patient's blood pressure and pulse was as follows at 13.20 hrs:

- Blood Pressure **81/40** mmHg
- Pulse rate **150** per minute

The Staff Midwife also documented that the patient's consultant obstetrician/gynaecologist was contacted by the Clinical Midwife Manager (2) and that the patient's consultant came to review the patient after (s)he had gone to get the scanning machine. The Staff Midwife noted that the patient was complaining of back pain and was receiving pethidine 75mg intramuscularly (given at 13.45 hrs) and an antiemetic Zofran 4mg (given at 13.45 hrs).

The consultant completed a later note at 15.00 hrs but related to this time documenting their clinical review of the patient from approximately 13.20 hrs. The documented findings of the clinical assessment carried out by the patient's consultant was based on events from 13.20 hrs onwards and indicates that the consultant had been requested to review the patient's care. The record notes a sudden deterioration in the patient's clinical condition at 12.00 hrs as shown by hypotension, dyspnoea and myalgia. The consultant stated that the patient was tachypnoeic and dyspnoeic and was very unwell at the time of this assessment (13.20 hrs).

The patient's history of admission on the 21st October with a history of bulging membranes through the cervix was noted in the retrospective note and it is documented that a scan had been carried out on the 22nd October 2012.

The consultant documented that the patient had been commenced on oral antibiotic therapy (erythromycin 250gms orally six hourly) at 22.00 hrs on the 22nd October. The patient was noted to have had an elevated temperature in excess of 39.0 degrees Celsius on the morning of the 24th of October with tachycardia and it is documented that her blood pressure was stable at that time (in the morning). It is documented that the results of blood tests taken earlier that morning indicated a white cell count 1.7 with an elevated CRP (C-reactive protein

which is a general marker of inflammation in the body and suggests infection when taken in this clinical context) and normal urea and electrolytes.

As part of their clinical assessment, the patient's consultant obstetrician/gynaecologist carried out an examination of the patient's abdomen. The documented findings indicated that it was soft and mildly tender.

While it has not been documented in the clinical record, the consultant stated that the patient was complaining of rectal pressure at this time. A vaginal examination carried out indicated that the patient's cervix was 2 centimetres dilated, thick and ½ cm long and that the vertex was at station minus 2 (presenting part of the fetus was 2cm above ischial spines).

Following this review a diagnosis of septic shock was made, the cause of which was queried to be chorioamnionitis which was being considered by the consultant.

While it has not been documented in the clinical record, the patient's consultant obstetrician/gynaecologist stated that (s)he discussed the management of the patient with another consultant obstetrician/gynaecologist (B) at a time between 13.00 hrs and 15.00 hrs. The patient's consultant stated explaining to their colleague that the patient was very unwell, appeared septic and regardless of fetal heart, would the other consultant sign off (as a second consultant opinion) on the delivery and (s)he said they would. The patient's consultant stated that if there was a fetal heart (s)he would get their consultant colleague (B) to put a note in the chart. The second consultant (B) confirmed to the investigation team at interview that (s)he agreed with the assessment of the patient's consultant.

Following the above conversation the patient's consultant recalled going to the gynaecology theatre to speak with an anaesthetist about transferring the patient to the High Dependency Unit (HDU). (S)he also went to get another scanner.

Wednesday the 24th of October 2012: 13.50HRS

The Staff Midwife 6 has documented in a retrospective note timed 13.50 hrs that the patient's observations were as follows:

- Blood pressure **65/30** mmHg
- Pulse rate **152** per minute

Pethidine was withheld.

Wednesday the 24th of October 2012: 14.09HRS

The patient's obstetrician/gynaecologist (1) contacted Microbiology Consultant A by phone to discuss the patient's care (to determine if antibiotics were appropriate). A change to the patient's antibiotic regime was recommended by the microbiologist and was ordered on the basis of this discussion.

Consultant Microbiologist A documented this telephone discussion on the electronic microbiology laboratory record at 14.09 hrs indicating that the patient who was 17 weeks gestation was admitted over the weekend with an incompetent cervix as shown by bulging membranes, subsequently had spontaneous rupture of membranes on Monday (22nd of October at 00.30 hrs) and had been commenced on oral antibiotic therapy (erythromycin) as per protocol (protocol for ruptured membranes without signs of infection) on 22nd of October at 22.00 hrs).

Consultant Microbiologist A documented that they had been informed that the patient had developed a temperature of 39.2 degrees Celsius that morning with a tachycardia of 150 per minute and a blood pressure of 65/30 mmHg. In addition, the results of her blood test indicated a white cell count of $1.9 \times 10^9/L$ at 11.30 hrs with neutrophils of $1.2 \times 10^9/L$. Both counts were abnormally low.³⁰ She had normal renal function test and she had been commenced on Augmentin (Coamoxiclav) (first dose 07.00 hrs) and Metronidazole (first dose 08.30 hrs) that morning and that blood cultures had been sent at this time.

Consultant Microbiologist A documented that the advice given was that the patient should be commenced on Tazocin (Piperacillin/tazobactam) and a stat dose of gentamicin (5mg/kg body weight) and that the patient should continue on metronidazole. In addition the microbiologist advised that the patient's renal function should be reviewed the following day.

Following this discussion the patient was subsequently prescribed a stat (i.e. immediate) dose of gentamicin 300mgs intravenously which was administered at 14.40 hrs and was commenced on Tazocin 4.5 gms intravenously every eight hours and the first dose of which was administered at 14.45 hrs. The next dose of Metronidazole was given at 17.00 hrs.

The documented plan of treatment at this time was that a urinary catheter was to be inserted and fluid resuscitation (to correct the patient's hypotension) was to be commenced and that strict monitoring of the patient's fluid intake and output was to be undertaken.

In addition, the patient was to have a central line inserted (for monitoring, to assess fluid requirements, and to deliver drugs to improve blood pressure) and she was for transfer to the High Dependency Unit (HDU) and she was to be administered a medication called Misoprostol to induce delivery of the fetus once the patient was more haemodynamically stable. This medication was charted but not administered because the patient had a spontaneous delivery at 15:15hrs.

While availability of a bed was awaited in the High Dependency Unit (HDU) the patient was transferred to the operating theatre to facilitate and expedite the insertion of a central line as the critical care area of the hospital where this procedure was normally performed was at full capacity and could not accommodate the patient at this time.

Wednesday the 24th of October 2012: 15.00HRS

Based on the notes at 15.00 hrs, an ultrasound scan carried out indicated that there was no movement of the fetal heart at this time.

Wednesday the 24th of October 2012: 15.15HRS

The patient was transferred to the operating theatre to facilitate insertion of a central venous monitoring line and to continue resuscitation. While there the patient suffered a miscarriage with the spontaneous delivery of the fetus and placenta.

³⁰ A normal range for a white cell count in a second trimester pregnancy is between $6.2 - 14.8 \times 10^9/L$ (Bain, 2006).

A normal range for a neutrophils count in second trimester pregnancy is 3.8 - 12.3 (Bain, 2006).

The patient's consultant obstetrician/gynaecologist, who was present at this time, examined the placenta and has documented that it appeared complete and that swabs of the maternal and fetal surface of the placenta were sent for culture and sensitivity.

The consultant recalls that (s)he spoke to the patient's husband to inform him that the fetus had been delivered (spontaneously) in theatre and that patient's husband was taken into theatre to be with his wife who was extremely upset about the miscarriage.

Wednesday the 24th of October 2012: 16.15HRS – 16.45 HRS HDU Referral and Admission

14:15HRS:

Within the High Dependency Unit (HDU) admission note dated 24/10/12, the Senior House Officer Doctor (3), who is an Anaesthesia Basic Specialist Trainee, stated "*called to review at 14:15 hrs*". This timeline was confirmed at interview with O&G Consultant 1 and Consultant Anaesthetist B.

Consultant Anaesthetist A (the Consultant Anaesthetist in the gynaecology theatres that day) was the first Consultant Anaesthetist contacted by the patient's consultant obstetrician/gynaecologist.

Consultant Anaesthetist B was contacted following this regarding the patient's transfer to the High Dependency Unit/Intensive Care Unit. Consultant Anaesthetist B could not immediately attend the patient (as they were involved with another sick patient in the ICU). Consultant Anaesthetist B thus asked their colleague Consultant Anaesthetist C to attend.

The Senior House Officer doctor (3) attended with both Consultant Anaesthetist C and Consultant Anaesthetist A (consultant anaesthetist in gynaecology theatre). The note from the SHO doctor (3) defines the patient's blood pressure as **60/30** with a sinus tachycardia of **150/min**. (S)he described in their note the initial management with intravenous 3 L Hartmanns solution, 500ml gelofusine, phenylephrine increment, right internal jugular vein central venous catheter placement, a further 500ml gelofusine and commencing a noradrenaline infusion at 7ug/min. The note states that the patient's blood pressure (BP) responded to this treatment and was 140/66 mm Hg, heart rate was 155/min; **Lactate was 8.8 mol/L**; $S_{CV} O_2$ 91%. Capillary refill < 2 secs.

15:15HRS:

These actions were commenced in the gynaecology ward and she was then transferred to the gynaecology theatre for placement of the central venous catheter, left radial arterial line and vasopressor (noradrenaline) infusion. A note related to 15.15 hs but written later timed the transfer to theatre as 15:15 hrs.

Blood cultures are also noted to have been done; White cell count of $1.7 \times 10^9/L$ was noted, and confirmation of current antibiotic therapy (Tazocin, Metronidazole and Gentamicin).³¹

16:45HRS:

³¹ It was being queried by the senior house officer doctor (3) if the Gentamicin was to be continued but the understanding was this was to be determined after the repeat of the tests of renal function the next day.

The patient had a spontaneous vaginal delivery (SVD) during this time in the gynaecology theatre (according to note at 16:20 hrs, 24/10/12). The patient and her husband spent some time together in theatre, and transfer to the high dependency unit (HDU) is timed in this retrospective note as 16:45 hrs.

On-going management from the intensive care unit/high dependency unit team and transfer was supported by SpR 6 whilst the senior house officer doctor (3) went back to the intensive care unit to attend the evening handover round.³²

Wednesday the 24th of October 2012: 16.45HRS

The patient was transferred to the High Dependency Unit (HDU). It is documented that she was alert and responsive at the time of transfer.

Wednesday the 24th of October 2012: 17.06HRS Admission to HDU³³

Consultant Anaesthetist B handed over to Consultant Anaesthetist D and went to attend in the A & E Department.³⁴

Consultant Anaesthetist D examined the patient at 18:00 hrs (as per the nursing record). The patient's vital signs at this time consisted of a sinus tachycardia of 140 bpm, on facemask oxygen of 35% O₂, and she was haemodynamically supported with a noradrenaline infusion at 12ug/min. The patient's initial pH was 7.27, a base excess of -11.9, and a **serum lactate of 7.3 mmol/l**.

A number of actions were directed by Consultant Anaesthetist D over the overnight period, including further volume therapy, addition of hydrocortisone, and commencement of vasopressin infusion. The patient received a number of volume challenges to a total intake in HDU by 08:00 hrs the next day of +4847 ml.

Consultant Anaesthetist D discussed at interview the evolution of the patient's acute lung injury and the difficulties presented by the combination of her leaky capillaries secondary to sepsis, inflammatory response and acute lung injury, and the assessment of appropriate volume therapy. The patient further required blood, fibrinogen, platelets and Anti D.

³² Immediate access to a high dependency bed required some transfers of other patients within ICU/HDU to create a bed space. It was an appropriate action to have a consultant anaesthetist colleague and the non consultant hospital doctor on duty for the high dependency unit to attend to the patient on the ward and commence assessment and resuscitation. It was also an appropriate action on the gynaecology ward and gynaecology theatre to transfer the patient into the theatre environment as a suitably resourced facility to progress line placements, start vasopressor infusions and volume therapies. The approach taken would be a recognised approach across the nation's acute hospitals to address the immediate needs of a patient pending HDU/ICU bed availability. During this period the patient delivered the fetus spontaneously, in a high dependency type environment. The gynaecology ward and theatre are remote from the intensive care unit/high dependency unit in the hospital. The transfer of an unstable patient across the hospital prior to establishing the above therapies would have potential for risk, and would require the clinical judgement of the attending specialists to assess such risk prior to transfer.

³³ The following chronology is derived from the Clinical Information System data, medical paper record, and an interview with intensive care consultant on duty.

³⁴ At interview the intensive care/anaesthetist consultants described a very busy clinical environment with a number of simultaneous critical patient events occurring in the A & E Department and in the intensive care unit.

Wednesday the 24th of October 2012: 20.31HRS

Consultant microbiologist A contacted the ICU to inform them that blood cultures taken from earlier that day were positive and that the current antibiotics should be continued and to be reviewed with preliminary sensitivities the next morning.³⁵

Wednesday the 24th of October 2012: 23.00 HRS

Consultant Anaesthetist D recalls that the patient was seen by the obstetrical registrar on call at 23.00 hrs on the 24th October 2012. A portable scan taken at this time revealed no evidence of retained products of conception.

Thursday the 25th of October 2012: HDU

Thursday the 25th of October 2012: 00.20 HRS HDU

A note at 00:20 hrs on 25/10/12 from the gynaecology team defines the patient's clinical condition, and a portable abdominal ultrasound with the interpretation "*no obvious RPOC*". (retained products of conception).

Thursday the 25th of October 2012: 01.00 HRS HDU

At 01.00 hrs patient received a first dose of Vancomycin 900mg intravenously.

Thursday the 25th of October 2012: 03.00HRS – 03.30HRS ICU³⁶

Over the course of the night and up to 03:00 hrs the patient was noted to have on-going clinical deterioration with an increasing oxygen requirement (now requiring 80% O₂), increasing vasopressor requirement (noradrenalin infusion 60ug/min at 03:00) and worsening metabolic status (pH 7.27, BE -12.7, lactate 7.3). The patient was therefore transferred from the high dependency unit to the intensive care unit (which is in the same complex) at 03:00 hrs and intubated at approximately 03.30 hrs on the 25th of October, 2012.³⁷

³⁵ Based on the interview with Consultant Microbiologist A the investigation team learned that the first set of blood cultures grew bacteria after 7 hours of incubation and the second set grew after 11 hours of incubation.

³⁶ The following summary of care is derived from the Clinical Information System data, medical paper record, and interview with intensive care consultant on duty. Due to the copious amounts of documentation about clinical condition, observations and investigations while the patient was in the intensive care unit, the investigation team have summarised the salient points relating to the care received.

³⁷ The overnight care in the high dependency unit on 24.10.12-25.10.12 was to treat the progression of severe sepsis with associated inflammatory process and multi-organ involvement resulting in respiratory insufficiency and a need to initiate mechanical ventilation. The possibility of retained products of conception was considered within the high dependency unit as part of on-going bleeding and sepsis. An early seven hour growth of a gram negative rod in blood culture was identified and antimicrobial therapies were consistent with the recommendation from microbiology service and the hospital's antimicrobial guidelines.

Thursday the 25th of October 2012: 09.00HRS ICU

The intensive care unit team morning round was held at approximately 09:00 hrs.

The Anaesthetics Registrar's contemporaneous note within the file described the clinical scenario of septic shock, ARDS (acute respiratory distress syndrome), high inotropic support (Noradrenalin 50ug/min, vasopressin 2.4 iu/hr) and DIC (disseminated intravascular coagulation). The patient remained ventilated with a high oxygen requirement (70% O₂), sedated, a urine output of 25ml/hr, soft abdomen, and on going pyrexia (38°C).

The patient's white cell count was noted as 19 x 10⁹/l (based on a sample received by the laboratory at 04.21 hrs), and the patient's C-reactive protein was 206 (based on a sample received by laboratory at 03.00 hrs).

Actions defined on the ward round note were:

- Haematology consult
- Dobutamine infusion trial
- Hydrocortisone infusion
- Folic acid 15mg/d
- Modification to her mechanical ventilation strategy

All actions outlined above were completed.

A review by haematology on the 25th of October, 2012 (noted in an untimed note) concurred with a diagnosis of disseminated intravascular coagulation (DIC) secondary to sepsis and haematology made recommendations for management of the disseminated intravascular coagulation (DIC).

Thursday the 25th of October 2012: 12.00HRS ICU

The microbiology intensive care round lead by Consultant Microbiologist X was held at 12:00 hrs and noted gram negative bacillus growing from blood cultures, identification and sensitivities awaited.

Consultant Microbiologist X recommended a change in antibiotics from Piperacillin/tazobactam to Meropenem based on the preliminary sensitivity results showing a reduced zone possibly indicating potential issues with antibiotic resistance in the clinical context of the patient's serious clinical condition whilst the full report on susceptibilities was awaited. Consultant Microbiologist X recommended Meropenem 1G every 8 hours. The first dose was given to the patient at 13.00 hrs on October 25th.

Microbiology also noted that placental swabs received at 17.08 hrs on October 24th also had coliforms (coliforms is a term often applied to a broad group of Gram negative bacilli before they are fully identified to species level). A note stated that the intensive care unit staff were not aware if the patient had a background history of possible travel in recent months and also if history of diarrhoea in recent weeks but were requested by the microbiology team to check same.

The patient's metabolic status showed some improvement over the day. The patient's pH at 03:00 hrs was 7.17, later 7.23 at 12:00 hrs and 7.27 at 23:00 hrs. For the same time periods the patient's lactate was 6.5, 4.1, and 3.5 m mol/L respectively.

The patient's oxygenation requirement was 40 - 50% oxygen over the course of the day, on mechanical ventilation.

The patient's renal indices were a urea 10.7 mmol/l and creatinine 112 umol/l. Input + 4059ml to 08:00 hrs on 26/10/12.

Vasopressor requirements noted were noradrenaline 60 ug/min at 04:00 hrs, 50ug/min at 15:00 hrs and 38 ug/min at 23:00 hrs. Vasopressin was a continuous steady infusion rate of 2.4 iu/hr. Low dose dobutamine (< 5ug/kg/min) was also infused. CVP remained 12 - 15, and haemodynamic calculations via Vigileo defined a cardiac index of 3.9 - 4.3 l/min/m² and stroke volume variation of 13% at 06:00 hrs, and 6% at 22:00 hrs, with a CVP of 12-15.

Despite this lessening of vasopressor demand, the patient remained pyrexial (> 38°C) and tachycardic (Heart Rate approx 130/ min) throughout.³⁸

Friday the 26th of October 2012: ICU (General Timings)

Throughout 26th October 2012 the patient remained critically ill within the intensive care unit. The patient remained intubated, ventilated, and required significant vasopressor infusion therapies. The clinical picture was described by the intensive care consultant on duty interview as a hyperdynamic vasodilated state consistent with severe sepsis. The patient was described as 'warm' and 'well perfused', including the patient's peripheries. The dosage of the patient's vasopressor infusions was reduced between midnight and 19:00 hrs in parallel with her metabolic, clinical, and haemodynamic status. However these dosages remained significant, with a noradrenalin infusion of 38ug/min and vasopressin infusion at 2.4 units/hr at 02:00 hrs, tapering to noradrenalin 26ug/min at 21:00 hrs, with the vasopressin dosage remaining constant throughout her critical care period once established at that dosage.

The patient's cardiac output was noted to have decreased in the afternoon, and an adrenalin infusion 10ug/min was commenced at 19:00 hrs, followed by an increase in cardiac output and reduction in this dosage to adrenalin 6ug/min by 20:00 hrs. Cardiac output and associated haemodynamic variables were tracked using Vigileo monitoring throughout. Central venous pressure during this time period was variable between 10 and 18 mmHg, and increasing to 24mmHg at 23:00 hrs. Oxygenation and ventilation was within a range of 40% to 60% O₂, with PEEP (i.e. Positive End Expiratory Pressure) weaned from 14cmH₂O to 12 cmH₂O by 11:00 hrs, mechanically ventilated with tidal volumes approximately 450 ml and mean airway pressures less than 20cmH₂O .

The patient's acid-base status was variable through the day, with a pH of 7.29 at 01:00, pH 7.4 at 10:00 hrs, and pH 7.28 at 23:00 hrs.³⁹ Her serum lactate at the same time points was

³⁸ Although there were some apparent improvements in metabolic state and vasopressor requirements, pyrexia persists and sepsis state is still aggressive. A trial of dobutamine is aimed at improving microcirculatory perfusion. Microbiology consultation directs a change of antibiotic from Piperacillin/tazobactam to Meropenem, reflecting a possibility of resistance of the identified blood culture bacteria (gram negative bacilli which is a type of bacteria, the name being derived from a type of staining called Gram staining where these particular bacteria do not retain the stain) to Piperacillin/tazobactam, and a clinical context of on-going severe sepsis. Clinical and haemodynamic profile informed volume and pressor management along with mechanical ventilation strategy are consistent with international guidelines and patient context.

³⁹ A combination of pH, base excess, and lactate are routine measurements in the critically ill to help monitor, quantify, and track tissue and organ perfusion and the response to therapies to treat poor perfusion if present. A low pH (less than 7.3), a negative base excess (a minus value is abnormal), and an elevated serum lactate (greater than 4mmol/l) are suggestive of poor organ perfusion in this context, and hence their inclusion in this chronology.

3.4 mmol/l, 2.2 mmol/l, and 4.4 mmol/l respectively. The patient's renal function was sustained with maintenance of adequate urine output, but with an elevation of urea 10.7 mmol/l and creatinine 112 umol/l. Input +6948 ml to 08:00 hrs on 27/10/12.

The consultant on duty for intensive care expressed hi(s)her concerns at interview that despite these apparent improvements, he/she remained concerned about the possibility of an on-going focus for infection. The ICU notes of 26/10/12 state "patient critically unwell. ? CT TAP. ? EUA + ? ERPC".⁴⁰

These concerns were in view of her persistent hyperdynamic state and persistent pyrexia (temperature 40°C at 09:00 hrs, 39.5°C at 11:00 hrs) and remaining pyrexial throughout the day and evening. Her WCC was 23.4 X 10⁹/L that morning.

The record of the gynaecology clinical review states that the patient was in septic shock, not improving but deteriorating, and an interpretation that a portable ultrasound scan at that time showed an empty uterus, and a query as regards free fluid in the pelvis. This was discussed with O&G Consultant 3 and the anaesthetic team and a decision to proceed with a CT TAP urgently, which was performed and reviewed, with the clinical note (20:00hrs) stating there was "no indication for surgery intervention as no RPOC"⁴¹

The intensive care unit note dated 26th of October and timed 18.30 hrs described an increase in oxygenation requirement, an increase in noradrenaline infusion requirement, an increase in lactate, worsening acidosis, and increased intra-abdominal pressure.

Friday the 26th of October 2012: 12:00HRS Consultant Microbiology Ward Round ICU

The Consultant Microbiologist ICU round at approximately 12:00 hrs identified the Gram negative bacillus as ESBL (extended spectrum beta-lactamase)-producing *E. coli*⁴² in blood cultures and the bacteria from the placenta maternal and fetal surfaces which had been provisionally categorized as coliforms (on the previous day) had now been confirmed as *E. coli* also. This organism was reported as susceptible to Tazocin (Piperacillin/Tazobactam) with MIC (minimum inhibitory concentration) of 2.0-3.0ug/ml and was also susceptible to Meropenem and Gentamicin as per Microbiology laboratory reports. Viridans Group *Streptococcus* was also isolated from Placenta surface swab (Foetal)⁴³.

⁴⁰ CT TAP is a Computerised Scan of the Thorax, Abdomen and Pelvis; EUA is Examination Under Anaesthetic; and ERPC is Evacuation of Retained Products of Conception.

⁴¹ The patient remained critically ill, and multi-disciplinary consultations reflected a concern that a motor for continued sepsis was not fully addressed. The CT scan of thorax, abdomen, and pelvis is an essential part of this search, but proves not to yield a source amenable to operation or intervention. The organism from the blood culture of 24th October was identified as an ESBL *E. coli*, and the antibiotic management was correct. A blood culture was taken that afternoon and it reported no growth over the next 5 days, suggesting an absence of bacteria in the blood at that time point. This did not exclude occult sources of infection (e.g. intra-abdominal, intra-uterine or other), although the CT report was reassuring in that context. RPOC stands for Retained Products of Conception

⁴² *E. coli* (*Escherichia coli*) is one of several types of Gram negative bacilli bacteria that normally inhabit the intestine of humans. Some strains of *E. coli* are capable of causing disease under certain conditions. Coliform(s) is a term often applied to a broad group of Gram negative bacilli before they are fully identified to species level by the Microbiology laboratory. ESBL-producing *E. coli* has a particular pattern of acquired antimicrobial resistance that can be a community-acquired or healthcare-associated source.

⁴³ The bacteria, *E. coli*, that was isolated from the patient's blood culture and placental swabs had a particular pattern of acquired antimicrobial resistance which can be associated with either a community-acquired or healthcare-associated source. However this ESBL-producing *E. coli* was reported as susceptible to Tazocin (Piperacillin/Tazobactam) and Gentamicin; the antibiotics recommended for use in local Guidelines for management of sepsis.

Friday the 26th of October 2012: Continued General Timings

Antibiotic management was continued as established with Gentamicin 300mg daily, Metronidazole 500mg eight hourly and Meropenem 1g eight hourly. This management was noted in the medical record of the 26th of October at 20:00 hrs "*on appropriate antibiotic cover*".

An Infection Control and Prevention sticker was placed in the patient's chart on October 26th regarding the Extended Spectrum Beta Lactamase (ESBL) identified from a placenta surface swab.⁴⁴

Saturday the 27th of October 2012: ICU

The note of the intensive care ward round held at 11:30 hrs described the patient as critically unwell at this time.

The note from this round defined the plan for the day to include continuous renal replacement therapy, continue antibiotics, platelet transfusion if bleeding or a platelet count less than $30 \times 10^9/L$, and to continue current management.

The patient remained on mechanical ventilation with 50% oxygen requirement with an increasing airway pressure over the course of the day.⁴⁵

The patient's vasopressor requirements remained very high and increasing through the day, but particularly reflecting an acute change at 16:00 hrs. This is also reflected in the patient's acid-base status, with a pH at 01:00 hrs of 7.45, 7.31 at 11:00 hrs, 7.14 at 15:00 hrs. Over the same time periods her base excess changes from -6.8 to -16, and her serum lactate rises from 5mmol/l to 10.3 mmol/l.

The patient's temperature was 38.7°C at 07:00 hrs, but cooled to 35.9°C at 11:32 hrs with the commencement of continuous renal replacement therapy.

Consultant Anaesthetist E (Consultant on duty for Intensive Care) met the patient's husband and their friend (noted in the intensive care unit nursing note between 11:32 hrs and 13:00 hrs).

A note in the medical record at 16:30 hrs recorded a consultation with the Consultant Microbiologist on call who recommended an increase in meropenem dosage to 2G per dose, and recommencement of vancomycin with a loading dose of 25mg/kg, and maintenance of 15mg/kg per dose. (wcc was $24 \times 10^9 / L$). These recommendations were actioned.

Onset of hypoglycaemia is noted at 15:30 hrs (within the intensive care nursing notes), and treated with 50% dextrose bolus followed by infusion.

A transoesophageal echo was performed by Consultant Anaesthetist E who noted a dilated right ventricle, severe tricuspid regurgitation, hypokinetic left ventricle and the possibility of a

⁴⁴ Extended-Spectrum Beta-Lactamases: ESBL-producing bacteria are bacteria that produce enzymes that may break down commonly used antibiotics.

⁴⁵ The patient's clinical and haemodynamic profile informed volume and pressor management along with mechanical ventilation strategy and was consistent with international guidelines and the patient's clinical context.

pulmonary embolism. A decision to heparinise the patient was made. (Medical note 20:30 hrs, the procedure was conducted at 17:21 hrs). Consultant Anaesthetist E consulted with an intensive care colleague, Consultant in Anaesthesia and Intensive Care F, O & G Consultant 3, and the general surgeon.

In discussion with the obstetric team the concern regarding possible on-going intrauterine sepsis was again raised (noted in the retrospective note within the intensive care unit records timed 17:30 hrs). A medical note from O & G Consultant 3 timed 18:30 hrs noted reviewing the course to date including results of the CT scan and pelvic ultrasound, and a discussion with both O&G Consultant 1 and Consultant Obstetrician 4 with a conclusion that there was nothing to be gained from gynaecological surgical intervention at this point and to continue current care. O & G Consultant 3 also met with the husband at this time with Consultant Anaesthetist E⁴⁶.

The patient's condition continued to deteriorate despite on-going measures including further volume challenge, blood products, increase in vasopressor infusion dosage, continuous renal replacement therapy, bicarbonate infusions, insulin and dextrose for hyperkalaemia, and muscle relaxation to assist mechanical ventilation.

Sunday the 28th of October 2012: ICU

The patient suffered a cardiac arrest at 00:45 hrs on the 28th of October, 2012. Cardiopulmonary resuscitation was continued to 01:09 hrs (Medical note, ICU nursing notes, Cardiac Arrest Prescription / Audit form). The patient was pronounced dead at 01:09 hrs.

⁴⁶ The patient remained critically ill as defined in the medical case notes. Further multi-disciplinary consultations involved the gynaecology consultants, and intensive care consultant (and intensive care consultant colleague from whom intensive care consultant on duty sought further advices) and microbiology consultant advices. An increase in meropenem dosage and an addition of vancomycin reflected such concerns rather than newly identified treatment goals. The decision to commence continuous renal replacement therapy at this stage would be consistent with the management of such a patient, particularly with an evolving acute kidney injury, persistent acidaemia, and complex fluid management. Concerns remained evident regarding possible unresolved, unidentified, sources of sepsis.

A review of the investigations to date (ultrasound pelvis and CT thorax abdomen and pelvis) did not open an avenue or option for new intervention. The acute deterioration noted in the late afternoon is in the context of persistent lactic acidosis and over the course of this day a persistent elevation of central venous pressure. The patient's haemodynamic profile also deteriorated at approximately 15:00, with a lower cardiac index.

The intensive care consultant performed a transoesophageal echo. This investigation may have added new information as to the cause of the patient's deteriorating cardiac status, despite earlier derived values suggesting a high cardiac output state. The results raised a number of possibilities, including the possibility of a pulmonary embolism. The finding of poor left ventricular function may have reflected a sepsis induced cardiomyopathy. Should post mortem findings show insignificant or no coronary artery disease flow limitation, the significant Troponin T (cardiac enzyme) elevation of the 26th and 27th October may support a diagnosis of sepsis induced cardiomyopathy. The decision to treat the possibility of a pulmonary embolism with anticoagulation is reasonable based on these findings, but with little prospect of success. The patient's on-going clinical deterioration despite all these measures culminated ultimately in a cardiac arrest. It would be unusual to have success at cardiopulmonary resuscitation in a context of the high levels of intensive care management and interventions required to sustain life through that day.

Section 3: Aftermath of Incident

Following this patient's tragic and untimely death on the 28th of October, 2012 those caring for her offered their sympathies and condolences to the patient's husband.

The Coroner was advised of the case by the senior house officer doctor (SHO) in Anaesthetics at 03.00hrs on the 28th of October.

On the 31st of October 2012, the Clinical Director of the Hospital wrote to the patient's husband conveying his condolence and advising him of the hospital's internal investigation into the matter.

Bereavement counselling was offered to the patient's husband in line with normal hospital practice in such circumstances.

On the 1st of November the Maternal Death Enquiry – MDE Ireland Enquiries (formerly CMACE) was informed verbally by the clinical nurse manager 3 in the Obstetrics Department of the death to inform the work of the confidential enquiry in the UK and Ireland. This clinical nurse manager 3 registered the written notification of this maternal death to MDE on the 9th of November.

The details of the case were escalated for the attention, support and oversight of the HSE National Incident Management Team by the hospital on the 1st of November, 2012. A local investigation team was established by the hospital. Incident report forms were completed by both the Gynaecology Department and the ICU department.

Details of the investigation into this death chaired by Professor Sir Arulkumaran were announced by the HSE on Monday the 19th of November, 2012.

The investigation team made attempts to engage with the patient's husband in relation to this investigation. The patient's husband did not wish to meet with the investigation team chairperson or other members to discuss his account of events, and the investigation team respected the patient's husband's wishes not to be involved in the information gathering process of this investigation.

However, prior to completion of this report and in the aftermath of the verdict of the Coroners' Court members of the investigation team met the legal representative of the deceased's husband and a family friend and considered observations made on their behalf.

Section 4: Key Causal Factors, contributory factors, incidental factors and linked recommendations

The aim of this investigation was to seek to establish the circumstances of what happened, and whether any aspects of the care of this patient contributed to the untimely death of this 31 year old mother following a miscarriage at 17 weeks of gestation. In particular the investigation team aimed to focus on the chronology of events leading to this patient's admission to the Intensive Care Unit from the Gynaecology Ward on the 24th of October, 2012. If aspects of care were considered to have contributed, a further aim was to identify the underlying causes of these so that these causes can be addressed to improve the care given to mothers experiencing miscarriage in this and other maternity hospitals.

Purpose

The purpose of this investigation was to:

- Establish the factual circumstances leading up to the incident
- Identify any key causal factors that may have occurred
- Identify the contributory factors that may have caused the key causal factors
- Recommend actions where necessary that seek to address the contributory factors so that the risk of future harm arising from these factors is eliminated or if this is not possible, is reduced as far as is reasonably practicable.

Key Causal Factors

Key causal factors are defined by the HSE Guidelines for Systems Analysis Investigation of Incidents and Complaints (HSE, November 2012)⁴⁷ as issues that arise during the process of delivering and managing health services that are considered by the investigation team to have had an effect on the eventual adverse outcome. Following an analysis of the chronology, this investigation identified the following 3 key causal factors:

⁴⁷ HSE Guidelines of "Systems Analysis Investigation of Incidents and Complaints" (HSE, November 2012 can be downloaded at http://www.hse.ie/eng/about/Who/qualityandpatientsafety/Quality_and_Patient_Safety_Documents/QPSDGL5211.pdf

Key Causal Factor 1:

Inadequate assessment and monitoring that would have enabled the clinical team to recognise and respond to the signs that the patient's condition was deteriorating due to infection associated with a failure to devise and follow a plan of care for this patient that was satisfactorily cognisant of the facts that:

- the most likely cause of the patient's inevitable miscarriage was infection and
- the risk of infection and sepsis increased with time following admission and especially following the spontaneous rupture of the patient's membranes.

Key Causal Factor 2:

Failure to offer all management options to a patient experiencing inevitable miscarriage of an early second trimester pregnancy where the risk to the mother increased with time from the time that membranes were ruptured.

Key Causal Factor 3:

Non adherence to clinical guidelines related to the prompt and effective management of sepsis, severe sepsis and septic shock when it was diagnosed.

Each of these three key causal factors was analysed by the investigation team to identify the "*contributory factors*". Contributory factors are considered to be hazards and potential causes of future harm, if not mitigated (through appropriate recommendations being put in place).

The list of contributory factors outlined within the Contributory Factors Framework used to analyse each of the key causal factors within this investigation is included under Appendix E of this report.

The following sections of this report analyse each of the three key causal factors specified above and the "*contributory factors*" identified for each.

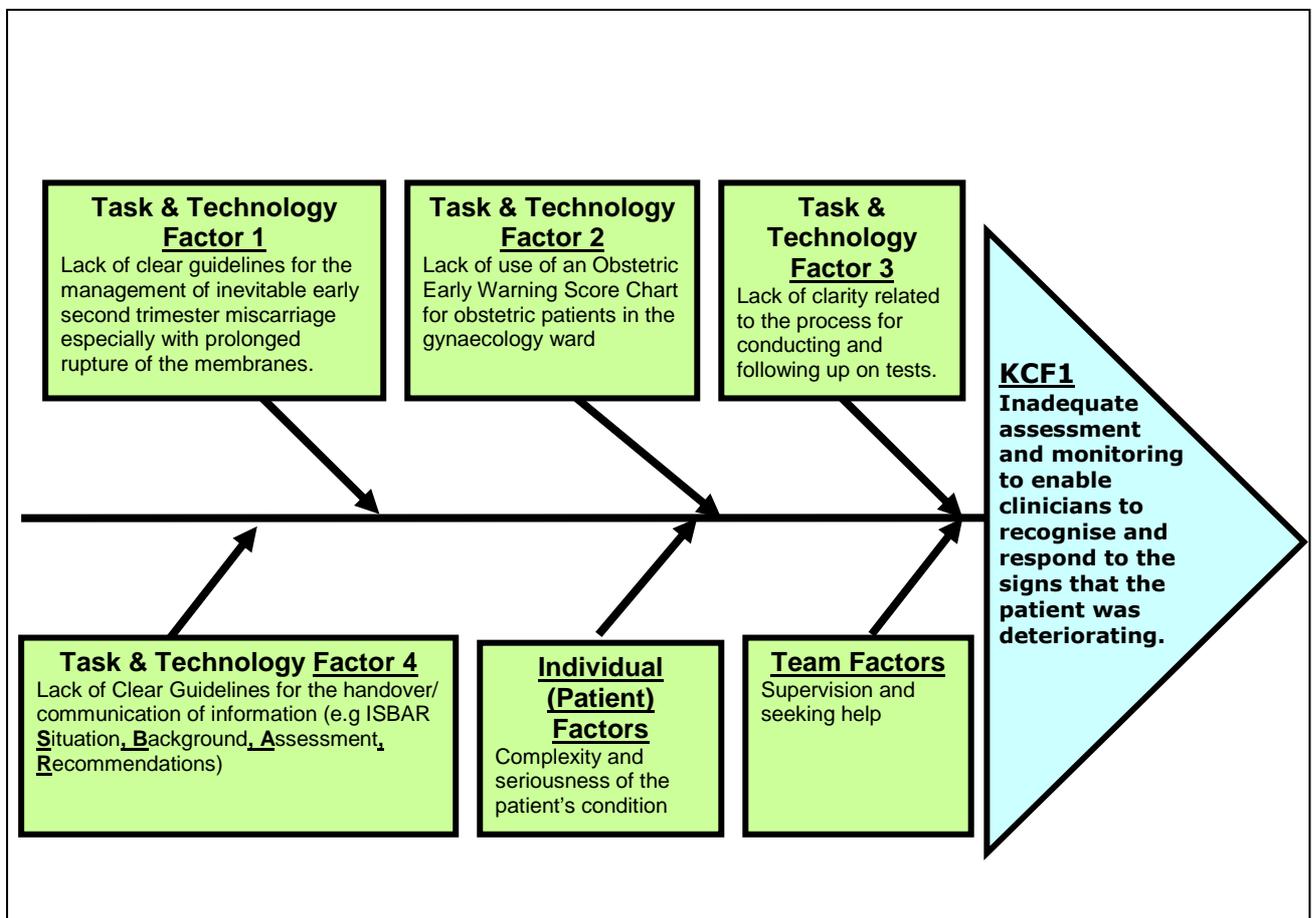
Key Causal Factor 1:

Inadequate assessment and monitoring that would have enabled the clinical team to recognise and respond to the signs that the patient's condition was deteriorating due to infection associated with a failure to devise and follow a plan of care for this patient that was satisfactorily cognisant of the facts that:

- the most likely cause of the patient's inevitable miscarriage was infection and
- the risk of infection and sepsis increased with time following admission and especially following the spontaneous rupture of the patient's membranes.

Factors that contributed to Key Causal Factor 1:

Figure 1: Key Causal Factor 1 (KCF1) and associated Contributory Factors.



Individual (patient) factors - Complexity and Seriousness of the patient's Condition:

In terms of factors that contribute to incidents, patient factors are aspects of the patient's condition that present challenges for medical management. In this regard, the clinical context in this case was of a rare and serious condition comprising second trimester pregnancy at 17 weeks, with prolonged spontaneous rupture of the membranes. Added to this is the fact that diagnosing sepsis is difficult in pregnancy given the associated natural physiological changes.

Task and technology factors:

The investigation team identified four task and technology factors that contributed to key causal factor 1 as follows.

- **Task and Technology Factor 1:**
- **Lack of clear guidelines for the management of inevitable early second trimester miscarriage of a pregnancy where there is prolonged rupture of membranes**

Second trimester miscarriage in itself is an uncommon condition estimated to be about 1 – 2% of all pregnancies (Allanson et al, (2010)). Excluding those associated with fetal abnormality, the incidence is 0.5% (Westin et al, (2007) with 77% associated with infection (Allanson et al, (2010)). Overall with chorioamnionitis, around 0.5% will develop sepsis and 0.1% will die (Lappen et al, (2010)).

The clinical condition in this case of ruptured membranes, presence of infection and a live fetus is a rare clinical scenario. Therefore, staff would not be used to managing cases with this clinical context. If infection sets in, it is a potentially serious condition. Staff dealing with clinical conditions that are rare and serious require clear guidelines and training in relation to these conditions. *However, there are no national or international guidelines on the management of inevitable miscarriage in the second trimester.* The signs of sepsis in this case is based on a review of the RCOG Green-top Guidelines on Bacterial Sepsis in Pregnancy which state that “*clinical signs suggestive of sepsis include **one or more** of the following: pyrexia, hypothermia, **tachycardia**, tachypnoea, hypoxia, hypotension, oliguria, impaired consciousness and failure to respond to treatment. These signs, including pyrexia, may not always be present and are not necessarily related to the severity of sepsis.*” (RCOG, 2012) The presence of sepsis could have been further substantiated through the ordering of additional tests such as a white cell count. A white cell count as suggested by the RCOG 2012 guidelines was not performed in this case when clinical signs suggestive of sepsis such as tachycardia and/or vomiting were present.

Spontaneous rupture of the membranes (SROM) at such early gestation carries with it a risk of an inevitable miscarriage and of maternal and fetal sepsis. The occurrence of SROM in the early second trimester increases the risk of miscarriage and fetal/neonatal death up to 80% and is more likely to be inevitable death of the fetus in the presence of infection (Hunter et al, 2012, Dewan et al, 2001).

Rupture of membranes may be caused by infection and vomiting indicates that the patient was unwell increasing the possibility of infection becoming systemic to causing sepsis. At interview, clinicians indicated that their management decisions were guided by the Royal College of Obstetricians and Gynaecologists Green-top guidelines for the Management of Preterm Pre-labour Rupture of the Membranes (RCOG Green-top Guideline No.44 2006 amended 2010). The patient was commenced on erythromycin at 22.00hrs on the 22nd of October. Erythromycin is indicated for use prophylactically in preterm pre-labour rupture of the membranes in the absence of signs such as a faster pulse or lower blood pressure or raised temperature (Green-top Guidelines No 44 (2006 with amendment Oct 2010)). Erythromycin has also been shown to delay delivery which is beneficial in the management of preterm pre-labour rupture of the membranes but not in cases of inevitable miscarriage. However, in cases of preterm pre-labour rupture of the membranes where signs of sepsis occur, best practice guidelines promote that delivery is expedited.

The appropriate management of spontaneous rupture of the membranes in cases of inevitable miscarriage where infection is a possible underlying cause is somewhat different to

the appropriate management of Preterm Pre-labour Rupture of the Membranes where the incidence of infection at presentation is lower and the survival of the fetus is more likely.

There are no accepted clear local, national or international guidelines on the management of inevitable early second trimester miscarriage (i.e. less than 24 weeks) including the management of miscarriage where there is prolonged rupture of the membranes. The reason for the absence of such guidelines may be that clinical practice in other jurisdictions would have led to an early termination of pregnancy in equivalent clinical circumstances. It is recommended that such guidelines be developed for such patients as a matter of urgency and they should be explicit in the guidance given as to when one should offer termination based on symptoms and signs of infection implying increasing health risk to the mother which may even threaten her life.

We recognise that such guidelines must be consistent with applicable law and that the guidance so urged may require legal change.

Recommendation 3:

The HSE should develop, disseminate and implement national guidelines on infection and pregnancy. The HSE should also develop multidisciplinary educational programmes to improve the quality of care in pregnancies complicated by infection.

Specifically, there is a need for the development, implementation and audit of compliance with guidelines on the management of infection in pregnancy, suspected sepsis and sepsis in cases of inevitable miscarriage of an early second trimester pregnancy including where there is prolonged rupture of membranes and where the risk to the mother increases with time from the time that membranes were ruptured. These guidelines should emphasise the:

- Need to focus appropriate attention on the early detection and management of infection and the prevention and management of sepsis, including vigilant monitoring of the time that has elapsed since the rupture of the membranes and consideration of appropriate antibiotic therapy and management or removal of the source of infection.
- Need for appropriate and early involvement of the multidisciplinary team to include a microbiologist anaesthetist, intensive care specialist, infections diseases specialist and other relevant specialists in cases of sepsis or suspected sepsis.
- Need for clarity about who is responsible for following up, reviewing and acting upon the results of tests ordered.
- Clear pathways for most efficient access to blood gas and lactate testing (preferably at point of care), along with appropriate training.

Recommendation 4a

Develop, implement and audit compliance with guidelines on the management of early second trimester inevitable miscarriage that are cognisant of the possible rapid deterioration of the patient from sepsis to severe sepsis to septic shock which could be within a few hours. These guidelines must also be cognisant of the high mortality rate (up to 60%) associated

with this. These guidelines should include but may not necessarily be limited to the following:

- Appropriate monitoring for efficient detection of infection and sepsis as per appropriate clinical guidelines for the Management of Suspected Sepsis and Sepsis in Obstetric Care; and Antimicrobial Guidelines
- Appropriate management that recognises the fact that the risk to the mother increases with time from the time the membranes are ruptured.
- Clarity about who is responsible for following up, reviewing and acting upon the results of tests ordered.
- Clear pathways for most efficient access to blood gas and lactate testing (preferably at point of care), along with appropriate training.

→ **Task and Technology Factor 2:**

→ **Lack of use of an Obstetric Early Warning Score Chart for obstetric patients in the gynaecology ward.**

The investigation team established that there were issues with monitoring for the signs of infection and sepsis that contributed to the failure to promptly diagnose and manage infection and sepsis in this case. Hospital guidance requires four-hour monitoring of patients with preterm pre-labour rupture of membranes (PPROM), (Preterm Pre-labour Rupture of Membranes: Revision 3, 2009). At interview, medical staff indicated that they were aware of this hospital guidance. However, in this case monitoring of the patient was less frequent (see appendix F). In addition, the fact that the (*modified*) Obstetric Early Warning Score (OEWS) Chart was not used for pregnant patients in the Gynaecology ward contributed to these issues i.e. the monitoring and diagnosis of infection and sepsis as shown in the following paragraphs.

Staff indicated that they were aware that infection was a common cause of second trimester pregnancy loss and that they were aware that infection may have been an underlying cause of this patient's inevitable miscarriage at the time of her admission on Sunday the 21st of October 2012. Although the most common causes of second trimester loss are fetal abnormality (Allanson et al, (2010), those presenting with a live fetus and bulging membranes are associated with infection in 77% of cases (Westin et al, (2007)). Therefore, the presence of infection should have been assumed and the progression to sepsis closely monitored for.

The spontaneous rupture of the membranes at 00.30hrs on the 22nd of October could have been due to either a natural progression of the inevitable miscarriage or a worsening of the situation potentially related to infection of the membranes. In any event, it significantly increased the possibility of infection in the uterus with the progression of time. It meant that the chances of fetal death, either by miscarriage or by increasing infection was certain and the risk of maternal infection was also increasing. Hence, there was a need for increased vigilance to identify early infection which may require termination of pregnancy to reduce the infection risk and prevent deterioration of the maternal condition. If an obstetric early warning score chart had been used, and the observations plotted on it, the rise in pulse rate and temperature would have been noted and, in all probability, acted upon. A decision not to

terminate the pregnancy, for whatever reason, increases the need for this clinical vigilance since the probability of worsening maternal condition is increased.

At 15.25 hrs on Monday the 22nd of October 2012 the patient's blood pressure was 92/58mmHg. This represents relative hypotension and would be noted as a yellow on the hospital (modified) Obstetric Early Warning Score (OEWS) Chart. At first examination on 21.10.12 blood pressure was 113/73 as per clinical notes. The patient's blood pressure at her booking appointment on the 11th of October, 2012 was 102/65mm Hg.

At 18.00hrs on the 22nd of October, the patient's temperature was 37.1 degrees Celsius, her heart rate was **102** beats per minute, and her blood pressure was **98/62** mmHg. In the context of a patient with pre-term prelabour rupture of membranes and a raised pulse rate, the use of an early warning score chart and more frequent observation and monitoring may have better alerted the staff of a change in the patient's condition and the need for additional investigations to check for the possibility of sepsis (See Appendix F).

By 00.30hrs on the 23rd of October, 24 hours had elapsed since the spontaneous rupture of the patient's membranes. Clinical literature suggests that the risk of infection in the uterus increases after 24 hours and the need for intervention to empty the uterus is increased. The balance of risks between conservative management and intervention is therefore changed. This means that the clinical situation needs constant review. This further emphasises the need for clear guidelines for the management of early second trimester inevitable miscarriage of a pregnancy including in cases where there is prolonged rupture of the membranes, and the need for the use of a modified Obstetric Early Warning Score (OEWS) Chart for obstetric patients in this gynaecology ward and regular four-hourly observations in line with hospital guideline on 'Preterm Pre-labour Rupture of Membranes (PPROM) (Revision 3, (2009).

At 14.45 hrs on the 23rd of October, the patient's pulse rate was elevated again to **100** beats per minute. Within the clinical context (of PPROM and previously elevated white cell count), this further episode of tachycardia (elevated pulse) should have prompted more frequent observations and consideration for laboratory investigations including white blood cell count and a blood test for levels of C-reactive protein (CRP) as suggested by RCOG Guideline 64a – "*Bacterial sepsis in pregnancy*" (Royal College of Obstetricians and Gynaecologists April 2012).

At 19.00hrs on the 23rd of October, the patient's pulse rate was recorded as **114** per minute. This tachycardia represented a significant change. In this specific clinical context, this significant change should have triggered a medical review with investigations based on this review. The Royal College of Obstetricians and Gynaecology Green-top Guideline 64a – "*Bacterial sepsis in pregnancy*" (Royal College of Obstetricians and Gynaecologists April 2012) outlines the following guidance to prompt recognition of sepsis in pregnant women:

"All healthcare professionals should be aware of the symptoms and signs of maternal sepsis and critical illness and of the rapid, potentially lethal course of severe sepsis and septic shock. Suspicion of significant sepsis should trigger an urgent referral to secondary care.

*"Clinical signs suggestive of sepsis include **one or more** of the following: pyrexia, hypothermia, **tachycardia**, tachypnoea, hypoxia, hypotension, oliguria, impaired consciousness and failure to respond to treatment. These signs, including pyrexia, may not always be present and are not necessarily related to the severity of sepsis."*

At 20.00 hrs on the 23rd of October, the patient's pulse rate was **108** per minute. Tachycardia (i.e. persistently elevated pulse) was present from the observation at 14.45 hrs

on 23.10.12. The patient's pulse rate was elevated for more than 5 hours at 20.00hrs and should have indicated a need to suspect sepsis and investigate further.

At 21.00hrs on the 23rd of October nursing documentation stated that the patient's pulse rate had ranged from 90-100 beats (regular) per minute since admission on the 21st of October. Nursing documentation added that the woman had been complaining of 'weakness' earlier in the night. The investigation team established that the patient's pulse rate was recorded as more than 100 beats per minute on four prior occasions (102 p/m at 18.00hrs on 22nd of October, 102 p/m at 21.40hrs on 22nd of October, 114 p/m at 19.00hrs on the 23rd of October and 108 p/m at 20.00 hrs on the 23rd of October). In addition, the documented 'weakness' from earlier in the night should have indicated that the patient was unwell warranting a medical review and investigations.

At 21.00hrs on the 23rd of October, new clinical observations included a pulse rate of **106** beats per minute. This new symptom of weakness and an elevated pulse rate suggests possible sepsis and did trigger a request for a medical review. However, SHO 2 was busy with other ill patients at this time and could not attend until approximately 01.00hrs.

At this time the patient had symptoms of weakness and ongoing tachycardia with approximately 48 hours having elapsed since the spontaneous rupture of her membranes and approximately 54 hours following admission to hospital. According to the Royal College of Obstetricians and Gynaecology, Green-top Guideline 64a on "*Bacterial Sepsis in Pregnancy*" (Royal College of Obstetricians and Gynaecologists (April 2012)) and the hospital Guidelines on the Management of Suspected Sepsis and Sepsis in Obstetric Care (July 2012), tachycardia of greater than 100 beats per minute is a sign of sepsis given the clinical context. These symptoms and signs indicated the need for medical review to include checking for an elevated temperature, maternal tachycardia, uterine tenderness and/or offensive vaginal discharge. This change in the patient's clinical condition indicated that a work up for sepsis should commence including full blood count (FBC); C-reactive protein (CRP); mid-stream urine (MSU)/urinalysis; vaginal swab and blood cultures. Removal of the septic focus needed to be urgently considered. The hospital Guidelines on the Management of Suspected Sepsis and Sepsis in Obstetric Care (July 2012) state that empiric antibiotic therapy should be commenced immediately:

"...without waiting for the results of investigations/tests and contact a consultant microbiologist as soon as possible to discuss further/ongoing management. Antibiotic therapy will be reviewed and modified, if indicated, based on clinical progress and culture results".

At 04.15hrs on the 24th of October, it is documented by Staff Midwife 3 that the patient was complaining of feeling cold and shivery. At interview Staff Midwife 3 recalled that the patient's "*teeth were chattering*". This is suggestive of rigors caused by blood stream infection. The patient's temperature was 37.7 degrees Celsius at this time. The patient's blood pressure and pulse were not recorded at this time, or over the next two hours. The patient was administered 1 gram of Paracetamol orally to manage her temperature.

The shivering and rising temperature warranted immediate medical review, investigation and management as outlined above. Blood cultures are a particularly essential investigation with these symptoms. It was now over 48 hours since the patient's spontaneous rupture of the membranes. The view of the investigation team is that infection/sepsis was present but not recognised at this time and there may have been possibilities for identifying deterioration due to infection by earlier closer monitoring and investigations of some subtle symptoms and signs of infection. Use of a guideline for the management of inevitable miscarriage of second trimester pregnancy and use of an Obstetric Early Warning Score chart may have been

helpful in enabling staff to focus more specifically on the signs of infection and sepsis and the changing clinical situation.

At 04.20hrs on the 24th of October Staff Midwife 3 documented that the patient had vomited up some water (but that she did not vomit up the tablets that she had been administered previously) and that both the patient and her husband had been given an extra blanket as the room that they were in was cold. Staff Midwife 3 indicated at interview that she believed that:

“The radiator in the room was not working”.

Staff Midwife 3 documented that at 05.15 hrs on the 24th of October that the patient's temperature had been rechecked and was now 37.5 degrees Celsius. There are no other clinical observations documented at this time. As above, there was an urgent need for clinical review in the clinical context of prolonged spontaneous rupture of the membranes and the risk of sepsis.

At 06.30hrs on the 24th of October, nursing staff documented in the clinical records that the patient was complaining of **feeling weak** with general body aches and that her temperature was checked at this time and was **39.6** degrees Celsius. The patient's pulse, blood pressure and oxygen saturations were also checked at this time. These are documented as pulse rate of **160** per minute, blood pressure **94/55** mmHg, respiratory rate 15 per minute and oxygen saturations 97% on room air.

SHO 2 was contacted and reviewed the patient shortly thereafter at approximately 06.40hrs when he/she found the patient's pulse rate to be **160** per minute and her blood pressure was **94/45** mm Hg. An intravenous cannula was sited and bloods taken for CRP, FBC and blood cultures. Paracetamol was administered intravenously at 06.45 hrs. At 07.00 hrs the patient's temperature was **39.6** degrees Celsius despite Paracetamol and the pulse rate was **160** per minute. The patient's blood pressure was **100/60** mm Hg and her E.C.G. showed a sinus tachycardia of **166** per minute. The patient was administered **40% oxygen** supplementation and the oxygen saturation was 98-99% (Oxygen supplementation suggests that staff were concerned about the condition of the patient and that the patient was clinically unwell).

SHO 2 found **tenderness over the left iliac fossa and the right iliac fossa and suprapubic regions. A foul smelling brownish vaginal discharge** was present, and a high vaginal swab was taken. The impression documented by SHO 2 at the time of this review was that the patient was suffering from **Chorioamnionitis with probable sepsis**. Intravenous antibiotic – Augmentin (Coamoxiclav) was administered to the patient. SHO 2 also prescribed intravenous fluids and Oxygen which was brought by cylinder to the patient's Room.

The new onset of severe tachycardia (**160/min**) and a **rise in temperature** at 06.30 hours in the clinical context of prolonged spontaneous rupture of the membranes is consistent with sepsis and a clinical **suspicion of severe sepsis**. SHO2 was concerned about this possibility and ordered **a lactate test** to assess tissue perfusion and sent the blood to the laboratory.

The following is a summary of the symptoms and signs of sepsis that had been present in this patient by 06.30hrs on the 24th of October.

- The patient had an elevated white cell count on admission (16.9 X 10⁹/L) on 21.10.12.⁴⁸
- The patient had a raised pulse rate ≥ 100 /min from 14.45 hrs on 23.10.12.
- The patient had a raised temperature from 04.15 hrs on 24.10.12.
- At 06.30hrs on 24.10.12 a pulse rate of 160 beats per minute was unusually high.
- A blood pressure observation of 94/55 mm Hg at 06.30 hours on the 24th of October was relatively low for this patient. At first examination on the 21st of October the patient's blood pressure was 113/73 as per clinical notes. The patient's blood pressure at her booking appointment on the 11th of October, 2012 was 102/65mm Hg.
- The patient had been experiencing rigors, pain and vomiting.

The investigation team considers that during the hours between 04.15hrs to 06.30hrs on the 24th of October the patient went from sepsis to a clinical suspicion of severe sepsis, where the very significant tachycardia acted as a compensatory mechanism delaying the manifestation of more profound hypotension, and measurement of serum lactate therefore was appropriate to seek evidence of hypo perfusion.

The clinical evidence is that women with maternal infection can deteriorate rapidly to sepsis, severe sepsis and septic shock. Hence vigilance in observation is required and this can be assisted by recording the observations on a (*modified*) Obstetric Early Warning Score (OEWS).

From 06:30 hrs - 08:00 hrs the hospital (*modified*) Obstetric Early Warning Score (OEWS) observation chart (if in use at that time for pregnant women on the gynaecology ward) would score the patient with **3 red scores** (pulse rate, temperature, vaginal loss quality) and **1 yellow score** (blood pressure at 06:30 hrs). This is a clear flag for urgency of intervention (the instruction on the hospital (*modified*) OEWS chart in use on the obstetrics ward is to contact a doctor for early intervention for 1 red score). A lactate result may have supported this. The consultant became aware of the situation on the morning round at 08.25 hrs on the 24th of October.

At the ward round at 08.25hrs the patient's temperature was noted to be 37.9 degrees Celsius and her pulse rate was 144 per minute and the assessment of blood pressure at 07:50hrs was 98/54mmHg. This is a significant rise in pulse rate associated with a reduction in blood pressure from 113/73 mmHg when the patient was assessed first 09.35 hrs on 21.10.12. The patient's blood pressure at her booking appointment on the 11th of October, 2012 was 102/65mmHg. There was no noted clinical direction about this reduction in blood pressure or the episodes of tachycardia observed overnight recorded in the observation chart.

To illustrate how the patients observations may have been recorded if staff in the hospital had been using the hospital (Modified) OEWS Chart for pregnant patients on the gynaecology ward the investigation team have transposed all observations noted for this patient from the 21st of October 2012 to the 24th of October 2012 (up until transfer to HDU at 16.00hrs) onto the mOEWS chart (please see appendix F).

The investigation team considers that the fact that the (*modified*) Obstetric Early Warning Score (OEWS) Chart was not used for pregnant patients in the Gynaecology ward contributed to the difficulty and delay in the diagnosis and management of infection and sepsis in this case. The investigation team emphasises that sepsis is difficult to diagnose in

⁴⁸ A normal white blood cell range in second trimester pregnancy is between 6.2 – 14.8 x 10⁹/L (Bain, 2006).

pregnancy due to the associated natural physiological changes. Early Warning Score charts are useful to assist and focus multidisciplinary care teams on potential derangement of physiology and act to alert, not diagnose. However, clinical professional judgement and clinical context cannot be replaced by Early Warning Score Charts. Well trained nurses and senior doctors are required to put meaning on any variance from any guideline, early warning scoring chart, or care pathway.

Recommendation 1:

Prompt introduction – followed by audit of compliance with - an appropriate Maternity Early Warning Scoring Systems Chart for patients receiving care for pregnancy complications on gynaecology wards. The Maternity Early Warning Scoring System Chart should define a coupled process of monitoring with activation of an escalating nursing, medical and multi-disciplinary response.⁴⁹

→ **Task and Technology Factor 3:**

→ **Lack of clarity related to the processes for conducting and following up on tests.**

The results of tests on bloods drawn for a full blood count on the patient's admission on the afternoon of the 21st of October showed that her white blood cell count (WBC) was 16.9×10^9 with a neutrophil count of 13.8×10^9 . The Hospital Guidelines on the Management of Suspected Sepsis and Sepsis in Obstetric Care (July 2012) states that a white blood cell count of greater than 12×10^9 /L is a sign of suspected sepsis or sepsis. A normal white blood cell range in second trimester pregnancy is between $6.2 - 14.8 \times 10^9$ /L, the normal range of a neutrophil count is $3.8-12.3 \times 10^9$ /L (Bain, 2006). The patient's white blood cell count on admission may have been due to pregnancy but was too high to be normal and was suggestive of possible infection in the absence of any other obvious causes at this time. However, these blood test results taken on the 21st of October 2012 were never followed up.

The investigation team considers that there was a lack of clarity about who was responsible for following up and acting on these blood test results. The investigation team identified that the information about who is responsible for following up on blood test results must be instantly specified in guidelines and training. It is the duty of the doctor leading the clinical assessment of a patient to review all test results. If this was done in this case, the elevated white cell count would in all probability have prompted more clinical investigations. The white blood cell count taken on the 21st of October 2012 was insufficient for the purposes of the effective clinical investigation and care of this patient. It is not possible for this white blood cell count result to be considered a transient test result since it was not repeated.

⁴⁹ The investigation team was aware at the time of preparation of this investigation report that twelve of the nineteen maternity units in the country were using a (modified) Obstetric Early Warning Score. The review team is aware that all HSE hospitals providing acute obstetric care have commenced planning and implementation of the Irish Maternity Early Warning System (I-MEWS) that has been developed by the Clinical Care Programme in Obstetrics and Gynaecology. The I-MEWS should be implemented in association with a multidisciplinary educational programme and its use should be audited in all maternity units. The National Early Warning Score (NEWS) will be applied for gynaecological patients and the I-MEWS will be applied for pregnant women and in the immediate postpartum period. A final design of the I-MEWS has been agreed and a training programme has been arranged. It is planned to roll out the I-MEWS during March 2013 and to pilot it for the month of April 2013. After the month of April it is planned to audit its practice for 12 months and to assess whether the sensitivity of the triggers need to be adjusted upwards or downwards. I-MEWS is a tool to assist midwifery staff in the course of their daily clinical practice to identify any deviation from normal and seek early medical advice and treatment from the Obstetrician and/or the Anaesthetist.

At approximately 06.40 hrs on the 24th of October when SHO2 was concerned about the possibility of sepsis in this patient, (s)he appropriately ordered a lactate test to assess tissue perfusion (which is affected in severe sepsis) and sent the blood to the laboratory. (S)He was not aware that the laboratory did not do this routinely and that (s)he should use the blood gas analysers on the labour ward to carry out the test. The fact that the laboratory did not do the lactate test appears not to have been communicated immediately by laboratory staff to the SHO 2. The fact that the laboratories do not process the lactate was not known to the SHO 2. The obstetric team did not contact the laboratory to establish the test results.

Some staff members stated at interview that they were not aware that a lactate test could be done in the blood gas analyser (on the labour ward) which takes less than five minutes. Knowledge and results of the lactate might possibly have expedited immediate and aggressive management preventing the patient reaching the next stage of septic shock with grave prognosis. The fact that a labour ward blood gas analyser can be used for lactate tests needs to be highlighted clearly in hospital guidelines and training.

The patient was reviewed by her O&G Consultant at approximately 08.25hrs on the ward round. The documented impression of the team was that the patient had Chorioamnionitis.

On the ward round a mid stream urine for laboratory analysis to test for an infection of the urinary tract and a high vaginal swab was ordered and Flagyl was added to Coamoxiclav as antibiotic cover for infection.

There was no clinical follow-up review plan for the patient and no active search appears to have taken place to find out the results of the tests previously ordered at 06.40 hrs that morning by the senior house officer (SHO) which would have helped in the formulation of a clinical management plan.

(Part of recommendation 3 and 4a):

Guidelines on the management of infection in pregnancy and on the management of early second trimester pregnancy and associated induction and continuing education should specify clearly:

- Clarity about who is responsible for following up, reviewing and acting upon the results of tests ordered.
- Clear pathways for most efficient access to blood gas and lactate testing (preferably at point of care), along with appropriate training.

- **Task and Technology Factor 4:**
- **Lack of Clear Guidelines for the handover/communication of information (e.g. SBAR (Situation, Background, Assessment, Recommendations)).**

At approximately 07.00HRS on the 24th of October 2012, SHO 2 discussed the patient's case and plan of treatment over the phone with O&G SpR 3 who was busy in the labour ward at this time. There is a difference in the recollections of SHO 2 and O&G SpR 3 about this telephone discussion. SHO2 recalls telling O&G SpR 3 about all of the patient's clinical observations while the O&G SpR 3 recalls that (s)he was informed about the patient's temperature and not about her pulse rate and blood pressure. When asked by the investigation team might the patient's management have been different if SpR 3 had been aware of the blood pressure and heart rate parameters SpR 3 stated that it may have been. This demonstrates a need to implement proper verbal and documented communication mechanisms such as SBAR (Situation, Background, Assessment, Recommendations) as recommended within the UK Royal College of Obstetricians and Gynaecologists – Good Practice Guideline No. 12, December 2010, Improving Patient Handover).

Recommendation 5 (National):

The HSE should implement and audit compliance with improved communication practices between all disciplines and grades of staff, and implement improvements in the handover for acutely ill patients including between staff shifts. Adoption of appropriate definitive communication tools to assist clear and focussed communication of information in relation to the deterioration of a woman's condition, and/or consultation, and/or handover to a higher level of care, such as ISBAR (HSE Acute Medicine Programme, 2013) which is a modification of SBAR as recommended within 'Improving patient handover – RCOG Good Practice No 12' (Dec 2010) is recommended.

Team Factors – Supervision and Seeking Help

At 21.00hrs on the 23rd of October the patient complained of **weakness** with a pulse rate of **108** beats per minute. This new symptom and a persistently elevated pulse rate suggested possible sepsis. The patient's blood pressure was 106/60 mmHg. A medical review by SHO 2 was requested at this point. However, SHO 2 was busy with other ill patients at this time and could not attend until approximately 01.00hrs on the 24th. With the possibility of sepsis at 21.00hrs, help from a senior doctor such as a registrar should have been requested if the SHO was unable to attend.

Sometime after 06.40Hrs on the 24th of October when SHO 2 followed up with O&G SpR 3 about the review, O&G SpR 3 indicated that (s)he was busy on the labour ward and not in a position to review the patient at this time. SHO 2 and O&G SpR 3 recall discussing that the clinical team managing the patient's care would be in the hospital and could review the patient at 08.00 hrs. There was a need for the midwife/nurse to escalate this case to the night sister and the SHO/SpR to escalate it up to the consultant level when the patient was so ill (Royal College of Obstetricians and Gynaecology Good Practice Guideline No. 8 (2009) Responsibility of Consultant on Call). In such situations when the workload is high and junior doctors are busy there should be a mechanism to call for a senior doctor to attend especially when there is serious concern about a patient to include a defined process of monitoring with activation of an escalating nursing, medical and multi-disciplinary response. This could

include situations where there is a serious case and/or where workloads pose challenges for the team. The Royal College of Obstetricians and Gynaecologists Good Practice No. 8, *“Responsibility of Consultant On-Call”*, (Royal College of Obstetricians and Gynaecologists (March 2009). Early involvement of senior midwives, obstetricians, anaesthetists and critical care consultants is crucial (Surviving Sepsis Campaign; 2011).

The team factor “supervision and seeking help” is highlighted in the analysis of adverse events in obstetrics by the UK National Patient Safety Agency (NPSA) published in the Royal College of Obstetricians and Gynaecologists Working Party Report *“The Future Role of the Consultant”* Royal College of Obstetricians and Gynaecologists (December 2005). This analysis by the NPSA established that two common reasons for adverse events were failure to attend patients on time due to episodes of excess workload and inadequate staff or due to senior staff being unable to attend.

Recommendation 6:

Development, implementation and audit of compliance of guidelines in line with the Royal College of Obstetricians and Gynaecologists Guidelines on the “Responsibility of the consultant on call” (RCOG Good Practice No. 8 - March 2009).

These guidelines should clarify the need to call in senior medical staff including consultants if indicated due to difficulty coping with case load or to consult on a suspected serious case. These guidelines should reflect that a midwife/nurse should be able to summon this help from a senior nurse midwifery manager or the Director of Nursing on duty including call the consultant directly as appropriate and as needed.

Key Causal Factor 2:

Failure to offer all management options to a patient experiencing inevitable miscarriage of an early second trimester pregnancy where the risk to the mother increased with time from the time that membranes were ruptured.

The investigation team is aware that clinical circumstances can and have arisen in Ireland where a termination of pregnancy is an appropriate and necessary clinical step in the medical treatment and care of a patient. In this regard the investigation team notes the evidence which was given to the Oireachtas Joint Committee on Health and Children to discuss the implementation of the Government decision following the publication of the expert group report on matters relating to the case A, B and C v. Ireland by Dr. Sam Coulter-Smith and Dr. Rhona Mahony on the 8th of January, 2013.⁵⁰

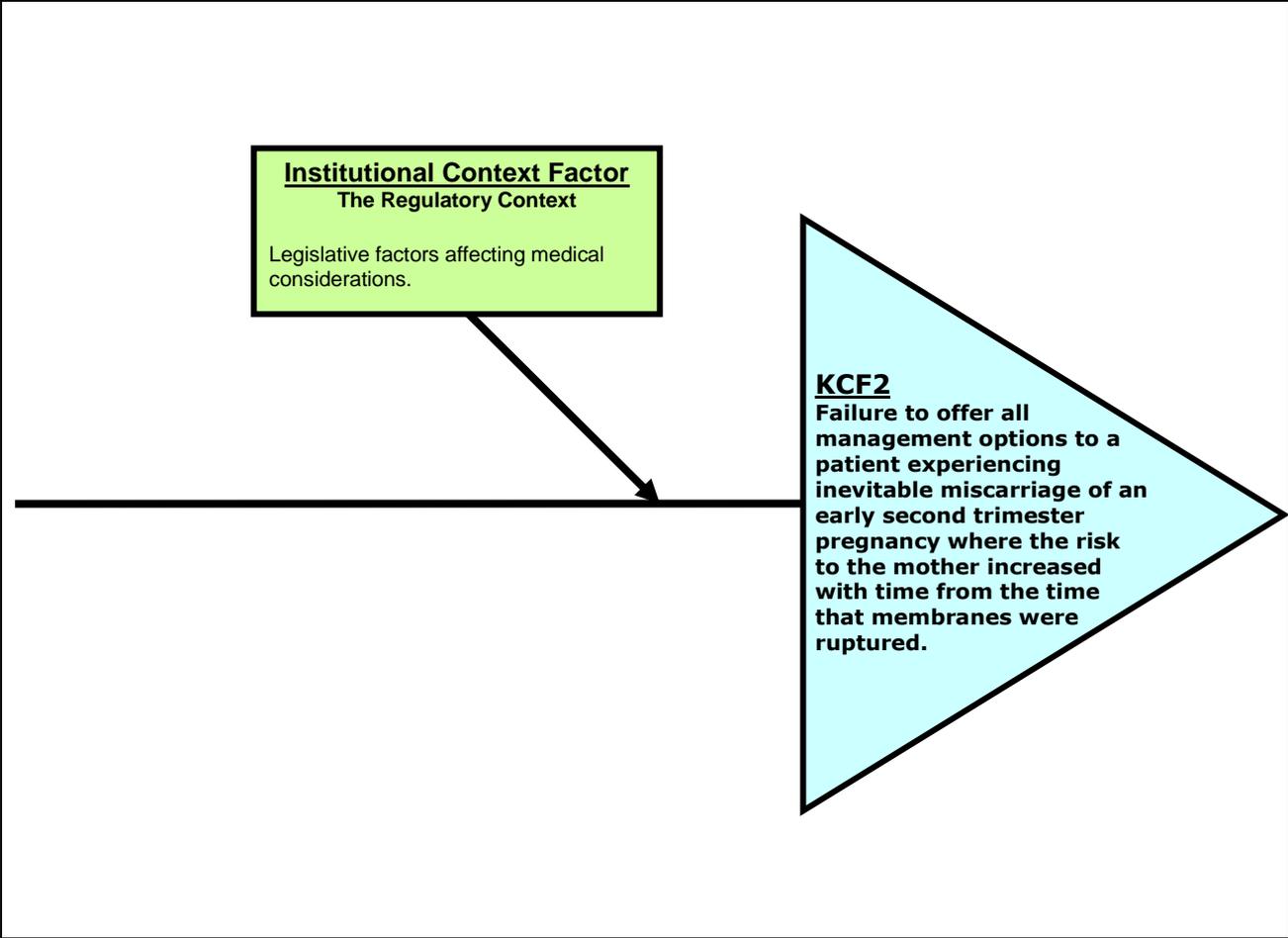
The purpose of this investigation is not to carry out a legal review of the law in Ireland in relation to a situation where a clinician has to consider whether a termination is in the best clinical welfare interest of a patient. This investigation is concerned with establishing in so far as is practicable the clinical circumstances in which a patient in hospital died in a tragic and untimely manner. The investigation team is satisfied that concerns about the law, whether clear or not, impacted on the exercise of clinical professional judgement. The investigation team did not have the remit to attempt to review this aspect of Irish Law. The investigation team received an outline legal context of the law in relation to the termination of pregnancy in Ireland from Senior Counsel. See appendix A.

⁵⁰ Source

(<http://oireachtasdebates.oireachtas.ie/Debates%20Authoring/DebatesWebPack.nsf/committeetakes/HEJ2013010800002?opendocument>)

Factors that contributed to Key Causal Factor2:

Figure 2: Key Causal Factor 2 (KCF2) and associated Contributory Factors.



Institutional Context Factors - The Regulatory Context: Legislative factors affecting medical considerations:

Maternal death is rare at a rate of approximately 1 per 10,000 (CMACE, 2011). In this case in the presence of Chorioamnionitis the risk of death is higher at approximately 1 per 1,000 i.e. ten times higher (Lappen et al, 2010). As the infection progresses to sepsis and severe sepsis the risk to the mother increases steeply. Fetal demise is certain in an inevitable miscarriage at 17 weeks where there is spontaneous rupture of the membranes and infection in the uterus. The risks to the mother can be reduced by expediting delivery. Continuation of the pregnancy is putting the mother at increasing risk with no potential benefit to mother or fetus. In this clinical context, there is an increasing need for a level of awareness and clinical judgment. This should be based on training, expertise and clinical experience to identify at risk patients because test results may not be available immediately when clinical events occur and therefore clinical professional judgement and close monitoring is essential.

International best practice includes expediting delivery in this clinical situation of an inevitable miscarriage at 17 week with prolonged rupture of the membranes and infection in the uterus because of the risk to the mother if the pregnancy is allowed to continue. Expediting delivery (either medically or surgically as appropriate or feasible, and within the law) at the earliest signs of infection in the uterus is a critical part of management to reduce the risk of progression to sepsis, severe sepsis and septic shock and maternal morbidity and death.

The records and interviews confirmed that - from the time of her admission, up to the morning of the 24th of October - the management plan for the patient was to “*await events*” and to monitor the fetal heart in case an accelerated delivery might be possible once the fetal heart stopped. The interviewees stated to the investigation team that this was because of their interpretation of the law related to pregnancy termination. The investigation team emphasises that, in the legal context related to termination in Ireland, there is a need for increased vigilance in clinical assessment of the patient in relation to the risk of infection, especially, infection in the uterus as failure to offer termination of pregnancy directly increases these risks.

The investigation team established that there was no documentation of a comprehensive plan, including appropriate laboratory tests and follow up to monitor for infection. A pulse rate greater than 100 should have triggered tests for white blood cell count/differential count and C-reactive protein and this would support a diagnosis of sepsis.

Further significant change in the patient’s condition with a pulse rate of 160/min, hypotension and fever is consistent with sepsis and a clinical suspicion of severe sepsis in this clinical context. This should have been pro-actively looked for by performing and following up on a test for serum lactate. The Royal College of Obstetricians and Gynaecology Green-top Guideline No. 64a (April 2012), *Bacterial Sepsis in Pregnancy*”, appendix 1 states:

“Blood cultures are the key investigation and should be obtained prior to antibiotic administration’ however, antibiotic treatment should be started without waiting for microbiology results.

Serum lactate should be measured within six hours of suspicion of severe sepsis in order to guide management. Serum lactate ≥ 4 mmol/l is indicative of tissue hypoperfusion”.

By 00.30hrs on the 23rd of October, 24 hours had elapsed since the spontaneous rupture of the patient’s membranes. Clinical evidence within the literature suggests that the risk of infection in the uterus increases after 24 hours and the balance of risks between

conservative management and intervention is therefore changed. This means that the clinical situation needs constant review and the probable need for termination increases with time. At approximately 07.00 hrs on the 24th of October, SHO 2 documented his/her impression that the patient was suffering from Chorioamnionitis and possible sepsis. Once sepsis is present, fetal demise is certain and the risk to the mother of developing severe sepsis with its sequelae of serious morbidity and high mortality increases.

It is not possible to definitively say when the patient progressed from sepsis to “septic shock”. as additional fluid challenge was not instituted by the clinical team to confirm septic shock and to resuscitate the patient until 13.00 hours. However, the investigation team considers that it is likely that this patient progressed from sepsis to “septic shock” within six hours (04.15 hrs to 10.30 hrs) and this progression is associated with an increasing risk of an adverse outcome for the patient (Royal College of Obstetricians and Gynaecology Green-top Guideline No. 64a (April 2012), *Bacterial Sepsis in Pregnancy*). From 06.30 hrs to 10:30 hrs on the 24th of October, the investigation team considers that the patient progressed from the clinical suspicion of severe sepsis to “septic shock” with hypotension despite IV fluids in progress. The mortality rate with severe sepsis can be as high as 60% (Royal College of Obstetricians and Gynaecology Green-top Guideline No. 64a (April 2012), *Bacterial Sepsis in Pregnancy*).

Different patients respond differently to treatment of sepsis for a variety of reasons some of which are not fully understood at this point in time.

Different management options needed to be considered - including termination of the pregnancy - as removal of the source of infection reduces the potential risk of sepsis thereby potentially avoiding rapid deterioration in the patient’s clinical condition due to progression to severe sepsis and septic shock with an associated high mortality rate.

The Royal College of Obstetricians and Gynaecology Green-top Guideline No. 64a (April 2012), *Bacterial Sepsis in Pregnancy*) state that:

“Severe sepsis with acute organ dysfunction has a mortality rate of rate of 20 to 40%, which increases to 60% if septic shock develops. Studies in the non-pregnant population have found that survival rates following sepsis are related to early recognition and initiation of treatment”.

O&G Consultant 1 recalled at interview that on the 23rd of October the patient and the patient’s husband enquired about the possibility of using medication to induce labour as they indicated that they did not want a protracted waiting time when the outcome was going to be an inevitable miscarriage. The consultant stated at interview that (s)he advised the patient and her husband that this was not possible under Irish law. At interview, the consultant indicated that the law is such that:

“If there is a threat to the mothers’ life you can terminate. If there is a potential major hazard to the mothers’ life the law is not clear.... There are no guidelines for inevitable miscarriages”

There is difficulty in interpretation of law in relation to ‘what constitutes a potential major hazard or threat to mother’s life’. This needs clarification. The consultant clearly thought that the risk to the mother had not crossed the point where termination was allowable in Irish law on the morning ward round on the 24th.

The investigation team considers that appropriate tests were not performed to confirm the presence of infection, despite clinical signs. By the time of the discussion about termination with the family on the 23rd of October there had been suggestions of possible underlying

infection since the patient's admission. At that point in time, it was over 24 hours since the spontaneous rupture of the patient's membranes. The risk of infection of the uterus was increasing and the need to monitor for, identify and remove/address any source of infection and for appropriate antibiotic therapy was increasing. The clinical features of tachycardia (108/min) and weakness at 21.00hrs on the 23rd of October were of concern and a request for a medical review was made. If medical review had occurred at this time it may have prompted appropriate investigations to confirm infection/sepsis in the context of prolonged preterm prelabour rupture of membranes. The hospital Guidelines on the Management of Suspected Sepsis and Sepsis in Obstetric Care (2012) outline the importance of attempting to establish the focus of infection and to treat any obvious source. This guideline states that it is imperative that any infective focus should be identified with removal of the source of infection to be completed as quickly as possible. In this clinical context, that would be termination of pregnancy.

The investigation team considers that here was an apparent over-emphasis on the need not to intervene until the fetal heart stopped together with an under-emphasis on the need to focus appropriate attention on monitoring for and managing the risk of infection and sepsis in the mother.

The consultant stated the (s)he received a call to review the patient at 13.10 hours on the 24th of October. The consultant recalled going to the gynaecology theatre en route to the gynaecology ward to collect a scanner.

The interpretation of the law related to lawful termination in Ireland, and particularly the lack of clear clinical guidelines and training is considered to have been a material contributory factor in this regard.

Similar incidents with a similar clinical context could happen again in the absence of:

- Clarity as to the application of the law in a situation where it may be necessary for a doctor to consider, in the exercise of their clinical professional judgement, the termination of a pregnancy in the clinical welfare interest of their patient
- An absence of appropriate national clinical guidelines on the clinical management of inevitable miscarriage in the early second trimester including the management of prolonged rupture of membranes with infection

The following recommendations have been made by the investigation team to address the Institutional Context Factors (the regulatory context and the legislative factors affecting medical considerations) that contributed to key causal factor 2 in this case.

Recommendation 4a:

Develop, implement and audit compliance with guidelines on the management of early second trimester inevitable miscarriage that are cognisant of the possible rapid deterioration of the patient from sepsis to severe sepsis to septic shock which could be within a few hours. These guidelines must also be cognisant of the high mortality rate (up to 60%) associated with this. These guidelines should include but may not necessarily be limited to the following:

- Appropriate monitoring for efficient detection of infection and sepsis as per appropriate clinical guidelines for the Management of Suspected Sepsis and Sepsis in Obstetric Care; and Antimicrobial Guidelines
- Appropriate management that recognises the fact that the risk to the mother increases with time from the time the membranes are ruptured.
- Clarity about who is responsible for following up, reviewing and acting upon the results of tests ordered.
- Clear pathways for most efficient access to blood gas and lactate testing (preferably at point of care), along with appropriate training.

Recommendation 4b.

There is an immediate and urgent requirement for a clear statement of the legal context in which clinical professional judgement can be exercised in the best medical welfare interests of patients. There is a parallel immediate requirement for clear and precise national clinical guidelines to meaningfully assist the clinical professionals who have the responsibility, often in circumstance of rapid deterioration or emergency, as to how to exercise their clinical professional judgement in a particular case. We recommend that the clinical professional community, health and social care regulators, and the Oireachtas consider the law including any necessary constitutional change and related administrative, legal and clinical guidelines in relation to the management of inevitable miscarriage in the early second trimester of a pregnancy including with prolonged rupture of membranes and where the risk to the mother increases with time from the time that membranes were ruptured including the risk of infection. These guidelines should include good practice guidelines in relation to expediting delivery for clinical reasons including medical and surgical termination based on available expertise and feasibility consistent with the law.

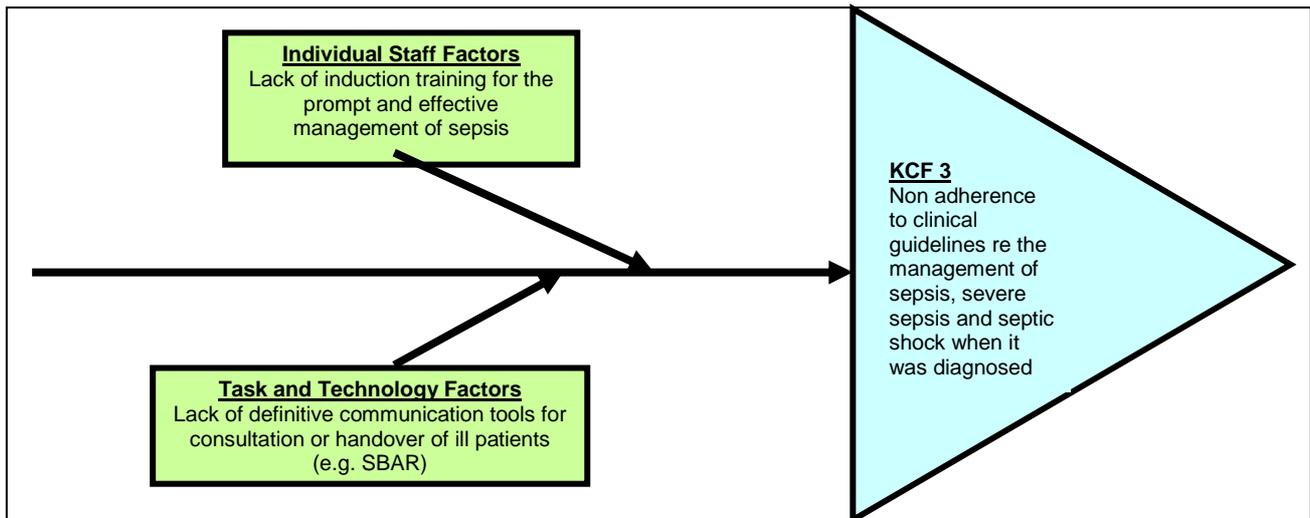
We recognise that such guidelines must be consistent with applicable law and that the guidance so urged may require legal change.

Key Causal Factor 3:

Non adherence to clinical guidelines related to the prompt and effective management of sepsis, severe sepsis and septic shock when it was diagnosed.

Factors that contributed to Key Causal Factor 3:

Figure 3: Key Causal Factor 3 (KCF 3) and associated Contributory Factors



Individual (staff) factors (Key Causal Factor 3):

Lack of induction training on guidelines for the prompt and effective management of sepsis

The paragraphs below outline how the hospital Guidelines for the Management of Suspected Sepsis and Sepsis in Obstetric Care (July 2012) and the hospital Antimicrobial Guidelines (Adults), Version 6 (2012) were not followed in this case.

SHO2 comprehensively reviewed the patient at approximately 06.40hrs on the 24th of October and documented that the impression following this review was that the patient was suffering from Chorioamnionitis with possible sepsis.

The signs of sepsis were present as suggested by the rapid tachycardia, hypotension and elevated temperature. The SHO took blood to measure serum lactate which would help assess the degree of metabolic lactic acidosis caused by poor perfusion and appropriately escalated the case immediately to the registrar.

Staff stated at interview and within feedback that, at approximately 07.00hrs on the 24th of October they felt and hoped that the patient had been improving as shown by the decrease of temperature to 37.9 degrees centigrade with a blood pressure reading of 100/55 and a pulse rate of 140 per minute. However, the apparent improvement of the condition was probably due to the administration of Paracetamol and could not be assumed to be due to a clinical improvement.

The investigation team is satisfied that at the time the clinical signs were consistent with that of sepsis and a clinical suspicion of severe sepsis requiring intensive multidisciplinary care

from the Obstetrics and Gynaecology Team; the Anaesthetics/Intensive Care Team; and the Microbiology Team.

At 07.50hrs SHO 2 discussed the patient with O&G R 2 and asked if the patient should be commenced on a different antibiotic regime such as Metronidazole and recalled that (s)he was advised by O&G R 2 that (s)he would come to review the patient shortly and that in the interim the patient was to be continued on Augmentin (Coamoxiclav).

The diagnosis of sepsis was confirmed by O&G Consultant 1 at 08.25hrs. With ongoing signs of sepsis and clinical suspicion of severe sepsis, the intervention at that time was a request for a midstream urine for laboratory analysis, high vaginal swab and the addition of the antibiotic Metronidazole (Flagyl) with no documented plan for escalation of care to a multidisciplinary review or planned medical review for later that morning. The responsibility of the medical team includes full assessment of the clinical situation, clinical charts and blood tests and to follow-up on significant clinical issues rather than await further calls.

At this point (08.25hrs) the diagnosis is sepsis secondary to chorioamnionitis. The presence of sepsis and clinical chorioamnionitis merits expediting delivery to reduce the risk to the mother of developing severe sepsis and septic shock by removing the source of the infection. The gravity of the situation was increasing but appears not to have been recognised and acted upon. This was a complex clinical situation and a request for advice/support from a consultant colleague and other specialities would have been beneficial.

The investigation team considers that the situation was complicated by the difficulty associated with the application of the law in Ireland relating to the termination of a pregnancy. The investigation team is satisfied that concern about the law, whether clear or not, impacted on the exercise of clinical professional judgement.

O&G Consultant stated at interview that the focus of the team at this time was to identify the source of infection. The consultant advised the patient and her husband that a termination might have to be considered. O&G Consultant 1 added Metronidazole 500 mgs intravenously eight hourly to the patients prescription and this was commenced immediately at 08.30hrs. The patient was to continue on Augmentin (Coamoxiclav).

According to the hospital Guidelines on the Management of Suspected Sepsis and Sepsis in Obstetric Care (July 2012) and the Green-top Guidelines for the Management of Bacterial Sepsis in Pregnancy (April 2012) – the investigation team believes that the findings of the clinical review at this time were consistent with signs of sepsis and a clinical suspicion of severe sepsis requiring intensive multidisciplinary care from the Obstetrics and Gynaecology Team; the Anaesthetics/Intensive Care Team; and the Microbiology Team. The consultant microbiologists provide a 24 hours seven days per week service at the hospital whereby they provide advice about appropriate antibiotic therapy over the phone to consultants, non-consultant hospital doctors and nurses as required. However, they were not contacted at this time. O&G Consultant 1 did not contact the microbiology department until approximately 14.00hrs that day to discuss the best antibiotic option for the mother who was then in septic shock and was not responding well to the prescribed antibiotics.

The hospital Guidelines on the Management of Suspected Sepsis and Sepsis in Obstetric Care (2012) outline the importance of attempting to establish the focus of infection and to treat any obvious source. This guideline states that it is imperative that any infective or necrotic foci should be identified with removal of the source of infection to be completed as quickly as possible.

The focus of the team at this time (08.25hrs) was to identify the source of infection. The consultant stated at interview that they felt they could wait for the results to come back and if

they did need to intervene it would be later that day following blood results. The hospital Guidelines on the Management of Suspected Sepsis and Sepsis in Obstetric Care (July 2012) states that empiric antibiotics (i.e. antibiotics effective against known bacteria associated with such infections) therapy must be commenced without waiting for the results of investigations and that the consultant microbiologist should be contacted as soon as possible to discuss further/ongoing management. Awaiting the blood results and not fully appreciating the deteriorating and complex clinical situation missed an opportunity for early and appropriate intervention with the help of multidisciplinary input.

Clinical suspicion of severe sepsis was made at 07.00hrs on 24th of October. The patient was reviewed on the ward round at 08.25hrs. By 10.30 hrs on the 24th of October there was further deterioration with signs of possible septic shock which was not confirmed due to the fact that a fluid challenge had not been administered which was essential in this situation to aid diagnosis and treatment. Appropriate antibiotic therapy, in line with guidelines, was started at a time between 14.40 to 14.45 hrs on the 24th. In cases of septic shock, every hour of delay in administering an appropriate antibiotic therapy in adequate doses worsens the prognosis (Kumar et al, 2006).

The investigation team considers that the multidisciplinary team needed to urgently consider the option of immediate optimisation of the patient's condition and expedite delivery in the adjacent operating theatres versus transfer to the HDU which was not adjacent; and the potential for delay in definitive therapy whilst awaiting transfer. Early administration of medication to expedite delivery, appropriate broad spectrum antibiotics for management of sepsis, and adequate fluid replacement was indicated at 10.30 hrs that morning.

As per the Hospital Guidelines on *the "Management of Suspected Sepsis and Sepsis in Obstetric Care"*, there was a need for an ICU consultation at this stage to determine the need for admission to HDU/ICU and to advise resuscitative management. However, such consultations did not take place until approximately 14.00 hrs that afternoon.

The failure to appreciate the developing sepsis by established criteria, and querying the source of the infection when it should have been clear that it was the uterus (i.e. the fact that the patient's membranes had ruptured over 48 hours earlier and there was a **foul smelling** vaginal discharge with **lower abdominal tenderness** as documented by SHO2) delayed active intervention. The patient's vital signs and the fetal heart were to be monitored and the plan was to induce labour when the fetal heart stopped. However, the intrauterine infection necessitated termination of pregnancy to reduce the maternal risks.

At noon on the 24th of October, Staff Midwife 5 documented that the patient's blood pressure had decreased to **76/46** mmHg and that the rate of her intravenous fluid therapy regime had been increased to manage this and that she was subsequently transferred to room 9 to facilitate more close monitoring of her clinical condition following the further deterioration in her clinical observations.

At 13.00hrs, Staff Midwife 6 documented that the patient's blood pressure was **72/38** mmHg, her pulse was **156** beats per minute and that she was complaining of chest discomfort and that an ECG had been recorded. The rate of the patient's intravenous fluids had been increased and the intern on call had been contacted to review the patient's condition. Persistent hypotension despite fluid replacement is indicative of septic shock. Intensive care team consultation was again indicated at this time in conjunction with advice from the Microbiologist to discuss appropriate antimicrobial therapy as per the local Guidelines.

At 13.40hrs on the 24th of October, Staff Midwife 6 documented that the patient's blood pressure was **81/40**mmHg and her pulse rate was **150** per minute and that the Consultant (O&G Consultant 1) had come following a request to review the patient's care at this time.

The documented findings of the clinical assessment carried out by O&G Consultant 1 at this time indicates that a review had been requested in light of a sudden deterioration in her clinical condition at 12.00 hours approximately as demonstrated by hypotension (low blood pressure), dyspnoea (difficulty in breathing) and myalgia (muscle pain). O&G Consultant 1 recalls that the patient was tachypnoeic (rapid respiratory rate) and dyspnoeic (difficulty in breathing) and was very unwell at the time of this assessment. It is documented that the results of blood tests taken earlier that morning indicated a **white cell count 1.7 units** with an elevated CRP of **38.9**. O&G Consultant 1 spoke to O&G Consultant B about the need to terminate the pregnancy even though there was a fetal heartbeat. Both O&G Consultant 1 and O&G Consultant B agreed that a termination was necessary even if the fetal heartbeat was present.

O&G Consultant 1 contacted the Microbiology Consultant to discuss the patient's condition as the patient was septic with deterioration in clinical status and a change to the patient's antibiotic regime was suggested on the basis of this discussion in line with the Hospital's Antimicrobial Guidelines. Consultant Microbiologist A documented that, at 14.09hrs on the 24th of October, he/she advised that the patient should be commenced on Piperacillin/Tazobactam (Tazocin) and a daily dose of Gentamicin at a dose of 5mg/kg body weight and that she should continue on Metronidazole. In addition (s)he advised that the patient's renal function should be reviewed the following day. First doses of the new antibiotic regimen were administered at 14.40 hrs and 14.45 hrs respectively, 10 hours following the initial signs of sepsis and 8 hours after the diagnosis by the SHO.

Following this, an ultrasound was conducted which showed that the fetal heart had stopped.

The paragraphs above show that the hospital Guidelines for the Management of Suspected Sepsis and Sepsis in Obstetric Care (July 2012) and the hospital Antimicrobial Guidelines (Adults Version 6 (2012)) were not followed in this case until the afternoon of October 24th.

The investigation team established that the microbiology service responded to all requests to deliver training on these guidelines and contributed to induction training. The hospital offers induction to all staff in the unit. The current system involves an internal rotation process and use of an induction package to support this.

New guidelines or revised guidelines are implemented on the local Q-Pulse system and an email is sent to each clinical area for the attention of the Clinical Midwife Managers. The Advanced Life Support in Obstetrics (ALSO) course (attended by 10 midwives from the hospital in 2012) covers all major obstetrics emergencies and complications in early pregnancy.

Despite induction being offered, all the staff on the gynaecology ward were not inducted/trained in the use of the local guidelines.

The investigation team recommends mandatory induction of all staff in the gynaecology ward in relation to these guidelines as a matter of urgency.

Recommendation 2:

Mandatory induction and education of all clinical staff working in obstetrics and gynaecology on the early recognition, monitoring and management of infection, sepsis, severe sepsis, and septic shock in accordance with appropriate clinical guidelines including guidelines for the Management of Suspected Sepsis and Sepsis in Obstetric Care and Antimicrobial Guidelines, and as per the Royal College of Obstetrics and Gynaecology Green-top guidelines on Bacterial sepsis (Green-top Guidelines No 64a April 2010) and as per the chapter on sepsis from the Centre for Maternal and Child Enquiries (CEMACE) 'Saving Mothers' report 2006 - 2008. This induction of staff must highlight the need for early and appropriate involvement of the multidisciplinary team to include an anaesthetist, intensive care specialist, microbiologist, infectious diseases specialist, and other relevant specialists in cases of sepsis or suspected sepsis. This induction should be provided on an appropriately regular basis to address the training needs of nursing /midwifery and medical staff where they change and rotate frequently. There should be regular updating of:

- a) induction programmes and
- b) ongoing and continuing professional education programmes.

Task and Technology Factors:

Lack of definitive communication tools for consultation or hand over of ill patients (e.g. SBAR Situation, Background, Assessment, Recommendations):

The investigation team is concerned with the clinical practice of effective communication of information between doctors in this particular case. An example being the specific concern highlighted on page 67. In the example on page 67, SHO2 recalled giving all the vital signs and O&G R 2 did not recall SHO 2 giving details of the patient's pulse rate or blood pressure. This indicates the need for consideration of the use of communication tools such as SBAR (Situation, Background, Assessment, Recommendation) for proper hand over as effective communication and the input of a senior clinician was warranted at this stage.

Recommendation 5:

The HSE should implement and audit compliance with improved communication practices between all disciplines and grades of staff, and implement improvements in the handover for acutely ill patients including between staff shifts. Adoption of appropriate definitive communication tools to assist clear and focussed communication of information in relation to the deterioration of a woman's condition, and/or consultation, and/or handover to a higher level of care, such as ISBAR⁵¹ (HSE Acute Medicine Programme, 2013) which is a modification of SBAR as recommended within 'Improving patient handover – RCOG Good Practice No 12' (Dec 2010) is recommended.

⁵¹ ISBAR stands for Identify, Situation, Background, Assessment, Recommendation.

Incidental factors:

Incidental factors are defined as issues that are identified in the course of an investigation which did not impact directly on the outcome but which serve to identify issues for safety improvement.

Incidental factor 1:

The investigation team was aware that this was the first direct maternal death⁵² to have occurred in 16 years at the hospital (the last direct maternal death had occurred in October 1996). From October 1996 to December 2012, 51,440 births were recorded at the hospital. Maternal mortality is uncommon in terms of incidents that occur in maternity services. There might be several severe morbidities (i.e. associated severe illness which can lead to death) which may go unrecorded unless monitored as a measured patient outcome. If adverse events are monitored, there is an opportunity to take early remedial action before major morbidity or deaths occur.

Recommendation to address incidental factor 1:

The review team recommends consideration of a national quality assurance programme for obstetrics and gynaecology as an initial step to maintain confidence amongst patients/service users, staff, the public, administrators and regulators and to put into place safe systems before a catastrophe happens. Monthly work loads, clinical outcomes and adverse incidents should be monitored by using a dash board to include green, amber and red signals to warn of the possibility of impending problems (Ref; Maternity Dashboard: Clinical Performance and Governance Score Card – RCOG Good Practice No. 7 Jan 2008).

Incidental factor 2:

The investigation team established that counselling is provided after miscarriage occurs rather than when an inevitable miscarriage has been diagnosed.

Recommendation to address incidental factor 2 (National):

Ensure that the psychological impact of inevitable miscarriage is appropriately considered and that a member of staff is available to offer immediate support and information at diagnosis. Members of staff should also advise of the availability of counselling services for women and partners at diagnosis. Care given, including counselling and support, should be documented. The availability of counselling services for women, partners and families who have suffered any incident or bereavement in childbirth should be reviewed, considered and developed as appropriate at each maternity site.

⁵² A maternal death is defined within the UK Confidential Enquiry as "Deaths of women while pregnant or within 42 days of the end of the pregnancy from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes". Maternal deaths are sub-divided into four further groups, including direct maternal deaths. Direct maternal deaths are those that result from obstetric complications of the pregnant state (pregnancy, labour and puerperium), from interventions, omissions, incorrect treatment or from a chain of events resulting from any of the above (classification 8 of the ninth revision of the International Classification of Diseases, Injuries and Causes of Death).

Incidental factor 3:

The investigation team considered that there was consistent poor quality of documentation within the obstetrics and gynaecology records of the plan of care and care delivered. The quality of record keeping should be such that continuity of care for a patient /client /family is always supported.

Examples of documentation that would not meet recommended practices for Healthcare Records Management within the healthcare records of this patient included:

- Staff signatures were not legible on all entries
- All staff entries were not dated
- All entries were not timed
- Staff making a referral or consulting with another member of the healthcare team did not always clearly identify the other member of staff in the record.
- The patients /clients name and record number (i.e. hospital number) did not appear on every page of the record.

Recommendation to address incidental finding 3 (National):

Implement the *HSE Standards and Recommended Practices for Healthcare Records Management V3.0 (May 2011)* and make arrangements for an audit of compliance with this standard (and any subsequent standard) within a six-month timeframe and yearly thereafter.

References

- Allanson, B., Jennings, B., Jaques, A., Charles, A.K., Keil, A.D., Dickinson, J.E., (2012) "Infection and fetal loss in the mid-second trimester of pregnancy", Australian and New Zealand Journal of Obstetrics and Gynaecology, 2010, **50**, 221 – 225.
- Barbara, B.J. (2006) *Blood Cells a Practical Guide*. Fourth Edition. Oxford, U.K: Wiley-Blackwell.
- Centre for Maternal and Child Enquiries (2011) *Saving Mothers' Lives; Reviewing maternal deaths to make motherhood safer: 2006 - 2008*. The Eighth Report of the Confidential Enquiries into Maternal Deaths in the United Kingdom. Wiley-Blackwell
- Costeloe KL, Hennessy EM, Haider S, Stacey F, Marlow N, Draper ES. (2012) "Short term outcomes after extreme preterm birth in England: comparison of two birth cohorts in 1995 and 2006 (the EPICure studies)". *BMJ*. Dec 4;345:e7976. doi: 10.1136/bmj.e7976.
- Dewan H, Morris JM. (2001) "A systematic review of pregnancy outcome following preterm premature rupture of membranes at a previable gestational age". *Aust N Z J Obstet Gynaecol*. Nov;41(4):389-94.
- Groenendaal F, Uiterwaal C. (2012), *Long term follow-up of extremely preterm neonates*. *BMJ*. Dec 4;345:e8252. doi: 10.1136/bmj.e8252.
- Hunter TJ, Byrnes MJ, Nathan E, Gill A, Pennell CE. (2012) "Factors influencing survival in pre-viable preterm premature rupture of membranes". *Sep;25(9):1755-61*. doi: 10.3109/14767058.2012.663824. *J Matern Fetal Neonatal Med*. Epub 2012 Mar 16
- Kumar, A, Roberts, D, Wood, K.E., Light, B., Parrillo, J.E., Sharma, S., Suppes, R., Feinstein, D., Zanotti, S., Taiberg, L., Gurka, D., Kumar, A., Cheang, M. (2006) "Duration of hypotension before initiation of effective antimicrobial therapy is the critical determinant of survival in human septic shock" *Crit Care Med* Vol. 34, No. 6.
- Lappen, J.R., Keene, M., Lore, M., Grobman., W.A., Gossett., D.R., (2010), "Existing models fail to predict sepsis in an obstetric population with intrauterine infection". *Am J Obstet Gynaecol* 2010; 2003;573.e1-5
- Margato MF, Martins GL, Passini Júnior R, Nomura ML. (2012) "Previably preterm rupture of membranes: gestational and neonatal outcomes". *Arch Gynecol Obstet*. Jun;285(6):1529-34. doi: 10.1007/s00404-011-2179-0. Epub 2011 Dec 28
- Moore T, Hennessy EM, Myles J, Johnson SJ, Draper ES, Costeloe KL, Marlow N. (2012), "Neurological and developmental outcome in extremely preterm children born in England in 1995 and 2006: the EPICure studies." *BMJ*. Dec 4;345:e7961. doi: 10.1136/bmj.e7961.
- Westin, M., Källén, K., Saltvedt, H., Almströms, M., Grunewald, C., and Valentin, L., (2007), "Miscarriage after a normal scan after 12-14 gestational weeks in women at a low risk of carrying a fetus with chromosomal anomaly according to nuchal translucency screening". *Ultrasound Obstet Gynaecol* 2007; **30**; 728 – 736. Published on line 7 September 2007 in Wiley InterScience (www.interscience.wiley.com) DOI: 10.1002/uog.5138

Local Guidelines:

Guideline 'Management of miscarriage' (29.05.12)

Guideline on 'Management of Late Miscarriage; Stillbirths and Neonatal Deaths' (01.09.10) & appendices

Guidelines for the 'Management of Post Partum Haemorrhage (PPH)' and Early Warning Score & Maternity Observation Chart (18.07.12)

Guideline on the 'Management of Suspected Sepsis and Sepsis in Obstetric Care' (19.07.12) & Appendix 1 Flow Chart on the Management of Sepsis- (Adapted - MOET (2003, p.229)

Obstetric Early Warning Score (EWS) Chart (18.07.2012.)

Antimicrobial Guidelines (Adults) for [hospital name] Version 6 (2012)

Guideline on 'Management of Late Miscarriage; Stillbirths and Neonatal Deaths'

Guideline on 'Preterm Pre-labour Rupture of Membranes (PPROM), revision 3, (11/11/2009)

Guideline on 'Preterm Pre-labour Rupture of Membranes (PPROM), Guideline 44 revision 4, (06/11/2012)';

(Irish) National Policy and Guidance Documents

An Bord Altranais (November, 2002) *Recording Clinical Practice Guidance to Midwives and Nurses*

Health Service Executive (May 2011) *HSE Standards and Recommended Practices for Healthcare Records Management V3.0*

Royal College of Physicians of Ireland and Directorate of Strategy and Clinical Programmes, Health Service Executive (April 2012) *Clinical Practice Guideline: Management of Early Pregnancy Miscarriage, Institute of Obstetricians and Gynaecologists.*

Royal College of Physicians of Ireland and Directorate of Quality and Clinical Care, Health Service Executive (December, 2010) *Clinical Practice Guideline: Ultrasound diagnosis of early pregnancy miscarriage, Institute of Obstetricians and Gynaecologists.*

International/European Policy and Guidance Documents:

Oireachtas Joint Committee on Health and Children Debate (2013)

(<http://oireachtasdebates.oireachtas.ie/Debates%20Authoring/DebatesWebPack.nsf/committeetakes/HEJ2013010800002?opendocument>)

Royal College of Obstetricians and Gynaecologists (2005) *The Future Role of the Consultant: A Working Party Report.* London: RCOG.

Royal College of Obstetricians and Gynaecologists. (2006, amended 2010). *Green-top guidelines for the management of Preterm Pre-labour Rupture of the Membranes (RCOG Green-top Guideline No.44)* London: RCOG <http://www.rcog.org.uk/womens-health/clinical-guidance/preterm-prelabour-rupture-membranes-green-top-44>

Royal College of Obstetricians and Gynaecologists (2008) *Maternity Dashboard: Clinical Performance and Governance Score Card (Good Practice No. 7)* London: RCOG. <http://www.rcog.org.uk/womens-health/clinical-guidance/maternity-dashboard-clinical-performance-and-governance-score-card>

Royal College of Obstetricians and Gynaecologists (2009) *Responsibility of Consultant On-call (Good Practice No. 8)* London: RCOG. <http://www.rcog.org.uk/responsibility-of-consultant-on-call>

Royal College of Obstetricians and Gynaecologists (2010). *Improving patient handover (Good Practice No 12)* London: RCOG. <http://www.rcog.org.uk/womens-health/clinical-guidance/improving-patient-handover-good-practice-no-12>

Royal College of Obstetricians and Gynaecologists (2012) *Bacterial Sepsis in pregnancy , (RCOG Green top Guideline 64a April 2012)*; London: RCOG. <http://www.rcog.org.uk/files/rcog-corp/25.4.12GTG64a.pdf>

Saving Mother' Lives – Reviewing maternal deaths to make pregnancy safer 2006-2008. Br J Obstetrics & Gynaecology Vol. 118; Supplement 1 –March 2011 – Chapter 7. Sepsis pages 87-100.

Surviving Sepsis Campaign: International guidelines for management of severe sepsis and septic shock (2008). Revised 2011. 3rd Edition Crit Care Med 2013 ; 41:580-637. (<http://www.survivingsepsis.org/>)

Appendix A

Summary outline of the legal position in Ireland with respect to the regulation of the termination of pregnancy and, in particular, as regards the protection of the right to life of the pregnant woman and of the unborn prepared by Mr. Peter Finlay, SC.

INTRODUCTION

1. A relatively concise statement is sought of the present law in Ireland with respect to the regulation of the termination of pregnancy with particular regard to the protection of the right to life of the pregnant woman and of the unborn. For this reason detailed consideration shall not be given to ancillary matters such as the law regulating information about abortion or the right to travel.
2. It should also be noted that, for the same reason, it is beyond the scope of this opinion to consider the issues relating to the legal status and/or protection of embryonic human life prior to implantation, to comment in detail on the legality or otherwise of abortion on grounds other than the risk to life of the woman or to speculate or advise on possible future developments of the law as it currently stands.
3. The Irish law on abortion is comprised of constitutional provisions, statute law and case law. From the perspective of a registered medical practitioner or a registered nurse the content of statutory professional codes of ethics, though not in themselves law, provide further relevant considerations. The law emanating from these different sources can be summarised as follows.

A. CONSTITUTIONAL LAW

Article 40.3.3°

4. Article 40.3 of the Constitution, as enacted, contained the following two subsections:

“1° The State guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate the personal rights of the citizen.

2° The State shall, in particular, by its laws protect as best it may from unjust attack and, in the case of injustice done, vindicate the life, person, good name and property rights of every citizen.”

5. In 1983 the Eighth Amendment of the Constitution added a further subsection which provides:

“3° The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right.”

6. Though there have been judicial dicta to suggest that unborn human life may already have enjoyed constitutional protection prior to the 1983 amendment⁵³ or could still enjoy such protection under other provisions of the Constitution,⁵⁴ it is beyond doubt that Article 40.3.3° represents the determinative provision for the purposes of considering the nature and interaction of the constitutional rights to life of the pregnant woman and the unborn.

⁵³ See *McGee v Attorney General* [1974] IR 284; *G v An Bord Uchtála* [1980] IR 32; *Finn v Attorney General* [1983] IR 154; and *Norris v Attorney General* [1984] IR 36.

⁵⁴ *Roche v Roche* [2010] 2 IR 321 at 396 (per Fennelly J).

The “X Case”

7. In *Attorney General v X & Others*⁵⁵ (the “X Case”) the Supreme Court considered the requirements of Article 40.3.3° in circumstances where the continuation of her pregnancy is deemed to pose a serious risk to the life of the woman. The case concerned a 14 year old girl who had become pregnant by rape. The Attorney General applied to the High Court for an injunction preventing the girl from travelling to England for an abortion. In the High Court a psychologist testified that the girl might commit suicide if she was refused an abortion. The High Court granted the injunction but its decision was overturned on appeal by a majority of the Supreme Court (Hederman J dissenting). In the course of their judgments each member of the majority considered how Article 40.3.3° was to be applied in circumstances where a pregnant woman’s right to life was deemed to be at risk as a consequence of her pregnancy.

8. Finlay CJ laid down the test to be applied in such cases as follows:

*“I, therefore, conclude that the proper test to be applied is that if it is established as a matter of probability that there is a real and substantial risk to the life, as distinct from the health, of the mother, which can only be avoided by the termination of her pregnancy, such termination is permissible, having regard to the true interpretation of Article 40, s. 3, sub-s. 3 of the Constitution.”*⁵⁶

9. The Chief Justice went on to hold that on the basis of the evidence before the trial judge, and on the findings which he had made, Miss X satisfied this test in that it had been

*“established as a matter of probability, that there is a real and substantial risk to the life of the mother by self destruction which can only be avoided by the termination of her pregnancy.”*⁵⁷

10. O’Flaherty J formulated substantially the same test in the following terms:

*“Until legislation is enacted to provide otherwise, I believe that the law in this State is that surgical intervention which has the effect of terminating pregnancy bona fide undertaken to save the life of the mother where she is in danger of death is permissible under the Constitution and the law. The danger has to represent a substantial risk to her life though this does not necessarily have to be an imminent danger of instant death. The law does not require the doctors to wait until the mother is in peril of immediate death. I believe the instant case to come within this principle.”*⁵⁸

11. Egan J likewise adopted a test largely equivalent in substance to the foregoing, namely:

*“In my opinion the true test should be that a pregnancy may be terminated if its continuance as a matter of probability involves a real and substantial risk to the life of the mother. The risk must be to her life but it is irrelevant, in my view, that it should be a risk of self-destruction rather than a risk to life for any other reason. The evidence establishes that such a risk exists in the present case.”*⁵⁹

12. McCarthy J framed the test as follows:

⁵⁵ [1992] 1 IR 1.

⁵⁶ [1992] 1 IR 1 at 53.

⁵⁷ [1992] 1 IR 1 at 55.

⁵⁸ [1992] 1 IR 1 at 87.

⁵⁹ [1992] 1 IR 1 at 92.

“In my view, the true construction of the Amendment, bearing in mind the other provisions of Article 40 and the fundamental rights of the family guaranteed by Article 41, is that, paying due regard to the equal right to life of the mother, when there is a real and substantial risk attached to her survival not merely at the time of application but in contemplation at least throughout the pregnancy, then it may not be practicable to vindicate the right to life of the unborn.”⁶⁰

13. In the later case of *In re Article 26 and the Information (Termination of Pregnancies) Bill 1995*⁶¹ Hamilton CJ, giving the single judgment of the Supreme Court, synthesised the wordings of the four majority judgments into the following formula:

“The Attorney General v. X. [1992] 1 I.R. 1 ... established that having regard to the true interpretation of the Eighth Amendment, termination of the life of the unborn is permissible if it is established as a matter of probability that there is a real and substantial risk to the life, as distinct from the health, of the mother and that that risk can only be avoided by the termination of her pregnancy.”⁶²

14. As is evident from the foregoing, a termination of pregnancy which is likely to impact adversely upon the constitutional right to life of the unborn is nevertheless lawful under the terms of Article 40.3.3° if both of the two conditions are established as a matter of probability, namely (1) that *“there is a real and substantial risk to the life, as opposed to the health, of the mother”* and (2) that *“that risk can only be avoided by the termination of her pregnancy.”*

Thirteenth and Fourteenth Amendments

15. Following the decision in the *X Case* three referendums were held in 1992 resulting in two amendments to Article 40.3.3°. The Thirteenth Amendment was directed at overturning dicta in three of the judgments in the *X Case* to the effect that where there was a conflict between the right to life of the unborn and the right to travel, the right to life would have to take precedence. It inserted the following clause into Article 40.3.3°:

“This subsection shall not limit freedom to travel between the State and another state.”

16. The Fourteenth Amendment concerned the provision of information relating to abortion. It inserted the following clause into Article 40.3.3°:

“This subsection shall not limit freedom to obtain or make available, in the State, subject to such conditions as may be laid down by law, information relating to services lawfully available in another state.”

17. The Regulation of Information (Services outside the State for Termination of Pregnancies) Act 1995 was enacted to implement that subsection.

The “C Case”

18. The interpretation of 40.3.3° provided in the *X Case* has only been judicially applied by the High Court on one occasion.⁶³ *A and B v Eastern Health Board*⁶⁴ (the “C Case”)

⁶⁰ [1992] 1 IR 1 at 80.

⁶¹ [1995] 1 IR 1.

⁶² [1995] 1 IR 1 at 33. See also 47.

⁶³ The case of *D (A Minor) v HSE & others* (unreported, High Court, McKechnie J, May 2007) concerned the right to travel under the Thirteenth Amendment rather than the *X Case* test. In that case a 17 year old girl in the care of the HSE expressed a wish to travel to the UK for an abortion when she discovered that the unborn had anencephaly. A social worker had notified the Gardai that Miss D was not entitled to leave the State but the High Court found that there was no impediment under 40.3.3° to her travelling abroad for an abortion.

⁶⁴ [1998] 1 IR 464.

concerned a 13 year old girl who became pregnant as a result of rape. The girl was taken into care by the Eastern Health Board and the Board applied under the Child Care Act 1991 to the District Court for certain orders allowing it to take the girl abroad for the purposes of obtaining an abortion on the basis of psychiatric testimony that she was likely to commit suicide if an abortion was not carried out. Miss C's parents judicial reviewed the orders made by the District Court but the High Court rejected the reliefs sought holding that the test laid down in the X Case had been satisfied.

Meaning of “unborn” in Article 40.3.3°

19. The questions of what precisely is meant by the term “unborn” in Article 40.3.3° and at what point in the continuum from fertilisation to birth an individual human life begins to enjoy constitutional protection under that Article were considered by the Supreme Court in *Roche v Roche*.⁶⁵ The case concerned a dispute between a separated married couple as to the future use of three cryopreserved embryos which they had conceived by IVF and were being stored at a private fertility clinic. One of the issues in the case was whether the embryos enjoyed a constitutional right to life pursuant to Article 40.3.3°. A majority of the Supreme Court held that they did not and the reasoning given is instructive as to the basis upon which an individual human organism qualifies for constitutional protection as an “unborn” under Article 40.3.3°.

20. Denham J held as follows:

“The concept of unborn envisages a state of being born, the potential to be born, the capacity to be born, which occurs only after the embryo has been implanted in the uterus of a mother.”

This analysis may be put in a slightly different form. The right to life of the unborn is not stated as an absolute right in Article 40.3.3°. Rather, it is subject to the due regard to the right to life of the mother. The right to life of the mother is not stated as an absolute right either. Article 40.3.3° refers to a situation where these two lives are connected and a balance may have to be sought between the two lives. Thus the physical situation must exist to require such a balancing act. No such connection exists between the plaintiff and the three surplus embryos now frozen and stored at the Clinic. ...

This connection, relationship, between the embryos and the mother does not arise until after implantation has occurred. After the implantation of an embryo the relationship between the embryo and the mother changes. The mother has carriage of the embryos, becomes pregnant, and the embryo enters a state of “unborn”. At that time an attachment begins between the two lives. It is that attachment which gives rise to the relationship addressed in Article 40.3.3°.

The words of Article 40.3.3° refers to a situation where the rights of the mother and the unborn are engaged. This occurs after implantation. Thus Article 40.3.3° does not apply to pre-implantation embryos.”

21. Hardiman J developed substantially the same “connection” test as follows:

⁶⁵ [2010] 2 IR 321.

“A capacity of the life of the unborn to impinge on the right to life of the mother, which is an essential postulate of the sub-Article, equally depends on some form of integration of the life of the unborn with the bodily structures of the other life in question, that of the mother.

In my view each of these approaches leads harmoniously and inevitably to the conclusion that the “unborn”, “na mbeo gan breith”, is the foetus en ventre sa mere, the embryo implanted in the womb of the mother. It is manifest that the embryo undergoing cryogenic preservation is not so implanted and is incapable of impinging in any way on the right to life of the mother or of having any physical effect whatsoever on her body or its structures.”⁶⁶

22. Geoghegan J made the point even more briefly as follows:

“Both on a simple reading but even more so given its historical context, I would take the view that “the unborn” refers to a child in the womb not yet born.”⁶⁷

Abortion outside of the X Case test

23. There has been no direct consideration by an Irish Court as to the permissibility under Article 40.3.3° of abortion on grounds other than that laid down in the X Case test.
24. In the case of *D v Ireland*,⁶⁸ and in the context of the State’s challenge on procedural grounds to the admissibility of the applicant’s case, the question arose before the European Court of Human Rights as to whether an arguable case could be made before an Irish Court that abortion might be permissible under Article 40.3.3° outside of the X Case test.
25. D was pregnant with twins when she was informed that one had stopped developing and the other had Trisomy 18 (Edward’s Syndrome). D was told by doctors that she was not eligible for an abortion in Ireland and so travelled to the UK for an abortion. The applicant alleged breaches of Articles 3, 8 and 10 of the Convention based on the effects on her of the need to travel abroad to have an abortion in the case of a lethal foetal abnormality and the restrictions on abortion information for which the 1995 Act provided. Counsel for the Attorney General argued that D had failed to exhaust available domestic remedies by forgoing the option of a declaratory action in the Irish Courts. The essence of the State’s case was that if it had been established that there was no realistic prospect of the foetus being born alive, then there was “at least a tenable” argument which would be “seriously considered” by the domestic courts to the effect that the foetus would not be protected by the provisions of Article 40.3.3°. ⁶⁹ The Court accepted the State’s claim that an “arguable” case could in principle have been stated by D in the High Court and, accordingly, D’s complaint was held to be inadmissible for failure to exhaust available domestic remedies.⁷⁰
26. In assessing the possible future significance of this decision two caveats should be noted. The first is that this argument was made prior to the decision of the Supreme Court in *Roche v Roche*⁷¹ which appears to hold that the scope of the protection

⁶⁶ [2010] 2 IR 321 at 381.

⁶⁷ [2010] 2 IR 321 at 392.

⁶⁸ 27th June 2006, Decision (Admissibility), 26499/02.

⁶⁹ At para 69.

⁷⁰ See paras 90 and 92.

⁷¹ [2010] 2 IR 321.

offered by Article 40.3.3° is determined by reference to the presence or absence of the physical connection between the embryo and mother which begins at implantation. The second point to note is that the State's argument in D seems hard to reconcile with the statement of Keane CJ, giving the unanimous judgment of the Supreme Court in *Baby O v Minister for Justice*,⁷² that

"The passage from Article 40.3.3° on which counsel relied, as explained by the judgments of the majority in this court in The Attorney General v. X. [1992] 1 I.R. 1, was intended to prevent the legalisation of abortion either by legislation or judicial decision within the State, except where there was a real and substantial risk to the life of the mother which could only be avoided by the termination of the pregnancy."⁷³

B. STATUTORY LAW

The Offences Against the Person Act 1861 ("the 1861 Act")

27. Abortion is criminalised in Ireland under the terms of the 1861 Act. Section 58 (as amended)⁷⁴ provides:

"Every woman, being with child, who, with intent to procure her own miscarriage, shall unlawfully administer to herself any poison or other noxious thing, or shall unlawfully use any instrument or other means whatsoever with the like intent, and whosoever, with intent to procure the miscarriage of any woman, whether she be or not be with child, shall unlawfully administer to her or cause to be taken by her any poison or other noxious thing, or shall unlawfully use any instrument or other means whatsoever with the like intent, shall be guilty of a felony and being convicted thereof shall be liable to be imprisoned for life."

28. Section 59 of the 1861 Act (as amended)⁷⁵ provides:

"Whoever shall unlawfully supply or procure any poison or other noxious thing, or any instrument or thing whatsoever, knowing that the same is intended to be unlawfully used or employed with intent to procure the miscarriage of any woman, whether she be or be not with child, shall be guilty of a misdemeanour and being convicted thereof shall be liable to be imprisoned for any period not less than three years and not exceeding five years."

29. The questions of what precisely is meant by the term "miscarriage" for the purposes of sections 58 and 59 and thus at what point prior to birth the criminalisation of abortion begins was considered by the English High Court in *R. (Smeaton) v Secretary of State for Health*.⁷⁶ In that case Munby J held that the offences created by the 1861 Act only applied from the time of implantation on. The decision in *Smeaton* was adopted with approval by Denham J in her judgment in *Roche v Roche*⁷⁷ and its analysis appeared to have found favour with Geoghegan and Hardiman JJ also.⁷⁸

⁷² [2002] 2 IR 169.

⁷³ [2002] 2 IR 169 at 181.

⁷⁴ As amended by: section 1 of the Statute Law Revision Act 1892; section 1 of the Statute Law Revision (No. 2) Act 1893; and section 11(2) of the Criminal Law Act 1997.

⁷⁵ As amended by: section 1 of the Statute Law Revision Act 1892; and section 11(2) of the Criminal Law Act 1997.

⁷⁶ [2002] EWHC 610 (Admin) and [2002] EWHC 886 (Admin), [2002] 2 FLR 146.

⁷⁷ [2010] 2 IR 321 at 369.

⁷⁸ [2010] 2 IR 321 at 381 (per Hardiman J) and 391-2 (per Geoghegan J). Contrast AG (*SPUC*) v *Open Door Counselling Ltd* [1988] IR 593 at 598 per Hamilton P.

30. The boundaries to the offence created by section 58 of the 1861 Act was considered in England and Wales in *Rex v Bourne*.⁷⁹ MacNaghten J held that an abortion to preserve the life of a pregnant woman was not unlawful. He went on to hold that where a doctor was of the opinion that the probable consequence of a pregnancy was to render a woman a mental and physical wreck he could be said to be operating for the purpose of preserving the life of the mother.

31. The status of *Bourne* in Irish law or the possibility of a *Bourne*-like interpretation of the 1861 Act by an Irish Court has been the subject of occasional and not wholly consistent obiter judicial comment. In *Roche v Roche*⁸⁰ Denham J stated that:

*“Rex v. Bourne [1939] 1 K.B. 687 was followed in many common law jurisdictions. However, it was never applied to or relied upon in this State. It was no part of our law.”*⁸¹

32. Some years previously in *S.P.U.C. v. Grogan (No. 5)*⁸² Keane J had reviewed the references to *Bourne* in the *X Case* judgments and reached the more tentative conclusion that:

*“All one can say with confidence at this stage is that the preponderance of judicial opinion would suggest that the Bourne approach could not have been adopted in this country consistently with the Constitution prior to the Eighth Amendment. ... Hederman J., who conducted the most detailed analysis of the decision in Rex v. Bourne [1939] 1 K.B. 687, was in agreement with McCarthy J. that it did not represent the law in Ireland prior to the Eighth Amendment”*⁸³

33. These comments would seem to suggest that the Eighth Amendment somehow increased the possibility of a *Bourne*-like interpretation of section 58. Such a suggestion would appear to be at odds, however, with the following dictum of Geoghegan J in *Roche v Roche* which, on the contrary, implies that the amendment in fact secured the exclusion of the *Bourne* approach from Irish law:

*“As a consequence of Rex v. Bourne and quite apart from the possibility of a statutory repeal or amendment, there was no guarantee prior to the constitutional amendment, that abortions of the kind not considered “unlawful” in Rex v. Bourne might some day be regarded with impunity by Irish courts.”*⁸⁴

Interaction between sections 58 and 59 of the 1861 Act and Article 40.3.3°

34. A variety of academic and obiter Irish judicial opinions have been expressed regarding the questions of (1) the meaning and scope of the offenses as created by sections 58

⁷⁹ [1939] 1 KB 687.

⁸⁰ [2010] 2 IR 321.

⁸¹ [2010] 2 IR 321 at 368. See the similar comments at 347 per Murray CJ.

⁸² [1998] 4 IR 343.

⁸³ [1998] 4 IR 343 at 381 and 386.

⁸⁴ [2010] 2 IR 321 at 392.

and 59 of the 1861 Act⁸⁵ and (2) the consequences of the Eighth Amendment, if any, upon the legal meaning, effect or operation of those sections.⁸⁶

35. Neither question, however, has ever been directly considered by an Irish Court (save for the discussion of “miscarriage” in *Roche v Roche* already noted above). This may partly be explained by the fact that, according to submissions made by the Attorney General to the ECtHR in 2010,⁸⁷ there has been no prosecution taken under these sections in living memory. Despite the absence of any authoritative determination of these issues, however, it is possible to make two relatively uncontroversial observations.
36. First, it should be noted that it is not necessarily the case that the 1861 Act and Article 40.3.3° coincide perfectly as regards the acts which they prohibit or permit respectively. It is possible that certain actions which are not criminalised by sections 58 or 59 may nevertheless constitute an unlawful interference with the constitutional right to life of the unborn under Article 40.3.3°.⁸⁸
37. Second, the possible existence of such a mismatch does not necessarily mean, however, that women or their doctors are at risk of a valid prosecution under the 1861 Act for acts done by them in compliance with the *X Case* test. There are several reasons why this is so. The first and most obvious is that any statute which purported to criminalise an act which was done in accordance with the *X Case* test in order to protect the right to life of a pregnant woman could not withstand a constitutional challenge. Other possible reasons relate to the terms of the section 58 and 59 offences themselves. It is beyond the scope of this opinion to evaluate or comment upon the different views in this regard and it suffices to merely note the following possible arguments:
 - Some have pointed to the early judicial interpretations of the section 58 and 59 offences, or their preceding statutory equivalents, as evidence that (long before the controversial *Bourne* decision) these provisions were not viewed as intending to criminalise terminations of pregnancy carried out by a qualified doctor in order to save the life of a pregnant woman.⁸⁹

⁸⁵ See, e.g., *AG (SPUC) v Open Door Counselling Ltd* [1988] IR 593 at 598 per Hamilton P; *Attorney General v X & Others* [1992] 1 IR 1 at 81 per McCarthy J (criticised by Kingston and Whelan, *Abortion and the law* (1997) p. 72); *S.P.U.C. v. Grogan (No. 5)* [1998] 4 IR 343 at 381 and 386; Keown, *Abortion, doctors and the law* (1988) pp. 49-59; and Morriss “The Statute Law on Abortion in Ireland” in Scheppe (ed), *The Unborn Child, Article 40.3.3° and Abortion in Ireland* (2008) p. 277.

⁸⁶ *Attorney General v X & Others* [1992] 1 IR 1 at 86 per O’Flaherty J; *Roche v Roche* [2010] 2 IR 321 at 347 (per Murray CJ), at 391-2 (per Geoghegan J) and at 381 (per Hardiman J); and Charleton, *Offences Against the Person* (1992) p. 184.

⁸⁷ *A, B & C v Ireland*, 16th December 2010, Judgment (Grand Chamber), 25579/05 at para 189.

⁸⁸ This is the view taken by Kingston and Whelan, *Abortion and the law* (1997) p. 78: “the exceptions allowed for by section 58 are wider than those allowed for by Article 40.3.3°.”

⁸⁹ See Keown, *Abortion, doctors and the law* (1988) pp. 49-59 and the references therein to *R v Wilhelm* (1858) 17 Med Tim Gaz 658, *R v Poole* [1873] 1 Lancet 422, *R v Collins* [1898] 2 Brit Med J 59, and *R v Bell* [1929] 1 Brit Med J 1061; and Morriss “The Statute Law on Abortion in Ireland” in Scheppe (ed), *The Unborn Child, Article 40.3.3° and Abortion in Ireland* (2008) p. 277.

- Others have argued that certain terminations of pregnancy (such as, e.g., those permitted by the X Case test) would fall within a defence of necessity as against any prosecution under the 1861 Act.⁹⁰
- Another possible argument is that the repeated use of the term “unlawfully” in the definition of the offences must mean, if the use of the word is not to be deemed redundant, that certain terminations of pregnancy can be carried out lawfully.⁹¹ A further variation of this view would be to claim that any procedures lawful under Article 40.3.3° are *ipso facto* excluded from criminalisation under the Act.
- Another possible argument is that the express emphasis on the “intent to procure a miscarriage” as a necessary and constitutive element of the various offences means that it might be a defence to show that one acted with the sole or dominant intent of saving the mother’s life.⁹²

Other relevant statutes

38. For the sake of completeness the following statutory provisions should also be noted.

39. Section 58 of the Civil Liability Act 1961 provides:

“For the avoidance of doubt it is hereby declared that the law relating to wrongs shall apply to an unborn child for his protection in like manner as if the child were born, provided the child is subsequently born alive.”

40. Section 10 of the Health (Family Planning) Act 1979 provides:

*“Nothing in this Act shall be construed as authorising -
 (a) the procuring of abortion,
 (b) the doing of any other thing the doing of which is prohibited by section 58 or 59 of the Offences Against the Person Act, 1861 (which sections prohibit the administering of drugs or the use of any instruments to procure abortion)
 or,
 (c) the sale, importation into the State, manufacture, advertising or display of abortifacients.”*

C. OTHER RELEVANT CASE LAW

A, B & C v Ireland

41. Though strictly speaking not a part of current national law on abortion, the judgment of the European Court of Human Rights in *A, B & C v Ireland*⁹³ is clearly a serious and significant legal development which merits mention in the present context.

42. This case involved multiple complaints brought against Ireland by three female applicants in relation to various aspects of Irish abortion law. The first and second applicants were unsuccessful on all grounds and in dismissing their claims the Court conclude at para 241 that

⁹⁰ See extensive references cited in Kingston and Whelan, *Abortion and the law* (1997) pp. 68-71.

⁹¹ For a discussion of the significance of the fact that the term “unlawfully” appears six times in the two sections see Morriss “The Statute Law on Abortion in Ireland” in Schweppe (ed), *The Unborn Child, Article 40.3.3° and Abortion in Ireland* (2008) p. 290. See also Kingston and Whelan, *Abortion and the law* (1997) pp. 71-72.

⁹² For a discussion of the significance of the references to “intent” in the two sections see Morriss “The Statute Law on Abortion in Ireland” in Schweppe (ed), *The Unborn Child, Article 40.3.3° and Abortion in Ireland* (2008) p. 286. For a detailed discussion of the legal concept of intention with respect to the regulation of abortion see the written submission of “A barrister’s group” [sic] to the All-Party Oireachtas Committee on the Constitution published as an appendix to the Fifth Progress Report (2000) at p. A520.

⁹³ 16th December 2010, Judgment (Grand Chamber), 25579/05.

“having regard to the right to lawfully travel abroad for an abortion with access to appropriate information and medical care in Ireland, the Court does not consider that the prohibition in Ireland of abortion for health and well-being reasons, based as it is on the profound moral views of the Irish people as to the nature of life (paragraphs 222-227 above) and as to the consequent protection to be accorded to the right to life of the unborn, exceeds the margin of appreciation accorded in that respect to the Irish State. In such circumstances, the Court finds that the impugned prohibition in Ireland struck a fair balance between the right of the first and second applicants to respect for their private lives and the rights invoked on behalf of the unborn.”

43. The third applicant, however, was successful with respect to her claim under Article 8. The facts of her case were as follows. C had been treated for 3 years with chemotherapy for a rare form of cancer. The cancer went into remission and the applicant unintentionally became pregnant. She was unaware of this fact when she underwent a series of tests for cancer, contraindicated during pregnancy. When she discovered she was pregnant, the first applicant consulted her GP as well as several medical consultants. She alleged that, as a result of “the chilling effect of the Irish legal framework”, she received insufficient information as to the impact of the pregnancy on her health and life and of her prior tests for cancer on the foetus. She therefore researched the risks on the internet. Given the uncertainty about the risks involved, the third applicant travelled to England for an abortion. As the Court put it: “On 3 March 2005 the third applicant had an abortion in England believing that she could not establish her right to an abortion in Ireland.”
44. In light of the foregoing the Court held that whereas the first applicant had travelled for an abortion for reasons of health and well-being and the second applicant for well-being reasons, the third applicant had sought an abortion abroad as she mainly feared her pregnancy constituted a risk to her life.
45. The essence of the Court’s ruling in favour of C is contained in the conclusion at para 267 that

“the authorities failed to comply with their positive obligation to secure to the third applicant effective respect for her private life by reason of the absence of any implementing legislative or regulatory regime providing an accessible and effective procedure by which the third applicant could have established whether she qualified for a lawful abortion in Ireland in accordance with Article 40.3.3 of the Constitution.”⁹⁴

46. An Expert Group under the chairmanship of Mr Justice Sean Ryan was established by the Government in 2012 to advise on the implementation of the A, B & C decision. It published its report in November 2012. The Government decided to adopt the last of the four options set out in that report which involves a package of legislation and ministerial regulation. In January 2013 the Joint Oireachtas Committee on Health and Children held three days of hearings in order to facilitate the Government in the preparation of the proposed measures. It is unnecessary and beyond the scope of this opinion to comment further in respect of this process of implementation of the A, B & C judgment.

⁹⁴ See also paras 263, 264, 274, 277 and 279.

D. PROFESSIONAL GUIDELINES

47. Finally, and for the sake of completeness, it is perhaps relevant to consider briefly the provisions of the statutory-based professional codes of ethics for registered medical practitioners and nurses (including midwives) respectively in so far as they touch upon the issue of abortion and the right to life.

48. Medical Council Guidelines

49. Section 7(2) of the Medical Practitioners Act 2007 requires the Medical Council to

“(i) specify standards of practice for registered medical practitioners, including the establishment, publication, maintenance and review of appropriate guidance on all matters related to professional conduct and ethics for registered medical practitioners,”

50. In 2009 the Council published the “Guide to Professional Conduct and Ethics for Registered Medical Practitioners” (7th ed). The sections relevant for present purposes are contained in paragraph 21 which provides:

“21.1 Abortion is illegal in Ireland except where there is a real and substantial risk to the life (as distinct from the health) of the mother. Under current legal precedent, this exception includes where there is a clear and substantial risk to the life of the mother arising from a threat of suicide. You should undertake a full assessment of any such risk in light of the clinical research on this issue.

21.2 It is lawful to provide information in Ireland about abortions abroad, subject to strict conditions. It is not lawful to encourage or advocate an abortion in individual cases.

21.3 You have a duty to provide care, support and follow-up services for women who have an abortion abroad.

21.4 In current obstetrical practice, rare complications can arise where therapeutic intervention (including termination of a pregnancy) is required at a stage when, due to extreme immaturity of the baby, there may be little or no hope of the baby surviving. In these exceptional circumstances, it may be necessary to intervene to terminate the pregnancy to protect the life of the mother, while making every effort to preserve the life of the baby.”

Nursing Board Guidelines

51. Section 51(2) of the Nurses Act 1985 provides:

“It shall be a function of the Board to give guidance to the nursing profession generally on all matters relating to ethical conduct and behaviour.”

52. In April 2000 the Board published the “Code of Professional Conduct for each Nurse and Midwife”. The Code states that

“The nurse must at all times maintain the principle that ever effort should be made to preserve human life, both born and unborn. When death is imminent, care should be taken to ensure that the patient dies with dignity.”

PETER FINLAY SC

Appendix B

Investigation Terms of Reference

**NIMT Case 50278
21st of November, 2012**

Introduction

These are the terms of reference for an investigation commissioned by the Clinical Director Galway University Hospital into an incident that arose at the hospital on 28/10/2012. This investigation will be overseen by the National Incident Management Team (NIMT). The final report will be provided to the National Director of Quality and Patient Safety.

Purpose

The purpose of this investigation is to:

- Establish the factual circumstances leading up to the incident
- Identify any key causal factors that may have occurred
- Identify the contributory factors that caused the key causal factors
- Recommend actions that will address the contributory factors so that the risk of future harm arising from these factors is eliminated or if this is impossible, is reduced as far as is reasonably practicable.

Scope of the Investigation/Review

The time frame of this investigation/review will be from patient's admission to GUH on the 21/10/2012 to the patient's death on the 28/10/2012.

The investigation members

Membership of the investigation team includes:

- Sir Sabaratnam Arulkumaran, Professor Emeritus of Obstetrics and Gynaecology, St. George's Hospital, University of London (Chairperson)
- Ms Cora McCaughan, National Incident Management Team (Deputy Chairperson)
- Professor James Walker, Consultant Obstetrician and Gynaecologist, University of Leeds.
- Prof. Mary Horgan, Consultant in Infectious Diseases, Cork University Hospital and Professor in the School of Medicine, University College Cork.
- Dr. Brian Marsh, Consultant in Intensive Care Medicine, Mater Misericordiae University Hospital, Dublin.
- Ms. Cathriona Molloy, Service User Advocate, Patient Focus
- Ms. Geraldine Keohane, Director of Midwifery & Nursing at Cork University Maternity Hospital .Cork

Through the Chairperson, the investigation team will:

- Be afforded the assistance of all relevant staff and other relevant personnel.

→ Have access to all relevant files and records (subject to any necessary consent/data protection requirements including court applications, where necessary).

Should immediate safety concerns arise, the Chair of the Investigation Team will convey the details of these safety concerns to the Commissioner as soon as possible.

Should the investigation team require further external independent input, the Chair of the Investigation team will discuss this with the commissioner; and will seek this input through the NIMT.

Investigation method

The investigation will follow the HSE Guidelines for Systems Analysis Investigation of Incidents and Complaints (QPSD November 2012) and will be cognisant of the rights of all involved to privacy and confidentiality; dignity and respect; due process; and natural and constitutional justice.

The investigation will commence with immediate effect and will be conducted in the shortest timeframe necessary to achieve the purpose of the investigation.

Following completion of the investigation, an anonymised draft report will be prepared by the investigation team outlining the chronology, findings and recommendations. All who participated in the investigation will have an opportunity to give input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

The anonymised report will be shared with the next of kin and may be published and may be subject to a Freedom of Information request.

Recommendations and Implementation

The report, when finalised, will be presented to the commissioner of the investigation.

Implementation of locally applicable recommendations will be undertaken by local managers.

Local managers will communicate nationally applicable recommendations to the National Director(s) and the National Director(s) will oversee the implementation of the nationally applicable recommendations.

Communication Strategy for the Investigation

An individual will be appointed for the purpose of communicating information pertaining to the investigation to the family/staff member(s) affected by and/or involved in the incident.

Appendix C

Interim Safety Recommendations Issued to the Hospital

To: Clinical Director, University College Hospital Galway (UCHG), Galway, Roscommon Hospitals Group.
Commissioner of NIMT 50278 Investigation

cc Chief Operating Officer, Galway, Roscommon Hospitals Group.

From: Professor Sir Sabaratnam Arulkumaran
External Independent Chairperson, NIMT 50278 Investigation.

Date: 30th of November, 2012* *version with amended reference*

Re: Interim safety recommendations for immediate action by the gynaecology ward within the Women and Children's Directorate in University College Hospital Galway (UCHG), Galway, Roscommon Hospitals Group.

As per the terms of reference for the investigation of NIMT reference 50278 (see attached terms of reference dated 21.11.12) the review team undertook that;

“Should immediate safety concerns arise, the Chair of the investigation team will convey the details of these safety concerns to the Commissioner as soon as possible.”

Please see the interim safety recommendations for immediate action by the gynaecology ward within the Women and Children's Directorate in University College Hospital Galway (UCHG), Galway, Roscommon Hospitals Group.

- Immediate introduction of the UCHG (*modified*) Obstetric Early Warning Score (OEWS) Chart for patients receiving obstetrics care on the gynaecology ward as per UCHG 'Guidance for Using the Maternal Obstetrics Early Warning Chart (2012)
- Induct all staff working in the gynaecology ward at UCHG on early recognition, monitoring and management of sepsis, severe sepsis (organ dysfunction or tissue hypoperfusion) and septic shock (persistence of hypoperfusion despite adequate fluid replacement therapy). Induction of staff should include highlighting the need for early involvement of the multidisciplinary team to include an anaesthetist, intensive care specialist, microbiologist, infectious diseases specialist, and other relevant specialists in cases of sepsis or suspected sepsis.

The following documents provide the required information.

- University College Hospital Galway, (2012) *Guideline on the Management of Suspected Sepsis and Sepsis in Obstetric Care*. Galway: University College Hospital Galway.
- University College Hospital Galway, (2012) Antimicrobial Guidelines (Adults) for Galway University Hospitals Version 6 (2012)
- Royal College of Obstetricians and Gynaecologists (2012) *Bacterial Sepsis in Pregnancy: Green-Top Guideline No. 64a* 1st edition. London: Royal College of Obstetricians and Gynaecologists [<http://www.rcog.org.uk/files/rcog-corp/25.4.12GTG64a.pdf>]
- Surviving Sepsis Guidelines : Implement the resuscitation bundle – within the first six hours of care
<http://www.survivingsepsis.org/Bundles/Pages/SepsisResuscitationBundle.aspx>
- Centre for Maternal and Child Enquiries (CMACE). Saving Mothers' Lives: reviewing maternal deaths to make motherhood safer: 2006–08. The Eighth Report on Confidential Enquiries into Maternal Deaths in the United Kingdom. BJOG 2011;118 Suppl 1:1–203.

[<http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2010.02847.x/pdf>]

- Considering the psychological impact associated with inevitable miscarriage the gynaecology ward should ensure that support and counselling services are available to women and partners at diagnosis. The care given (including counselling and support) should be documented.
- Implement the *HSE Standards and Recommended Practices for Healthcare Records Management V3.0* and make arrangements for an audit of compliance with this standard (and any subsequent standard) within a six month timeframe and yearly thereafter.

Professor Sir Sabaratnam Arulkumaran

A handwritten signature in cursive script, reading 'S. Arulkumaran', with a long horizontal flourish extending to the right.

External Independent Chairperson, NIMT 50278 Investigation.
30th of November, 2012

Appendix D

Sources of Information Reviewed by the Investigation Team

Healthcare Records

- Obstetrics and Gynaecology Chart
- Correspondence/Forms
- Antenatal blood tests
- Consent form
- Antenatal Records for period up to 21st of October, 2012
- Nursing and Doctors Records for admission 21st of October, 2012
- Antenatal In-Patient Records (combined nursing and doctor records) from 22nd of October to 28th of October, 2012.
- Records completed during antenatal visit
- Laboratory Reports (Haematology, Biochemistry, Microbiology, Pathology)
- Blood Component Records
- Pre-Operative Checklist
- Observation Chart
- Fluid Input-Output records
- Radiology Department reports
- Prescription Sheets
- Ultrasound Unit Record
- Fetal Medicine Report dated 22nd of October, 2012
- EEG/ECG/Radiometer records
- Microbiology Reports
- Drug Chart for Adults (antimicrobial edition)
 - ⇒ STAT drugs & pre meds only
 - ⇒ Antibiotic, antifungal, antiviral (except antiretrovirals)
 - ⇒ Regular (non IV, NON antimicrobial) DRUGS and ORAL NUTRITION
 - ⇒ As required drugs
- Blood/Blood Component / Product Prescription & Transfusion Record
- Massive or emergency transfusion
- Collection & Receipt records for Blood Components / Blood Products (& attached labels)
- Pre-operative / procedure Checklist Date:
- Pre-operative marking verification checklist
- Gastrografin and Omnipaque Prescription Sheet
- HSE ESBL Patient information leaflet
- Blood bank report
- ECG Reports

ICU Records

- Admission details
- Medical case notes
- Clinical information system electronic record
- Nursing shift records
- Nursing assessments – flow sheets
- Medication Sheets/Drug Chart
- Discharge Summary

Other

- Incident report forms
- HSE incident and risk escalation form
- Staff rotas
- Maternity Staff /Midwifery Professional Development Training Records

Appendix E

Framework of Contributory Factors

Extract from the HSE Guidelines for Systems Analysis Investigation of Incidents and Complaints (HSE, November 2012).

Factor Types	Contributory Factor (i.e. potential causes related to each key causal factor and incidental finding identified)
Individual affected/harmed	Condition (complexity & seriousness) 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 Policies etc. relevant, unambiguous, correct and realistic Availability and accuracy of test results 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 (leadership, congruence, consistency etc.)
Work Environmental Factors	Staffing levels and skills mix Workload and shift patterns Administrative and managerial support Environment - Physical and cognitive. Design, availability and maintenance of equipment
Organisational & Management Factors	Organisational structure Financial resources and constraints Policy, standards and goals Quality & Safety culture and priorities
Institutional Context Factors	Economic and regulatory context National health service executive Links with external organisations

Appendix F Patient Observation Scores

Page
1/5

Date	21-Oct-2012	21-Oct-2012	21-Oct-2012	22-Oct-2012	22-Oct-2012	22-Oct-2012	22-Oct-2012	22-Oct-2012	22-Oct-2012	22-Oct-2012	22-Oct-2012
Time	09.35	17.00	22.00	00.30	03.30-	06.00	06.50	08.30	11.00	15.25	18.00
RESP (write rate in box)	= or > 30										
	21 - 29										
	09 - 20	--	--	--			18	18		18	--
	0 - 08										
O2 Saturation	95 - 100%						99%	98%		97%	97%
	<95%										
O2 %											
Temp	= or >38										
	37.5 - 37.9										
	36 - 37.4	36.8	36.4	36.6			37	36.8		36.8	37.1
	< or = 35.9										
Maternal Heart Rate	= or >120										
	100 - 119										102
	50 - 99	82	90	--			92	92		98	
	0 - 49										
Systolic Blood Pressure	= or > 160										
	140 - 159										
	100 - 139	113	114	100			104	100		94	98
	90 - 99										
	0 - 89										
Diastolic Blood Pressure	= or >100										
	80 - 99										
	50 - 79	73	72	60			66	60		60	62
	0 - 49										
MAP < 50 > 125											
Proteinuria 0											
Proteinuria Trace - 1 - 2 +											
Proteinuria 3 - 4 +											
Sedation Score	Awake/normal sleep					ANXIOUS					
	Drowsy										
	Very Drowsy/unresponsive										
Pain Score	7 - 10										
	4 - 6	Lower back pain radiating	Pain tenderness	Abdominal pain							
	0 - 3				No pain		NO	Easier	NO	--	--
Urine passed	Yes ✓	Nad frequency						✓			✓
(Fluid Balance chart necessary?)	No ✓	No dysuria									
Vaginal Loss	Heavy/					MODERATE	CLOTS			Large	
	Normal	No			SROM	Pinkish	Minimal		SROM	Moderate	

(Please note: The observation scores in appendix D, pages 88-93 were based on observations noted in the patient's observations chart and clinical notes by staff in the hospital. The observations by staff were transposed by the investigation team for 50278 onto the Hospital's (modified) Obstetric Early Warning Score Chart that was not in use for pregnant patients on the gynecology ward at the time of this incident). This is not a copy of a chart that formed part of this patients medical records.

	Date	22- Oct - 2012						23- Oct - 2012	23- Oct - 2012
	Time	21.40						06.00	08.20
RESP (write rate in box)	= or > 30								
	21 - 29								
	09 - 20	18					18		
	0 - 08								
O2 Saturations	95 - 100%	98%					97%		
	<95%								
O2 %									
Temp	= or >38								
	37.5 - 37.9								
	36 - 37.4	37					37	37.1	
	< or = 35.9								
Maternal Heart Rate	= or >120								
	100 - 119	102							
	50 - 99						84	84	
	0 - 49								
Systolic Blood Pressure	= or > 160								
	140 - 159								
	100 - 139	110							
	90 - 99						96		
	0 - 89								
Diastolic Blood Pressure	= or >100								
	80 - 99								
	50 - 79	62					54		
	0 - 49								
MAP	< 50 > 125								
Proteinuria	0								
Proteinuria	Trace - 1 - 2 +								
Proteinuria	3 - 4 +								
Sedation Score	Awake/ normal sleep								
	Drowsy								
	Very Drowsy/ unresponsive								
Pain Score	7 - 10								
	4 - 6								
	0 - 3	No pain					No pain	No pain	
Urine passed	Yes ✓	--							
(Fluid Balance chart necessary?)	No ✓	--							
Vaginal Loss	Heavy/ Offensive								
	Normal						Minimal	SROM	

	Date	23-Oct - 2012	23-Oct - 2012	23-Oct - 2012	23-Oct - 2012	24-Oct - 2012	24-Oct - 2012	24-Oct - 2012	24-Oct - 2012	24-Oct - 2012	24-Oct - 2012	24-Oct - 2012
	Time	08.35	14.45	19.00	21.00	04.15	05.00	06.30	06.45	06.55	07.00	Chart?
RESP (write rate in box)	= or > 30											
	21 - 29											
	09 - 20	--	18	--	18	--	--	--	18	16	18	
	0 - 08											
O2 Saturations	95 - 100%	99%	97%	99%	98%			97%	97%	99%	99%	
	<95%											
O2 %								O2	O2 40%	O2		
Temp	= or >38							39.6				39.6
	37.5 - 37.9					37.7	37.5				37.9	
	36 - 37.4	36.6	37	36.6	36.8							
	< or = 35.9											
Maternal Heart Rate	= or >120							160	166	144	158	160
	100 - 119		100	114								
	50 - 99	84										
	0 - 49											
Systolic Blood Pressure	= or > 160											
	140 - 159											
	100 - 139		106	108	106				130	110	108	
	90 - 99	98						94				
	0 - 89											
Diastolic Blood Pressure	= or >100											
	80 - 99											
	50 - 79	64	74	66	60			55	74	64	64	
	0 - 49											
MAP < 50 > 125												
Proteinuria 0												
Proteinuria Trace - 1 - 2 +												
Proteinuria 3 - 4 +												
Sedation Score	Awake/normal sleep					COLD SHIVERY		WEAK				
	Drowsy											
	Very Drowsy/unresponsive											
Pain Score	7 - 10											
	4 - 6							Body aches				
	0 - 3		No pain		No pain							
Urine passed	Yes ✓		✓									
(Fluid Balance chart necessary?)	No ✓											
Vaginal Loss	Heavy/Offensive				Minimal brown pv loss on pad						Foul Brown	
	Normal	SROM	SROM	SROM			SROM	SROM	SROM	SROM	SROM	SROM

	Date	24- Oct - 2012	24- Oct - 2012	24- Oct - 2012	24- Oct - 2012	24- Oct - 2012	24- Oct - 2012	24- Oct - 2012				
	Time	07.20	07.30	07.50	08.25	08.50	10.00	10.30	12MD	12.50	13.00	13.15
RESP (write rate in box)	= or > 30											
	21 - 29											
	09 - 20	20	--	18	--	--	18	--	18			
	0 - 08											
O2 Saturations	95 - 100%	98%	99%	100%			99%		98%	99%	98%	
	<95%											
O2 %	40%	O2	O2	O2	O2	O2	O2	O2	O2	O2	O2	
Temp	= or >38											
	37.5 - 37.9		37.9	37.9	37.9							
	36 - 37.4					37.2	37.4	37	37	37		
	< or = 35.9											
Maternal Heart Rate	= or >120	164	154	140	144	150		150	142	156	144	156
	100 - 119											
	50 - 99											
	0 - 49											
Systolic Blood Pressure	= or > 160											
	140 - 159											
	100 - 139											
	90 - 99	98	98	98		98						
	0 - 89						88	84	74	72	78	80
Diastolic Blood Pressure	= or >100											
	80 - 99											
	50 - 79	60	54	54		66	50	50				
	0 - 49								44	40	42	46
MAP < 50 > 125												
Proteinuria 0												
Proteinuria Trace - 1 - 2 +												
Proteinuria 3 - 4 +												
Sedation Score	Awake/ normal sleep											
	Drowsy											
	Very Drowsy/ unresponsive					COLD ACHES HVS ⁹⁵						
Pain Score	7 - 10					Abdominal	Back pain					
	4 - 6											Back
	0 - 3	No abdomin										Pain
Urine passed	Yes ✓						MSU HVS sent					
(Fluid Balance chart necessary?)	No ✓											
Vaginal Loss	Heavy/ Offensive											
	Normal	SROM	SROM	SROM	PSROM	SROM	SROM	SROM	PSROM	PSROM	PSROM	PSROM

⁹⁵ HVS stands for High Vaginal Swab

Date	24- Oct - 2012	24- Oct - 2012	24- Oct - 2012	24- Oct - 2012	24- Oct - 2012	24- Oct - 2012	24- Oct - 2012	24- Oct - 2012	24- Oct - 2012	24- Oct - 2012
Time	13.45	13.50	14.00	14.15	14.30	14.50	15.00	15.10	16.00	16-20
RESP (write rate in box)	= or > 30									
	21 - 29					26	26	26	26	
	09 - 20				20					
	0 - 08									
O2 Saturations	95 - 100%					100%		100%		
	<95%									
O2 %	40%					O2		O2		
Temp	= or >38									
	37.5 - 37.9									
	36 - 37.4	37.2						37.3		
	< or = 35.9									
Maternal Heart Rate	= or >120	144	152	144	144	142	146	144		
	100 - 119									
	50 - 99									
	0 - 49									
Systolic Blood Pressure	= or > 160									
	140 - 159									
	100 - 139									
	90 - 99									
	0 - 89	68	65	74	70	80	80	68	80	80
Diastolic Blood Pressure	= or >100									
	80 - 99									
	50 - 79					50	50	50		
	0 - 49	34	30	40	40				40	40
MAP < 50 > 125										
Proteinuria 0										
Proteinuria Trace - 1 - 2 +										
Proteinuria 3 - 4 +										
Sedation Score	Awake/ normal sleep									
	Drowsy									
	Very Drowsy/ unresponsive									
Pain Score	7 - 10									
	4 - 6	Back pain	Back pain					Abdomen mildly		
	0 - 3									
Urine passed	Yes ✓									
(Fluid Balance chart necessary?)	No ✓									
Vaginal Loss	Heavy/ Offensive									
	Normal	PSROM	SROM	PSROM	PSROM	PSROM	SROM	SROM	PSROM	