



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

In confidence

REPORT

into the circumstances pertaining to the death of
Mrs Tania McCabe and her infant son Zach
at Our Lady of Lourdes Hospital, Drogheda
on Friday 9 March, 2007

EXECUTIVE SUMMARY



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

FOREWORD

The Review Team would like to extend our sympathy to Aidan and family on the tragic and untimely loss of Tania and their son Zach, RIP. Their forbearance and support at a time of inestimable loss has been humbling.



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

GLOSSARY OF TERMS

AmniSure®:	A bedside antigen/antibody test used to detect placental Alpha Microglobulin-1, a protein present in amniotic fluid.
BLS:	Basic Life Support
CEMACH:	Confidential Enquiry into Maternal and Child Health.
ICSI:	Intensive Care Society of Ireland
HSE:	Health Service Executive
HSE-DNE:	Health Service Executive Dublin North-East
RCOG:	Royal College of Obstetricians and Gynaecologists



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

1. EXECUTIVE SUMMARY

1.1 The Review Team was commissioned by the Hospital Network Manager HSE NE to examine the circumstances pertaining to the death of Mrs Tania McCabe and her son Zach at Our Lady of Lourdes Hospital, Drogheda on Friday 9 March, 2007. The review focussed on the clinical management of both Tania and Zach and also examined to what extent non clinical factors may have influenced the care she received.

1.2 Terms of Reference and Review Team Members

Terms of Reference in respect of the review into the death of Mrs Tania McCabe were:

- To examine the circumstances pertaining to the death of Mrs Tania McCabe and her infant son Zach at our Lady of Lourdes Hospital, Drogheda on Friday 9 March, 2007
- The scope of the review was to cover the period commencing with Mrs McCabe's first antenatal specialist consultation on 24 November, 2006 to her death at 06:05 hrs on 9 March, 2007.
- The Review Team members were;
 - Dr Seosamh Ó Coigligh, Consultant Obstetrician, (Chairperson)
 - Dr Rory Page, Consultant Anaesthetist, Cavan General Hospital
 - Ms Patricia Hughes, Director of Midwifery & Nursing, Coombe Women & Infants University Hospital
 - Mr Gerry Clerkin, HSE NE Risk Advisor
- The Review Team was to focus on the clinical management of Mrs McCabe and also examine to what extent non-clinical factors may have influenced the care received by Mrs McCabe.
- The Review Team was to examine protocols and procedures relevant to this incident taking into account prevailing standards of best practice.
- The Review Team was to access any additional specialist expertise which they deemed necessary i.e., Consultant Neonatologist
- The Review Team was to adopt a systems based approach utilising recognised risk management review frameworks and prepare a written report



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

for the Hospital Network Manager HSE NE to include such recommendations as it saw fit.

- 1.3 In this part of the world a maternal death is such an uncommon event that it seems an anachronism - something that just doesn't happen anymore. While huge advances have been made in the last 50 years or so, maternal deaths do still occur. Between 2000 and 2002 there were in the order of 10 maternal deaths in Ireland (CSO 2001 & 2002), giving a rate of about 5.8 per 100,000 live births. There were 261 maternal deaths in the UK during the same period. The maternal mortality rate in the UK over this time was 13.1 per 100,000 live births. (Confidential Enquiry into Maternal and Child Health 2004).
- 1.4 There is no doubt that this incident was a catastrophic and tragic event. In the space of a few hours Tania's husband Aidan, lost his wife and son during what should have been a time of joy. We can only try to imagine the effect that this has had on him and their family.
- 1.5 The healthcare workers have undergone a huge trauma and suffer from feelings of guilt and personal responsibility.
- 1.6 The thrust of this investigation is to identify learning for the service so as to assist in the prevention of future possible tragedies and to improve the quality of care. It was also to provide the answers required by Tania's family. The most important outcome following any adverse event and review is the process that promotes understanding to ensure that the organisation learns from the events and prevents recurrence.
- 1.7 The overwhelming majority of incidents that occur in healthcare are not caused by malicious intent or even by lack of competence on the part of the individual delivering care. The basic premise in the system approach is that humans are fallible and errors are to be expected, even in the best organisations (Reason 2000). The Review Team decided not to name the staff in this report in order to ensure that the focus of attention is directed on improvement. The actions of individuals are viewed within the context of the systems and processes that were in operation at the time of the incident.
- 1.8 The Review Team considered it necessary to group the contributing factors within a pre-defined classification framework. The National Patient Safety Agency UK (NPSA) (2004) developed its own contributing factors classification system which was based on the Vincent *et al* (1998) contributory factors framework. The NPSA classification framework includes the primary factors as:
 - Patient Factors



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

- Communication Factors (Verbal, Written or non-Verbal)
- Individual Factors
- Team Factors
- Task Factors
- Organisational Factors
- Equipment & Resource Factors
- Educational & Training Factors
- Working Environment

1.9 The findings and recommendations of the Review Team result from using this methodology to analyse information from the following:

1. Written evidence including relevant medical records, copies of policies and protocols and other information requested by the Review Team and provided to us by the Hospital
2. Personal interviews with Tania's husband Aidan and her mother, Barbara.
3. Consideration of relevant clinical guidelines and supporting literature, specialist advice from independent Consultants in Microbiology, Haematology, etc.
4. Individual interviews with 31 staff who were either directly or indirectly involved in the management of Tania's care and 5 other external experts.

1.10 The Review Team placed a high reliance on the contemporaneous accounts and records. The interviews with the family and staff concentrated on clarifying areas of uncertainty and drawing out explanations for decisions made during this episode of care.



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

1.11 **Key Findings**

The Review Team conclude that Tania died from sepsis with haemorrhage as a complicating factor. Zach had severe congenital abnormalities, consistent with otocephaly, a rare and potentially fatal condition not always readily diagnosable antenatally. Zach's death was an inevitable consequence of his congenital abnormalities.

1.12 The Review Team has identified two Care Management Problems which were:

- (a) **A working diagnosis of ruptured membranes was not made during Tania's first admission to hospital.**
- (b) **Septic shock was not recognised / diagnosed following her second admission and caesarean section.**

1. Retrospectively, the Review Team conclude that Tania's membranes had ruptured by 05:00 hrs on the 7 March 2007. Despite the use of appropriate examinations and tests, this was not the working diagnosis at the time of discharge from hospital. The diagnosis of ruptured membranes can be difficult to establish. Gaps in communication and an over-reliance on tests contributed to missing the diagnosis. It is unlikely that Tania would have been discharged home if ruptured membranes had been diagnosed.
2. Within hours of her second admission Tania became critically ill warranting in the first instance high dependency level care. This rapid deterioration was due to sepsis and occurred despite appropriate antibiotic therapy. The early warning signs of impending collapse largely went unrecognised. The absence of clear guidelines regarding required observations and reactions and the lack of a structured format for recording vital signs contributed to the delayed medical intervention.
3. Maternity Services at Our Lady of Lourdes Hospital have been under increasing pressure, with a significant increase in activity. This has resulted in the Maternity, Paediatric and Anaesthetic services being significantly under-resourced to cope with the current demands. This had an impact on Tania's care, with staff working long hours while carrying an excessive workload. Despite the good intentions of staff who were working in very difficult conditions, their practice and ultimately the care that they provided to Tania were compromised by their workload and the environment in which they were working.



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

- 1.13 The Review Team analysed this incident using the Incident Decision Tree (NPSA, 2004). Based on this the Review Team are satisfied that it was a system failure that led to Tania's death.



1.14 Summary of Recommendations

The summary of recommendations are listed in order of priority and are categorized by the terms High, Medium, Low. The purpose of this is to highlight the recommendations that require immediate, medium and long term actions, which is a reflection of their achievability.

No.	RECOMMENDATION	RATING	REFERENCE No.
1.	The hospital should invest in a physiological observation track and trigger system that promotes the early recognition of patient deterioration and appropriate intervention. This should be adopted hospital wide with the necessary adaptations for maternity.	High	Communication Factors - written (Ref. Para. 8.5)
2.	The immediate care a patient receives must be dictated by their needs and this should commence upon the recognition of their estimated required ICSI Level of Care. The HSE should embrace this approach and ensure adequate training and resources to support this new concept.	High	Patient Factors (Ref. Para. 7.20)
3.	All maternity units should ensure a structured approach to the care of their critically ill patients. This starts with their recognition, categorisation of Level of Care, team response, stabilisation and transfer to an appropriately resourced area. We strongly recommend that the ICSI and the Institute of Obstetricians & Gynaecologists should formulate a strategy for the care of the critically ill woman in pregnancy for all hospitals in Ireland.	High	Task Factors (Ref. Para. 11.10)
4.	The lead clinician should be clearly identified for the care of each patient and part of that clinician's responsibility is to ensure there are clear instructions on observations, goals and appropriate responses for the case midwife/nurse and medical team. This is particularly	High	Communication Factors – Verbal (Ref. Para. 8.14)



	essential for the “patient at risk”. The case midwife/nurse should ensure that he/she has a clear care plan which is within his/her scope of practice.		
5.	The primary consultant and his/her team should ensure timely follow up of all tests ordered.	High	Patient Factors (Ref. Para. 7.13)
6.	The unit should develop a guideline/policy for the diagnosis and management of ruptured membranes which is consistent with current RCOG recommendations. This needs to address the governance of the use of AmniSure® a) The use of AmniSure® should be restricted to medical and midwifery staff who have completed validated training in its use. b) The unit’s governance should encompass the introduction of all point of care tests and equipment.	High	Equipment & Resource Factors (Ref. Para. 13.5)
7.	Verbal information should be supported by documentary advice when patients are allowed home with suspected or confirmed ruptured membranes. This approach should be considered for other relevant conditions.	High	Patient Factors (Ref. Para. 7.10)
8.	The Review Team recommends that the HSE in conjunction with the Clinical Networks’ advice would seek to urgently upgrade the medical and midwifery staffing commensurate with the recommendations from Safer Childbirth (2007).	High	Organisational Factors (Ref. Para. 12.6)
9.	The HSE must streamline its processes in order to respond effectively to ensure safe staffing levels in known critical areas. Hospitals should have a programme of continual assessment of staffing levels, skill	High	Organisational Factors (Ref. Para. 12.17)



	<p>mix and workload and the HSE should strive to achieve flexibility and reduce response time to resource issues so as to effectively support frontline staff. Consideration should be given to a national annual system of appraisal of stress in frontline clinical staff to allow early corrective factors to be put in place.</p>		
10.	<p>The HSE should adopt the international Surviving Sepsis Campaign which encompasses awareness, early recognition and standardized treatments of sepsis. This would encourage the implementation of these standards nationally.</p>	High	<p>Patient Factors (Ref. Para. 7.23)</p>
11.	<p>There is a need for the anaesthesia department to review urgently its current mission in providing safe patient care within the resources allocated. This exercise which needs to be done in conjunction with the hospital management, should encompass clinical and administrative workloads, both current and projected.</p>	High	<p>Individual Factors (Ref. Para. 9.3)</p>
12.	<p>The HSE in conjunction with professional bodies should urgently develop a consistent and professional methodology for investigating and managing serious adverse events. The Review Team support the inclusion of Irish information into the CEMACH (UK) process.</p>	High	<p>Team Factors (Ref. Para. 10.11)</p>
13.	<p>a) A realistic review of workload distribution within the obstetric department should be undertaken. Hospital managers should ensure through agreed practice plans that protected time is given to consultants for administrative duties. b) Other clinicians including midwifery / nursing managers should have their administrative time respected in keeping</p>	High	<p>Organisational Factors (Ref. Para. 12.20)</p>



	with Safer Childbirth (2007). c) Appropriate administrative and clerical support should be put in place to support clinicians in management roles.		
14.	The assistance of a clinical haematologist should be sought at an early stage when dealing with coagulopathies.	High	Team Factors (Ref. Para. 10.5)
15.	The ward round needs to be recognised as the primary mechanism for direct multidisciplinary communication and the Review Team recommend that the case midwife should be directly involved in it.	High	Communication Factors – verbal (Ref. Para. 8.10)
16.	Initiation of pharmaceutical therapy should be based on direct review of the patient. The administration of any drug should be on the basis of a written prescription unless <i>in extremis</i> .	Medium	Task Factors (Ref. Para. 11.12)
17.	The process of delivery of blood products from the hospital laboratory to theatre and other critical areas should be reviewed to ensure expeditious delivery. This should be done in consultation with the Health & Safety Coordinator.	Medium	Work Environment Factors (Ref. Para. 15.3)
18.	There should be an agreed standard for estimating total blood loss leading to an agreed single measurement.	Medium	Communication Factors - written (Ref. Para. 8.7)
19.	The patient record and communication systems should be reviewed to ensure that all the processes are streamlined and that all documentation complies with minimum standards. (An Bord Altranais 2002 and NHO 2007).	Medium	Communication Factors- written (Ref. Para. 8.3)
20.	A process of ratification and review of guidelines and an audit of compliance should be put in place.	Medium	Task Factors (Ref. Para. 11.2)



21.	<p>a) The BLS certification should be mandatory for all who are in direct contact with patients. Consideration should be given by the HSE and professional training bodies to also making advanced life support courses mandatory. The skills gained from these courses should be supported by regular drills and targeted at staff in all critical areas.</p> <p>b) All newly appointed midwifery and nursing managers should complete training in management, ideally prior to taking up their post or within two years of commencement of their post. There should be a system of review of the training needs in relation to management competencies of all existing midwifery and nursing managers.</p> <p>c) On a national basis, induction for non consultant hospital doctors should take place as soon as possible after doctors take up duty.</p> <p>Attendance should be mandatory for all new doctors and attendance records maintained.</p> <p>Elective activity in hospitals should be suspended for the duration of the induction programme to facilitate mandatory attendance at the programme.</p> <p>In addition to general induction, clinical departments should arrange an induction programme specific to the speciality.</p>	Medium	<p>Education & Training Factors</p> <p>(Ref. Para 14.6)</p>
22.	<p>A Consultant Medical Microbiologist should be appointed to the Hospital.</p>	Medium	<p>Organisational Factors</p> <p>(Ref. Para. 12.27)</p>



23.	NCHD involvement in private patient care needs to be examined and roles and responsibilities must be clearly defined.	Medium	Task Factors (Ref. Para. 11.5)
24.	An agreed common baseline level of antenatal care such as is outlined in the NICE Guidelines (National Collaborating Centre for Women's and Children's Health 2003) should be adhered to.	Low	Patient Factors (Ref. Para. 7.4)
25.	The inclusion of maternal heart rate in the baseline antenatal physiological data recorded at booking should be considered. This would support the introduction of physiological observation, track and trigger type programmes in obstetric practice.	Low	Patient Factors (Ref. Para. 7.17)
26.	The Review Team recommend the setting up of a regional audit department responsible for audit education, administration and implementation in the region.	Low	Organisational Factors (Ref. Para. 12.24)
27.	Consideration should be given to a national standard of management structures for hospitals.	Low	Organisational Factors (Ref. Para. 12.22)

The HSE's clinical governance framework should ensure that the recommendations of this report are implemented within an acceptable timeframe.



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Signatures of the Review Team

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