Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Investigation into the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration, including those provided in University Hospital Galway, and as reflected in the care and treatment provided to Savita Halappanavar

7 October 2013

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is the independent Authority established to drive continuous improvement in Ireland's health and personal social care services, monitor the safety and quality of these services and promote person-centred care for the benefit of the public.

The Authority's mandate to date extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

Setting Standards for Health and Social Services – Developing person-centred standards, based on evidence and best international practice, for those health and social care services in Ireland that by law are required to be regulated by the Authority.

Social Services Inspectorate – Registering and inspecting residential centres for dependent people and inspecting children detention schools, foster care services and child protection services.

Monitoring Healthcare Quality and Safety – Monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.

Health Technology Assessment – Ensuring the best outcome for people who use our health services and best use of resources by evaluating the clinical and cost effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.

Health Information – Advising on the efficient and secure collection and sharing of health information, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

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Executive Summary

1. Introduction and background

This Report presents the findings from the Health Information and Quality Authority's (the Authority or HIQA) investigation into the safety, quality and standards of services provided by the Health Service Executive (HSE)* to patients, including pregnant women, at risk of clinical deterioration, including those provided in University Hospital Galway (UHG), and as reflected in the care and treatment provided to Savita Halappanavar.

At the outset of this investigation the Authority and Investigation Team wish to convey their sympathies to the husband and wider family of Savita Halappanavar for their loss.

Savita Halappanavar died on Sunday 28 October 2012 at 01:09hrs, seven days after her admission to University Hospital Galway (UHG), where she was treated on St Monica's Ward, a gynaecology ward within the Women's and Children's Directorate of the Hospital. She was a 31-year-old woman who was 17 weeks pregnant and in her first pregnancy. On 14 November 2012, the Health Information and Quality Authority sought assurances from University Hospital Galway that the care that was provided to Savita Halappanavar was in line with the *National Standards for Safer Better Healthcare*. In addition, UHG was asked to provide assurances that there were effective controls in place to manage and mitigate similar risks to other patients. In response, UHG communicated to the Authority that the care provided to Savita Halappanavar was in line with the *National Standards for Safer Better Healthcare* and that there were appropriate controls in place to manage and mitigate similar risks to other patients.

The Authority also asked the HSE corporately whether it had controls in place to manage and mitigate risks to patients in receipt of obstetrics and gynaecology services provided on behalf of the HSE and details of how the HSE – as a service provider – was assured that those controls were effective. In response, the HSE outlined the quality processes and initiatives that were in place to support the ongoing provision of high quality and safe obstetrics and gynaecology care in Ireland and sources of assurance of the quality of that care being delivered.

The Authority undertook a a review of Hospital documentation, which had been requested by the Authority from UHG, and considered a letter received from the Director General Designate† of the HSE outlining his belief that there may have been circumstances which gave rise to a potential serious risk to the safety, quality

* The Department of Health has a responsibility to ensure that all references to the HSE in this Report are applicable to its successor organisation(s).

† In November 2012, the role of Director General Designate, HSE, was an acting position which was subsequently formalised as the role of Director General, HSE, in July 2013. For the purposes of this report, the role is referred to as the Director General HSE throughout the remainder of this report.

and standards of services provided such that it would be appropriate for HIQA to conduct an investigation. In the letter, the Director General requested HIQA to consider undertaking an investigation in accordance with 9(1)(a) of the Health Act 2007.

Having considered all of the available information, the Board of the Authority made the decision to instigate an investigation on 23 November 2012.

The Terms of Reference were approved by the Board of the Authority on 27 November 2012 and the Investigation Team was announced on 19 December 2012.

While this Report is not a specific investigation into Savita Halappanavar's case, her death was the seminal event that led to concerns regarding potential serious risks to the standards of some services provided within the Hospital and the need to seek assurances that such risks were not replicated in other similar services in the country.

In carrying out the investigation, the Authority looked in detail at the safety, quality and standards of services provided by the HSE at University Hospital Galway to patients, including pregnant women, at risk of clinical deterioration and as reflected in, among other things, the care and treatment provided to Savita Halappanavar. This included a review of Savita Halappanavar's pathway of care as documented in her healthcare records. This was described in the findings of the West Galway Coroner's inquest and in the findings outlined in the HSE incident investigation.

The investigation also considered the effectiveness of the HSE's role in planning and delivering maternity services nationally in the most beneficial, effective and efficient manner to improve, promote and protect the health and welfare of the public. This included consideration of the arrangements that the HSE had in place to ensure that the care provided in the public maternity services was compliant with the *National Standards for Safer Better Healthcare* and relevant national and international evidence. In addition, the Authority reviewed the arrangements that the HSE had in place to assure the delivery of high quality, safe and reliable maternity services.

In the interest of wider service improvement, where the Authority believes that there are national implications from the findings of this investigation and therefore national applicability across the Irish healthcare system, recommendations are made accordingly.

2. Profile of Galway and Roscommon University Hospitals Group

University Hospital Galway (UHG) and Merlin Park University Hospital, both located in Galway City, together operate as Galway University Hospitals (GUH). The maternity service is provided by UHG, which forms part of the Galway and

Roscommon University Hospitals Group. UHG has 664 beds in total: 558 inpatient beds and 106 day case beds, which includes adult and children's beds. There are 49 inpatient maternity beds. There was no day obstetric unit at the time of this investigation.

In 2012, 3,377 births were recorded at the Hospital. The antenatal ward and postnatal ward frequently had 100% bed occupancy and when these wards were full, antenatal and postnatal patients were accommodated on St Monica's Ward, the gynaecological ward where Savita Halappanavar was cared for. Consequently, the casemix of patients accommodated on St Monica's Ward and their care needs were significantly diverse. Prior to December 2012, in addition to accommodating inpatient and day patients, all patients who presented outside of core hours with a gynaecology or maternity emergency were directed to St Monica's Ward for assessment.

St Monica's Ward has 15 beds with four trolley spaces allocated for day cases, a clinical examination room and an ultrasound scan room.

3. Summary of Findings

3.1 Care provided to Savita Halappanavar

The Authority identified, through a review of Savita Halappanavar's healthcare record, a number of missed opportunities which, had they been identified and acted upon, may have potentially changed the outcome of her care. For example, following the rupture of her membranes, four-hourly observations including temperature, heart rate, respiration and blood pressure did not appear to have been carried out at the required intervals. At the various stages when these observations were carried out, the consultant obstetrician, non-consultant hospital doctors (NCHDs) and midwives/nurses caring for Savita Halappanavar did not appear to act in a timely way in response to the indications of her clinical deterioration.

In summary, of the care provided there was a:

- general lack of provision of basic, fundamental care, for example, not following up on blood tests as identified in the case of Savita Halappanavar
- failure to recognise that Savita Halappanavar was at risk of clinical deterioration
- failure to act or escalate concerns to an appropriately qualified clinician when Savita Halappanavar was showing the signs of clinical deterioration.

The consultant, non-consultant hospital doctors (NCHDs) and midwifery/nursing staff were responsible and accountable for ensuring that Savita Halappanavar received the right care at the right time. However, this did not happen.

The most senior clinical decision maker involved in the provision of care to Savita Halappanavar at any given time should have been suitably clinically experienced and competent to interpret clinical findings and act accordingly. Ultimate clinical accountability rested with the consultant obstetrician who was leading Savita Halappanavar's care.

In addition, the clinical governance arrangements within the Hospital failed to recognise that vital Hospital policies were not in use nor were arrangements in place to ensure the provision of basic patient care on St Monica's Ward. These included guidelines relating to the observation of obstetric patients through the use of a maternal early warning score chart and the management of sepsis and pre-term pre-labour rupture of membranes. Furthermore, the healthcare medical record documentation of Savita Halappanavar's care lacked detail in relation to her clinical status and the potential risk of clinical deterioration at identified times throughout her care pathway.

3.2 The clinically deteriorating pregnant patient

The most basic means of identifying any patient at risk of clinical deterioration is to observe the patient's general condition and regularly monitor and track their clinical observations. This should be a basic component of caring for any patient.

Clinical observations include measuring blood pressure, heart rate, temperature, rate of respiration, oxygen saturation*, level of consciousness and urinary output. The use of an early warning score to record these observations is known to assist in achieving the best outcomes for the identification and management of a patient who is clinically deteriorating. The Authority found that UHG had developed a local Modified Obstetric Early Warning Score (MOEWS) chart and accompanying guidance in 2009. However, this investigation found that this chart or the accompanying guidance was not in use on St Monica's Ward in October 2012.

An early warning score is a valuable tool to support decision making. Timely and effective care and treatment depends on regular monitoring and recording of a patient's clinical observations, recognising their significance, communicating and escalating concerns, to include consultation to and by a senior clinical decision maker, about abnormal observations and the triggering of appropriate emergency responses. The Authority found at the time of the investigation that there was no formal clinical escalation protocol and no emergency response team in place at the UHG.

The Hospital had a guideline in place for the management of 'Suspected sepsis and sepsis in obstetric care'. However, the clinical governance arrangements were not robust enough to ensure adherence to this guideline. In addition, clinical staff had not received specific sepsis training in relation to the application of this policy and/or the specific management of a maternity patient with sepsis. The Hospital

* Oxygen saturation is a measure of how much oxygen the blood is carrying as a percentage of the maximum it could carry. It is measured by a small sensor which is placed over the patient's fingertip.

did not have in place effective arrangements to ensure that patient care was documented or that those caring for patients were fully informed of a patient's condition and treatment plan. The arrangements for the handover of patient care between the maternity clinical teams were not always effective and were not in line with best available evidence.

3.3 The maternity services at University Hospital Galway

The Investigation Team reviewed the patient pathway for pregnant women, both booked and unbooked*, attending the Hospital as an emergency during core hours (the working hours of 9am to 5pm, Monday to Friday) and outside of core hours to determine the access arrangements that were in place.

The Authority found that the care pathway for patients who required access during core hours to maternity services, including access to ultrasound, was not always timely or appropriate. Best practice guidelines for antenatal care recommend that all antenatal patients should be seen at 10 weeks and have an ultrasound scan carried out to determine gestational age and detect multiple pregnancies between 10 and 14 weeks' gestation. The Authority was unable to clarify if antenatal patients were receiving timely access to maternity services in line with best available evidence. In addition, there was no formal clinical pathway in place to refer high risk obstetric patients to an antenatal high risk service operated by an obstetric anaesthetist at the time of the investigation.

The care pathway for patients who required emergency access to maternity services outside of core hours – including access to assessment in the Emergency Department, ultrasound, and clinical examination – was not always appropriate and effective. In September 2012, the Women's and Children's Directorate in the Hospital identified risks to patients who presented out of hours to St Monica's Ward and proposed that all such patients were seen and triaged in the Emergency Department. The Authority was concerned that discussions between clinical teams in relation to such a patient-centred risk were ongoing over a prolonged period of time and remained a live issue under review for the duration of the investigation.

Patient healthcare records were not managed in line with the HSE's Standards and Recommended Practices for Healthcare Records Management. The National Maternity Healthcare Record was not in use in UHG and maternity patients did not carry their own healthcare records. In addition, there was evidence of a number of retrospective entries of information in the case of Savita Halappanavar, where notes were entered two weeks following her death.

* The term 'booked pregnant women' is used to describe pregnant women who have attended their first antenatal appointment, while the term 'unbooked pregnant women' is used to refer to pregnant women who have not attended their first antenatal appointment, as reflected in documentation received from University Hospital Galway.

The labour ward is a critical location for the pregnant patient and best practice is that patients being cared for in the labour ward have direct supervision and care by consultant obstetric staff with 24-hours seven-days-a-week senior midwifery cover. The Authority found that consultants on call for the labour ward were not present on the labour ward but, rather, engaged in other clinical activities. This is at variance with national and international best evidence.

In addition, the Authority found that that there were no guidelines or clear pathway of referral to ensure that patients were seen by a senior clinical decision maker in a timely manner. The Investigation Team found that St Monica's Ward was used as the overflow to accommodate antenatal and postnatal patients when the antenatal ward and the postnatal ward were full. St Monica's Ward also accommodated unscheduled presentations, out-of-hours, of patients with gynaecological and obstetric emergencies. Consequently, the casemix of patients accommodated on St Monica's Ward and their care needs were significantly diverse and complex. However, there was no evidence that the organisation of the workforce took account of the complexity and diversity of the patient casemix on St Monica's Ward.

3.4 The clinically deteriorating general adult patient

The National Early Warning Score (NEWS) and the ISBAR (Identify yourself; Situation; Background; Assessment; Recommendation) communication tool were introduced to all general adult areas in UHG on 5 November 2012. At the time of the investigation, approximately 1,200 staff had received training in the use of NEWS. This included approximately 50% of non-consultant hospital doctors (NCHDs) and only 23-27% of UHG consultant staff. The Authority was significantly concerned about the lack of involvement of key consultant staff, who hold ultimate clinical responsibility for the effectiveness of patient care, in the NEWS project. The Authority found that the clinical governance arrangements were not effective in the context of patient safety and quality systems, the development and implementation of hospital guidelines and the robustness of multidisciplinary working arrangements.

The Hospital reported that 167 maternity and non-maternity patients in total required ICU care as a result of sepsis in 2011 and 139 patients in 2012. The Hospital also reported that 70 patients required High Dependency Unit (HDU) care as a result of sepsis in 2011, while 89 general patients required such care in 2012. Despite this, the Authority found that at the time of the investigation, the Hospital did not have a hospital-wide guideline in place for the management of sepsis in adult patients. Furthermore, it found that there was no consistent definition of sepsis, severe sepsis and septic shock in use across UHG.

3.5 Governance of Galway and Roscommon University Hospitals Group and University Hospital Galway

Galway University Hospitals (incorporating Merlin Park University Hospital and University Hospital Galway), together with Portiuncula Hospital in Ballinasloe and Roscommon General Hospital were combined into one hospital group in January 2012, on an administrative, non-statutory basis. The Group has one overall group management team, one financial budget and one whole-time equivalent (WTE) ceiling. The new Chief Executive took up post in January, 2012 and a programme to establish the change in governance arrangements was commenced.

In June 2012, in line with the Government's health reform programme, and as a step in the move towards the formation of hospital trusts and the proposed governance arrangements, the Minister for Health appointed a Chairperson to the Group.

UHG provided the Investigation Team with the Corporate and Clinical Governance Framework for the Hospital Group. This included terms of reference for the Hospital Group's Board of Directors.

At the time of Savita Halappanavar's death, the Board was not in place. The first meeting of the Interim Board of Directors took place in February 2013. As part of the investigation the Authority examined the governance arrangements and structures that had evolved in the months following her death.

The terms of reference of the Hospital Group's Board of Directors identifies that the strategies and policies developed by the Board of Directors are consistent with the standards developed by HIQA and the Department of Health. The composition of the Board, as identified in the terms of reference, includes 11 directors. These directors include the Chairperson, six non-executive directors (external and independent of the Hospital Group) and four executive directors (who hold posts within the Hospital Group). The non-executive directors are selected and appointed through an independent selection process on the basis of having the necessary skills, experience and competencies required to fulfil the role effectively. The term of their appointment is up to a maximum of three years. The remaining four directors are executive directors and comprise the Hospital Group's Chief Executive, Chief Financial Officer, Clinical Director and Director of Nursing and Midwifery, with the Group's Chief Financial Officer acting as the Board Secretary.

The appointment by the Chairperson of the four executive directors is not in line with the Authority's recommendations in its 2012 investigation report into the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (Tallaght Hospital), adopted by the Department of Health. In September 2013, the Director General of the HSE advised the Authority that the members of the Board were appointed in line with extant arrangements. The terms of reference of

the Group Board as of September 2013 indicated that the structure of the Board composition had not been redefined to reflect this alignment. It is important that the HSE, in conjunction with the Hospital Group and its Board, convey jointly clarity on the composition of the Hospital Group Board, in line with the recommendations of the Authority's Tallaght Hospital report*.

The Investigation Team reviewed the governance arrangements at Galway and Roscommon University Hospitals Group, where, since the inception of the Group on 9 January 2012, a significant reorganisation of its corporate and clinical governance structure and quality assurance processes had been undertaken. This reorganisation placed the clinical directorate structure at the heart of the organisation, with one of its key priorities being to improve the quality of care provided.

While acknowledging the work that has been undertaken by the Hospital Group to establish these governance arrangements and assurance mechanisms, the Authority is concerned at the complexity of these structures and the large numbers of committees in place, with a number of these involving the same members, many of whom also have full-time clinical responsibilities. While the Authority is aware of the dependency of the Group's corporate and clinical governance committees on the involvement of these clinical staff, it will be important that robust arrangements are in place to ensure sustainability of this level of contribution while also ensuring that the provision of their clinical services is not compromised.

It is equally important that all clinical leaders are supported in developing the composite management and leadership competencies to undertake these roles within the respective clinical directorates.

Patients and members of the public are entitled to expect the highest level of healthcare. When the delivery of care falls below that level, they are entitled to ask why and be assured that measures have been taken to protect them and future patients from harm. The HSE, with the Hospital Group Board and Executive, has ultimate responsibility for the delivery of a safe, high quality service for patients. They must ensure that the recommendations of this investigation and the HSE incident investigation into the death of Savita Halappanavar are implemented. In addition, the Chief Executive of the Hospital Group, as the HSE delegated officer,

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* Boards should be of a sufficient size (up to a maximum of 12) and expertise to effectively govern the organisation. The board should be selected and appointed through an independent process established by the State and on the basis of having the necessary skills, experience and competencies required to fulfil the role effectively. The board should comprise non-executive directors and a chairperson and, in keeping with good governance, individuals with conflicts of interest, including employees of the hospital and those with other relevant conflicts of interest, should not be appointed to the board. The chief executive, and other designated executive officers (to include as a minimum, the equivalent of the director of finance, medical/lead clinical director and director of nursing) should be formally in attendance at the board with combined shared corporate accountability for the effective governance and management of the hospital.

In advance of such an independent process being established, the members of boards with the necessary knowledge, skills, competencies and experience should be appointed by the Minister for Health.

should consider the actions, omissions and practices of the professional's involved in the care of Savita Halappanavar, and make appropriate referral(s) to the relevant professional regulatory body/bodies.

3.6 Profile and national governance arrangements of maternity services

All pregnant women who are resident in Ireland are entitled to receive public maternity care under the 1954 Maternity and Infant Scheme. This care is provided by general practitioners (GPs) registered with the scheme and hospital obstetricians working within the public maternity services. At the time of this Report, this predominantly medical model of maternity care is one that has been in place for 59 years. At the time of the investigation, the HSE was the national agency accountable for the planning and delivery of health services including maternity services. Public and private maternity services are being provided in 19 maternity hospitals/units around the country. There is also one independent hospital, Mount Carmel Hospital, providing private maternity services in Dublin.

As part of the Government's health reform programme for the Irish health service, there were a number of changes to the governance arrangements of the HSE under way at the time of the investigation. These included the establishment of two Hospital Groups, the Galway Roscommon Hospital Group and the Mid-Western Regional Hospital Group.

In October 2012, the national responsibility for the delivery of maternity services by the HSE was delegated by the HSE's Director General to its National Director of Integrated Services, who in turn delegated this responsibility to the HSE's Regional Directors of Operations. However, in the case of the two Hospital Groups - the Mid-Western Regional Hospital Group and the Galway and Roscommon University Hospitals Group - responsibility was delegated to the Group Chief Executives. These Chief Executives subsequently reported to the HSE Director of Integrated Services in relation to operational delivery of services. It was reported that they also met with the HSE National Director of Quality and Patient Safety to discuss quality and risk matters.

In addition, the three stand-alone maternity hospitals in Dublin provide maternity services on behalf of the HSE through service level agreements and funding arrangements under section 38 of the Health Act 2004. Each of these three hospitals has a 'clinical master' who combines the role of senior clinician and chief executive and who reports directly to independent boards.

The role of the HSE's National Director of Quality and Patient Safety, as described at interview, was mainly focused on supporting and helping the services and investigating patient quality and safety events. However, it was reported at interview that there was no formal support structure in place nationally to support the escalation of risk within the services.

The Investigation Team also noted a wide variation in the local clinical and corporate governance arrangements in place across the 19 maternity hospitals/ units around the country. The Authority is of the opinion that, where such inconsistencies in governance structures exist, and given the Authority's concerns in relation to the lack of accessible, consistent and reproducible data relating to the quality of the various maternity services found during this investigation, it is impossible to assess the performance and quality of the maternity service nationally.

One further concern is the lack of evidence of any national review, or national population-based needs assessment, undertaken to demonstrate the appropriate allocation of resources, including multidisciplinary workforce arrangements, for the provision of maternity services in Ireland. The Investigation Team was also cognisant of the variation in models of maternity care with the predominance of consultant-led care. This included wide variation in the availability of obstetric beds to the number of births within hospitals. This raises questions as to the sustainability of the provision of maternity services in some areas. It was also noted that there were many areas where maternity service needs were not being fully met at the time of the investigation. This finding reinforces the Authority's concerns in relation to the inconsistency in the provision of maternity services in Ireland and the need to ensure that all pregnant women have appropriate access to the right level of care and support at any given time.

3.7 Workforce planning for maternity services

High quality maternity services rely on having an appropriate workforce with the leadership, skill-mix and competencies to provide proactive, excellent and safe care at the point of delivery.

There have been a number of national and international reports and recommendations in relation to maternity services that have explored the workforce requirements and arrangements for the delivery of safe care.

However, and as previously referred to, the Authority was unable to find evidence of any national review, or national population-based needs assessment, undertaken to demonstrate the appropriate allocation of resources, including multidisciplinary workforce arrangements, for the provision of maternity services in Ireland.

The Authority reviewed a published position paper produced by the HSE's Obstetrics and Gynaecology Clinical Care Programme on consultant workforce planning for obstetrics and gynaecology in the Republic of Ireland 2012-2022 (dated 2011). This position paper reported that there are a relatively low number of consultant obstetricians and gynaecologists in Ireland and that action should be taken to increase the numbers of trainees in the national system. The position paper further highlighted that failure to address this issue could potentially lead to serious adverse consequences for the provision of healthcare services in the medium and long term which could be associated with poorer outcomes for women and children.

At the end of 2012, the HSE reported that there were, in total, 126 consultant obstetricians and gynaecologists in Ireland. There is a small variation in the consultant-to-live-birth ratios in the existing four HSE regions. However, the report shows that the regions fall significantly short of the one consultant per 350 births recommended by The Future of Maternity and Gynaecology Services in Ireland 2006 – 2016 report as necessary for the provision of dedicated consultant cover on the labour ward for 40 hours per week, a figure supported by international evidence.

In respect of midwifery staff, the Authority reviewed a range of reports produced by, or on behalf of, the HSE. The HSE provided the Authority with five such reports that had been conducted either nationally or regionally between 2008 and 2012. Two of these were national reports regarding workforce planning for midwifery services.

The first report (2009) concluded that the role of the healthcare assistant should be part of any workforce planning or reconfiguration of the maternity services to enable midwives to realise their full potential in clinical practice.

The second report was conducted in early 2012 and was a review of the midwifery service workforce. The report highlighted that future analysis would need to take place after models of care for maternity services are agreed for implementation by the HSE. It was of concern to the Authority to note that, in subsequent information provided to the Investigation Team, there was limited connectivity between the HSE's National Clinical Care Programme for Obstetrics and Gynaecology and the HSE office responsible for nursing and midwifery services in respect of reviews of the midwifery service workforce – and therefore the development of overall models of maternity care.

Successive confidential enquiries into maternal deaths in the UK have stressed the importance of a dedicated obstetric anaesthesia service and the timely involvement of the anaesthetic team in the management of the sick obstetric patient. Obstetric anaesthetists play an important role in the maternity team: they are responsible not only for the provision of the epidural (a form of pain relief) service for women in labour but also the provision of anaesthesia for women who require Caesarean delivery and other theatre care. They are also required to assist with the resuscitation and care of pregnant women who become seriously ill as a result of haemorrhage (severe bleeding), pre-eclampsia* and other major complications.

National and international medical literature concludes that a duty anaesthetist should be immediately available for the delivery suite 24 hours-per-day and that there should be a clear line of communication from the duty anaesthetist to the supervising consultant at all times. The term 'duty anaesthetist' is defined as an anaesthetist who has been assessed as being competent to undertake the duties

* A medical condition pregnant women may develop resulting in high blood pressure and protein in the urine. This condition can lead to the development of eclampsia which may be life threatening.

of the delivery suite. If this duty anaesthetist has other responsibilities outside the delivery suite these should be of a nature that would allow the activity to be delayed or interrupted should obstetric analgesia (pain relief) or anaesthesia demands arise.

Recent professional guidelines published in 2013 state that there should be a nominated consultant in charge of the obstetric anaesthesia service and, as a basic minimum, there should be 12 consultant anaesthetist sessions allocated for every maternity unit. These guidelines also recommend that an agreed system for the antenatal assessment of high-risk mothers should be in place to ensure that the obstetric anaesthetist is given sufficient advance notice of all potential high-risk patients presenting.

The HSE must review its workforce arrangements for maternity services nationally to ensure maternity teams are made up of sufficient numbers of staff with the right mix of skills and deployed effectively both during core and on-call hours. This review should be conducted in line with advice from its Obstetrics and Gynecology Clinical Care Programme.

As a result of the findings of this investigation, the Authority is recommending that the HSE and Department of Health should, as a priority, conduct a review of the national maternity services and agree and implement standard, consistent models for the delivery of maternity services nationally in order to ensure that all pregnant women have access to the right level of safe care and support on a 24-hour basis. This review must establish the relevant corporate and clinical governance structures to ensure consistency in the provision of maternity services as they transition towards becoming a core component of Hospital trusts. The review should result in the development of a National Maternity Services Strategy that optimises and further develops the quality, safety and timeliness of the current maternity services so that these services are fit for purpose and in accordance with best available national and international evidence, for the future maternity services in Ireland.

3.8 Use of information

In order to provide assurances that pregnant women are receiving safe, high quality and reliable care during and after their pregnancy, maternity services must collect and analyse quality and safety performance measures to evaluate the performance of their clinicians and their service. These measures should be primarily focused on assessing quality and safety outcomes for patients.

The Lourdes Hospital Inquiry (into peripartum hysterectomy at Our Lady of Lourdes Hospital, Drogheda) in 2006 recommended that annual clinical reports of activity and clinical outcomes should be prepared and published within nine months of the previous year's end. During this investigation, the Authority found that eight of the 19 maternity units/hospitals do not produce any form of annual clinical report.

In addition, there are a number of data collection sources involved in the collection of maternal morbidity and mortality data in Ireland, including the National Perinatal Epidemiology Centre (NPEC) which provides the maternity services with a facility to undertake in-depth reviews of their own clinical practice, in particular in relation to severe maternal morbidity. The Authority is of the view that arrangements should be put in place nationally to build on the existing approaches to the collecting, analysing and reporting of maternal morbidity and mortality data at a local and national level, to improve coordination, consistency and integration of all approaches, including other national data collection sources, to inform service delivery, improve efficiencies within the service and ensure patient safety nationally.

Savita Halappanavar died as a result of sepsis which progressed to severe sepsis and eventually septic shock. The *Saving Mothers' Lives 2011* report (published in 2011) identified that mortality due to severe maternal sepsis was the leading cause of direct maternal death in the UK, and also that there are reported increases in maternal sepsis in Ireland. The Authority examined the evidence available for the recording of maternal morbidity related to sepsis nationally and found there was no nationally agreed definition of maternal sepsis, and that there were inconsistencies in recording and reporting of maternal sepsis.

At the time of the investigation, there was also no agreed national dataset of quality and safety measures for maternity services in Ireland and no consistent approach to reporting clinical outcomes. The Authority was significantly concerned about the absence of a national overview and structured assurance arrangements to monitor the safety and quality of maternity services in Ireland.

3.9 Antimicrobial surveillance

Gram-negative organisms are a large group of bacteria that can cause a wide range of infections in both community and hospital settings, including urinary tract infection, surgical wound infection and bloodstream infection. The Investigation Team reviewed the healthcare record of Savita Halappanavar which indicated that the results of blood tests had identified a particular strain of *Escherichia coli (E. coli)* called ESBL- (Extended-Spectrum Beta-Lactamase) producing *E. coli*. ESBL-producing *E. coli* are antibiotic resistant and consequently make the infections harder to treat.

Surveillance of infectious diseases in Ireland is coordinated by the Health Protection Surveillance Centre (HPSC) which monitors trends in relevant infectious diseases. However, the Authority identified significant gaps in relation to infectious disease epidemiology in Ireland, particularly for pathogens for which no national reference laboratory service currently exists. In addition, a national governance structure for microbiological reference laboratories was not in place.

The Authority found that there was no national laboratory-based alert system that enabled real-time analysis of data from local laboratory information systems, or

from other healthcare information systems (such as the national Computerised Infectious Disease Reporting [CIDR] system for notifiable infectious diseases) thereby facilitating timely recognition of emerging national microbial threats including antimicrobial resistance.

3.10 National incident management and learning

Healthcare will never be without risk. Therefore, sometimes things may go wrong for patients. This may happen despite the best efforts of staff providing the services. It is essential that health services at a national and local level ensure that there are robust arrangements in place to mitigate risk, and should an adverse event happen to a patient, that the services then investigate, analyse and learn from such incidents to prevent a recurrence.

In saying this, the Authority advises that organisations suitably balance the concept of (a) having an open and just culture that requires full disclosure of mistakes, errors, near misses and patient safety concerns, in order that system-based analysis can take place to identify learning against (b) the importance of holding to account those whose competencies and performance has fallen below what reasonably might be expected of them.

The Authority reviewed the national governance arrangements in place in relation to incident management. During the investigation, the Authority was unable to establish who had the overall accountability for, and governance of, the HSE's National Incident Management Team (NIMT). This national arrangement identified that there was potential for confused accountability in respect of the reporting, management and learning from national incidents. However, it was subsequently reported to the Authority in September 2013 that the HSE's National Director for Quality and Patient Safety has overall accountability for the NIMT.

The National Clinical Care Programmes are a joint initiative between the HSE and the Forum of Irish Postgraduate Medical Training Bodies with a shared objective of improving the quality of care that the HSE delivers to all patients and all users of HSE services. However, the HSE reported that each Clinical Care Programme has a strategic focus only and that the implementation of the Programme takes place through the HSE's Integrated Services Directorate. In addition, the HSE reported that it was not the responsibility of its National Clinical Care Programme Leads to respond to recommendations of national reviews and investigations. Therefore, it is imperative that the strategy for implementation of each Clinical Care Programme is aligned with the HSE's strategy for implementation of evidence-based recommendations of national investigations and reviews, as they relate to the objectives of each Clinical Care Programme and the quality and safety of HSE clinical services.

In looking at the process to ensure that there is national learning from national investigations and inquiries, the Authority reviewed the implementation status of the recommendations of the HSE inquiry into the death of Tania McCabe and

her infant son Zach at Our Lady of Lourdes Hospital in 2007. The HSE reported that these recommendations were implemented at a local HSE level with regional HSE oversight. On enquiry, the Authority noted with concern that only five of the 19 maternity hospitals/units were able to provide a detailed status update on the implementation of recommendations from the Tania McCabe report.

The lack of a nationally coordinated approach to the implementation of the recommendations of the HSE inquiry into the death of Tania McCabe, the lack of local governance arrangements to ensure that recommendations as applicable to their particular service are implemented, and the ambiguity regarding who has the overall ownership of and responsibility for implementing the National Clinical Care Programmes again raises a fundamental and worrying deficit in our health system. This is the inability to implement change and apply system-wide learning from adverse events across the system in a timely and appropriate manner, in order to prevent the recurrence of patient safety events that may cause harm, or worse, to future patients. This again emphasises the urgent need for 'ownership', accountability and responsibility within the health service's national and local structures for implementation of critically important recommendations made by various review bodies and organisations.

The Authority, in its Mallow Hospital report (2011), made a number of recommendations relating to the quality and safety of arrangements in place for the provision of critical care services both regionally and nationally. At the time of this investigation, the Authority was not assured by the HSE that these recommendations had been effectively implemented to include the maternity services. The Authority received evidence during 2013 that maternity hospitals/units were not routinely collecting and reporting information on the length of time that obstetric patients were waiting to be admitted to intensive care from the time of request for transfer. It was reported at interview that there was no system in place at the time of the investigation for recording the numbers of critically ill maternity patients who require Level 3 critical care nationally each year.

In recognising the significance of this step in the patient journey, as reported in previous investigations, and the potential risk that this poses to the safety and welfare of ill maternity patients, the Authority wrote to the Director General of the HSE on 5 July 2013 requesting assurances in relation to the provision of care for clinically deteriorating obstetric patients in a safe, timely manner and that associated risks had been identified and managed effectively. Following the review of the HSE response received on 27 August 2013, the Authority, while noting the response on assurances in respect of the safety of services in a number of hospitals, remained concerned that such assurances were not in place for every hospital providing maternity services. The Director General gave a commitment in his letter that assurance would be in place by September 2013. With this in mind the Authority will require further progress updates in respect of safety over the coming months.

4. Conclusion

The findings of this investigation reflect a failure in the provision of the most basic elements of patient care to Savita Halappanavar and also the failure to recognise and act upon signs of her clinical deterioration in a timely and appropriate manner. The Authority identified, through a review of Savita Halappanavar's healthcare record, a number of missed opportunities which, had they been identified and acted upon, may have potentially changed the outcome of her care.

Patients and members of the public are entitled to expect healthcare services that are at the very least safe and free from harm. Cognisant of this fundamental entitlement, and the responsibility of any service provider to provide safe health services, the Chief Executive of the Hospital Group, as the HSE delegated officer, should consider the actions, omissions and practices of the professional's involved in the care of Savita Halappanavar, and make appropriate referral(s) to the relevant professional regulatory body/bodies.

Every day there are patients who receive good, safe care at the Hospital Group and also at other maternity hospitals across Ireland. This investigation has identified that the provision of materity services, on occasion, may not be as safe as they should be or of sufficient quality. Where this is the case, this must be addressed as a matter of urgency.

Every health system must ensure that, both nationally and at a local level, there exists the ability to learn when things go wrong and ensure that errors are not repeated wherever possible, and also to learn from the best available evidence nationally and internationally to ensure that clinical practice and models of care are safe, effective and up-to-date. This includes learning from incidents within a healthcare setting and also learning from the findings and recommendations of relevant investigations, inquiries, and inquests nationally and also internationally. The responsibility to ensure that this happens sits locally with the Boards and Executives (or equivalent) of healthcare facilities and also nationally with the HSE and other corporate bodies providing health services.

This investigation found concerning deficits in how learning, particularly in the areas of maternity services and clinically deteriorating patients, has been adopted and implemented following previous investigations and inquiries. These deficits include an inability to apply system–wide learning from adverse findings in one part of the system to minimise clinical risk for all patients.

At the heart of the ability to learn is the culture and leadership within an organisation that actively seeks out ways to continually improve the quality and safety of services for its population in an open and transparent way with clear accountability and responsibility arrangements to do so. The achievement of this must be an aim for all healthcare providers.

Finally, the sequence of events that led to the death of Savita Halappanavar will constitute a difficult read for Praveen Halappanavar, his wider family, the public and healthcare staff across the country. What is critically important is that we must learn from this tragic event and ensure that the findings, learning and recommendations of this investigation, and of the HSE inquiry, are effectively implemented across the health service. This investigation clearly shows that where responsibility for implementation of learning is not clearly owned, then learning nationally does not happen, as demonstrated in the findings relating to the HSE enquiry into the death of Tania McCabe and her son Zach in 2007, the circumstances of which have a disturbing resemblance to the case of Savita Halappanavar.

As a result of the findings of the investigation, the Authority makes a series of recommendations that focus on the improvements required in University Hospital Galway and across all other maternity hospitals in Ireland.

These changes include the need to review and improve maternity services in respect of the management of sepsis, clinically deteriorating pregnant women, patient choice, models of care and providing a suitably skilled and competent workforce that can deliver safe and effective care at any given time.

Instrumental to the further development of our maternity services nationally is the recommendation requiring an urgent review of maternity services to ensure that the services purchased and provided on behalf of the State are safe and meet international best practice standards. This review should take account of the outcomes of this investigation and the other investigative processes initiated as a result of Savita Halappanavar's death. The review should inform the development and implementation of a National Maternity Services Strategy.

5. Moving forward

This investigation includes local and national recommendations for improvement that are specific to the Hospital and also apply nationally. The HSE governance arrangements to support the execution of these national recommendations must be clear, with a named accountable person with overall delegated responsibility for implementation – the implementation plans should include clear timelines and identified individuals with responsibility for each recommendation and action.

The HSE must ensure that every hospital should self-assess itself against the local recommendations within this report and national recommendations where applicable, and develop and implement a Quality Improvement Plan within the context of the National Standards for Safer Better Healthcare where shortcomings exist. The implementation of this Plan should be overseen by the HSE as part of its performance management arrangements and it will be considered as a high priority in the Authority's monitoring programme against the National Standards for Safer Better Healthcare where such services are provided.

Given the wide-ranging nature of this investigation's findings, and the applicability of the investigation's recommendations to the Galway and Roscommon University Hospital Group and to the national maternity services, the recommendations should not be viewed in isolation and therefore are not dispersed throughout this report. These recommendations are grouped together in accordance with the themes of the ***National Standards for Safer Better Healthcare*** and are reported in the following pages and also in Chapter 14 of this report.

Based on the findings of this investigation the Authority will submit this report to the relevant professional regulatory bodies for their consideration.

Recommendations

Local Recommendations **(L=Local, N=National)**

Leadership, Governance and Management	
L1	The Hospital Group must ensure that the recommendations of this investigation, and the HSE incident investigation, are implemented in full through the development of an implementation plan with clear timelines and identified individuals with responsibility for each recommendation.
L2	In accordance with recommendation N6, the Chief Executive of the Hospital Group, as the HSE delegated officer, should consider the actions, omissions and practices of the professional's involved in the care of Savita Halappanavar, and make appropriate referral(s) to the relevant professional regulatory body/bodies.
L3	The Chief Executive must be assured and provide assurance to the Hospital Group Board and the HSE about the quality, safety, timeliness and standards of care provided by the Hospital. These assurances should be provided through regular reviews of key performance indicators (KPIs), patient outcome measures and self assessments against National Standards. KPIs that measure the outcomes and experiences of women using the maternity services should be developed as a priority.
L4	The Hospital Group should review its current governance structures and arrangements, including cross committee membership, in order to ensure that these are in line with the principles of good governance and the recommendations of the HIQA Tallaght investigation.
L5	The Hospital Group should develop a clear action plan to implement the improvements necessary to comply with the *National Standards for Safer Better Healthcare* with a particular and urgent focus on aspects of non-compliance identified within this investigation.
Effective Care	
L6	The Hospital Group should review and amend where required, the models and pathways of care for pregnant women at UHG to include those who require emergency access to maternity services. Following the review, the Group should provide clear and accessible information to pregnant women/ their families and GPs in relation to these.
L7	The Hospital Group should continually review the arrangements to ensure that patients are cared for in a suitable clinical environment that facilitates the delivery of effective and safe care to patients.

L8	The Hospital Group should establish arrangements to ensure and demonstrate that all patient information including a plan of care, clinical observations, diagnostic tests and progress notes are actively followed up on and contemporaneously recorded by the relevant healthcare professional in an agreed format within an agreed patient healthcare record.
L9	The Hospital Group should urgently review the current arrangements for the referral of high risk antenatal pregnant women to a consultant obstetric anaesthetist and develop a clear referral pathway.
L10	The Hospital Group should review its clinical governance arrangements to ensure that all clinical areas are appropriately implementing local and national policies, procedures and protocols and put in place an assurance mechanism to monitor their effective implementation.
L11	The Hospital Group, as a priority, should review the arrangements in relation to the roll-out of NEWS ensuring that all relevant clinical staff are immediately involved and trained in its use and all other similar patient safety initiatives. The Group should develop a programme of mandatory induction and refresher training for maintaining competency in NEWS.
Workforce	
L12	The Hospital Group should ensure that all medical and midwifery staff involved in the care of antenatal and post natal women regularly maintain their professional knowledge, skills and competence in line with best practice and the needs of the patient group being cared for while fulfilling the requirements of professional regulation.
L13	The HSE and the Hospital Group must put in place arrangements to ensure that the clinical directors have the necessary competencies, as well as adequate time and support, to effectively meet the leadership and managerial requirements of the role.
Safe Care	
L14	The Hospital Group must ensure that arrangements are put in place to support and train all staff responsible for managing risk, adverse incidents, near misses, claims and complaints. The Group should ensure that the review, implementation and monitoring of actions, trend analysis and implementation of learning from such incidents are disseminated to staff and incorporated within the clinical governance arrangements in the Group.
Use of Information	
L15	The Hospital Group should ensure, as a matter of priority, that it reviews and addresses any shortfall in the storage and management of healthcare records in line with the HSE national policy.

National Recommendations

Leadership, Governance and Management	
N1	The HSE must ensure that every hospital providing maternity services self-assess's itself against the local recommendations within this report and national recommendations where applicable, and develop and implement a Quality Improvement Plan within the context of the *National Standards for Safer Better Healthcare* where shortcomings exist. The implementation of this Plan should be overseen by the HSE as part of its performance management arrangements and will be considered as a priority in the Authority's monitoring programme against the *National Standards for Safer Better Healthcare* where such services are provided.
N2	The HSE must put in place effective governance structures and accountability arrangements to assure the delivery of high quality safe health services, including maternity services. These corporate and clinical governance arrangements must include unambiguous lines of accountability for assuring, performance managing and improving the quality and safety of services at a national, regional, local and clinical level.
N3	The HSE must demonstrate that it has the governance structures and mechanisms in place to ensure that the findings, learning and performance management of relevant healthcare organisations, in respect of implementing safety and quality issues emanating from serious adverse incidents, near misses and their investigations, are implemented.
N4	The HSE must ensure that there are clear mechanisms that provide assurance for the implementation and monitoring of the National Clinical Care Programmes, to include clear descriptors of the accountability arrangements at a national, regional, local and clinical unit level. This should include a programme of audit and evaluation to ensure that programmes are consistently implemented by each service provider.
N5	The HSE, as the national agency accountable for the planning, delivery and commissioning of health services, should develop a robust system to ensure that all service providers can demonstrate compliance with the *National Standards for Safer Better Healthcare* and, where shortfalls are identified, apply mechanisms by which it can assure itself that proactive and corrective action is being taken by any given provider.

N6	The Department of Health should develop a 'Code of Conduct' for employers that clearly sets out employers' responsibilities in relation to achieving an optimal safety culture, governance and performance of the organisation. The Code should include the expected attributes, behaviours and responsibilities of all managers as representatives of the employer, and underpin their role and responsibility in achieving these aims. It should also clearly articulate the duties and responsibilities on them in the regulation of health and social care professionals in their organisation including referral of professionals to the appropriate regulatory body/bodies. The Code of Conduct should be incorporated into the recruitment, appointment, job descriptions and performance review of managers in health and social care services. The Chief Executive (or equivalent) of all health and social care organisations will be accountable for the implementation of this Code. HIQA will monitor compliance with this Code as part of its monitoring of National Standards.
Effective Care	
N7	The Department of Health and the HSE must, as a priority, conduct a review of the maternity services nationally and develop and implement a National Maternity Services Strategy. The purpose for the Strategy should be to implement standard, consistent models for the delivery of a national maternity service that reflects best available evidence to ensure that all pregnant women have appropriate and informed choice and access to the right level of safe care and support 24 hours a day. The National Strategy should include the following elements: ■ a population-based needs assessment with a review of current and future demand and activity to inform the models of care, workforce planning and clinical governance arrangements ■ the development of models of care that reflect modern day, reliable and integrated maternity services both in-hospital and in the out-of-hospital setting ■ consideration of core medical and midwifery workforce needs, skills and competencies in line with national and international recommendations and standards ■ the corporate clinical leadership, governance, management and measurement arrangements necessary at a local and national level to ensure the delivery of safe, high quality and reliable maternity services. ■ the development of integrated care pathways for pregnant women within different settings. This should include pathways for women at risk of clinical deterioration with agreed, safe and effective arrangements for escalation and access to critical care ■ monitoring and assurance arrangements at a local and national level ■ an implementation plan with timelines and a clear implementation structure that identifies national and local responsibilities ■ the relevant structures to ensure consistency in the provision of maternity services as they transition as a core component of Hospital trusts.

N8	The HSE must implement actions to mitigate risks identifed in the current model of materity services.
N9	The HSE should develop, and ensure the implementation of, a national guideline for the effective communication and clinical handover of information relating to the care of a patient both within and between clinical teams. This should be based on best available evidence and provide for effective handover in any clinical situation. Additional guidance should be provided to tailor this for the clinical handover of patients for different clinical settings with maternity services being the first setting to be prioritised.
N10	The HSE should develop a national clinical guideline on the management of sepsis and ensure that all hospitals put in place arrangements for formal staff training on the recognition and management of sepsis and on the clinically deteriorating patients, including pregnant women in line with the guideline. This guideline should incorporate an escalation/referral pathway that includes clinical, legal and ethical guidance for staff at critical clinical points and contain key elements of patient consultation and consent in respect of their treatment and associated interventions.
N11	The Department of Health should immediately review the current arrangements in place to ensure the National Clinical Effectiveness Committee is adequately resourced to support the national endorsement of key national guidelines.
N12	The HSE should ensure that nationally all diagnostic microbiology laboratory services are compliant with the *National Standards for the Prevention and Control of Healthcare Associated Infections* and include a designated surveillance scientist and surveillance pharmacist.
N13	The HSE should ensure that diagnostic microbiology laboratory services are supported by a network of appropriately resourced and accredited reference laboratory services that meet the European Centre for Disease Control (ECDC) definitions for reference laboratory services.
N14	The HSE should ensure, as a priority, that national early warning systems to include a mandatory education programme for the prompt identification and management of all patient groups at risk of clinical deterioration including maternity and paediatric patients, are agreed and rolled out. This should include clear descriptors of accountability for the implementation and audit at a national, local and clinical unit level.

Safe Care	
N15	The HSE should put in place arrangements to collate and review information from national and international inquiries, reviews, investigations and coroner's inquests and, where relevant, act on learning and recommendations so that valuable lessons learned can be applied by each service provider in order to improve the outcomes for patients in Ireland.
Use of Information	
N16	The HSE and key stakeholders should agree and implement effective arrangements for consistent, comprehensive national data collection for maternity services in order to provide assurance about the quality and safety of maternity services. This should include the development of an agreed and defined dataset and standardised data definitions to support performance monitoring, evaluation and management of key patient outcome and experience indicators.
N17	The arrangements for collecting, reviewing and reporting maternal morbidity and mortality should be reviewed by the HSE to facilitate national and international benchmarking for improved learning and safety in the provision of maternity services. This should include a formal process for the implementation of recommendations of the Confidential Maternal Death Enquiries.
N18	The HSE should develop a national laboratory alert system that allows for real time analysis of data from local laboratory information systems, or from other relevant healthcare information systems, to allow for timely recognition of emerging national microbial threats including antimicrobial resistance. These arrangements should also allow for a clear mechanism for communication of findings from the alert system, and clear lines of accountability for acting on such findings.
N19	The HSE, in line with the Department of Health's strategy, *Future Health*, should develop a more formal communication with the Clinical Indemnity Scheme in order to share information and learning on safety incidents within healthcare services and enable the effective prioritisation and development of tailored quality and safety programmes across services nationally. This learning should actively inform the respective Clinical Care Programmes and relevant guidelines and guidance.

Part 1

Introduction and Background, and Methodology

1 Introduction and Background

This Report presents the findings from the Health Information and Quality Authority's (the Authority or HIQA) investigation into the safety, quality and standards of services provided by the Health Service Executive (HSE)* to patients, including pregnant women, at risk of clinical deterioration and as reflected in the care and treatment provided to Savita Halappanavar at University Hospital Galway (UHG).

At the outset of this investigation the Authority and Investigation Team wishes to convey their sympathies to the husband and wider family of Savita Halappanavar for their loss.

This investigation was instigated by the Authority on the 23 November 2012 and was conducted under section 9(1) of the Health Act 2007[(1)]. It followed a review of documentation requested by the Authority from UHG and receipt of a letter from the Director General Designate† of the HSE outlining his belief that there may have been circumstances which gave rise to a potential serious risk to the safety, quality and standards of services provided such that it would be appropriate for HIQA to conduct an investigation. In the letter, the Director General Designate requested HIQA to consider undertaking an investigation in accordance with 9(1)(a) of the Health Act 2007‡. A copy of this letter is attached as Appendix 1.

This statutory investigation has been conducted in accordance with the Terms of Reference of the investigation, in order to make recommendations for improvements required to ensure the safety, quality and standards of services provided by the HSE.

In carrying out the investigation, the Authority looked at the arrangements in place at the Hospital for the provision of high quality, safe services for patients, including pregnant patients, at risk of clinical deterioration. This part of the investigation included the diagnosis and management of patients with sepsis (a potentially

* The Department of Health has a responsibility to ensure that all references to the HSE in this Report are applicable to its successor organisation(s).

† In November 2012, the role of Director General Designate, HSE, was an acting position which was subsequently formalised as the role of Director General, HSE, in July 2013. For the purposes of this report, the role is referred to as the Director General HSE throughout the remainder of this report.

‡ Galway University Hospitals, comprising of University Hospital Galway (UHG) and Merlin Park University Hospital (MPUH), provide a comprehensive range of services to emergency and elective patients on an inpatient, outpatient and day care basis across the two sites.

life-threatening complication of infection). The investigation also looked at the arrangements that the HSE has in place to ensure that the care provided in the public health service to these patients is compliant with the *National Standards for Safer Better Healthcare*[2] and relevant national and international evidence of what is known to achieve best outcomes for patients.

In addition, while reviewing the arrangements that the HSE has in place to assure the delivery of high quality, safe and reliable services, the Authority identified opportunities for improvement in the arrangements in place relating to incident management and the implementation of learning from the recommendations of reviews and investigations relating to the quality and safety of services provided by the HSE.

In the interest of wider service improvement, the Authority believes that there are national implications from the findings of this investigation and therefore recommendations with national applicability across the Irish healthcare system are made accordingly.

This Report is divided into eight parts:

- **Part 1** outlines the introduction and background to the investigation and the investigation methodology.
- **Part 2** outlines the profile of the Galway and Roscommon University Hospitals Group which includes maternity services.
- **Part 3** outlines the investigation findings in relation to the care provided to Savita Halappanavar at the Hospital. It includes a chronology and details of key clinical events and wider findings in relation to access arrangements, the healthcare record review, workforce arrangements for the provision of maternity services locally at the Hospital and the best available evidence to support those findings.
- **Part 4** outlines the investigation findings in relation to the corporate and clinical governance arrangements at the Galway and Roscommon University Hospitals Group (GRUHG) and University Hospital Galway (UHG).
- **Part 5** outlines the investigation findings in relation to the profile and governance arrangements for the provision of maternity services nationally. It also outlines the Authority's findings in relation to the provision of maternity services nationally and includes workforce arrangements for the provision of maternity services, use of information and sepsis.
- **Part 6** outlines the Authority's findings in relation to antimicrobial surveillance
- **Part 7** outlines the investigation findings in relation to incident management and learning within the health service at national level.
- **Part 8** outlines the conclusions and supporting information including references, a glossary of terms and abbreviations used in this Report, and appendices.

Elements of this investigation ran in parallel with the HSE's incident investigation into the circumstances that led to the death of Savita Halappanavar, the findings and recommendations of which the Authority commends and concurs with. Evidence gathering and hearings in respect of the Coroner's inquest to determine the cause of her death was also ongoing. In analysing the evidence gathered, the Investigation Team considered the relevance and outcomes of both of these processes.

The Authority has made recommendations for improvements and these are colour coded. Local recommendations that are specific to the Galway and Roscommon University Hospital Group are detailed in green, and national recommendations are detailed in blue. These are reported earlier in this section of the report and in Chapter 14. This Report is supported by a glossary of terms used and a number of appendices to provide the reader with additional information. In addition, the Report contains references that are identified by a superscript number in the body of the Report and which are listed at the end of the Report.

The Authority would like thank the staff at the Hospital, staff within the HSE, patients who contacted the Authority, patients who met with the Authority, external members of the Investigation Team, the Advisory Panel and all of the staff of the Authority who contributed to this investigation.

1.1 Background to the HIQA investigation

Overview of the care provided to Savita Halappanavar as indicated in her healthcare record and published and unpublished documentation received during this investigation.

On Sunday morning, 21 October 2012, Savita Halappanavar referred herself to the Hospital with a complaint of lower backache. She was a 31-year-old woman who was 17 weeks pregnant and in her first pregnancy. Following clinical assessment, she was advised to take medication for the lower back pain, was referred for a physiotherapy appointment and discharged home.

Later that day, at approximately 15:30hrs, she re-attended the gynaecology ward in the Hospital. Following clinical examination, it was recorded in her healthcare record that the diagnosis was that of an 'inevitable/impending pregnancy loss'. Savita Halappanavar was subsequently admitted to the gynaecology ward at the Hospital (St Monica's Ward) on Sunday 21 October 2012 for management of her inevitable miscarriage.

Savita Halappanavar's membranes spontaneously ruptured at 00:30hrs on Monday, 22 October. This meant that some of the fluid surrounding her baby was released (known as the waters breaking) without labour beginning at that point. At 08:20hrs Savita was reviewed by the consultant obstetrician and clinical team as part of the routine morning ward round. The care plan at that stage was to continue to observe Savita Halappanavar and record her clinical observations

(these include pulse, respiration, temperature and blood pressure) every four hours. An ultrasound examination confirmed the presence of a fetal heart beat. Savita Halappanavar was commenced on an oral antibiotic, Erythromycin, on 22 October at 22:00hrs. Erythromycin can be administered prophylactically (to prevent infection) in women with pre-term premature rupture of the membranes[3].

The recording of a lowered blood pressure on 22 October at 15:25hrs and 18:00hrs and an increasing pulse rate at 18:00hrs and 21:40hrs did not appear to alert staff to a potential change in her clinical condition and to further check for the possibility of developing sepsis. At 08:20 hours on Tuesday 23 October, Savita Halappanavar was again reviewed by the consultant obstetrician and clinical team as part of the routine morning ward round. The documented treatment plan was that the patient was to remain on antibiotic therapy, the fetal heart was to be monitored and consideration was to be given to carrying out a fetal ultrasound.

At 04:15hrs on Wednesday 24 October, Savita Halappanavar complained of feeling cold and shivery. Over the next number of hours her condition continued to deteriorate with clinical signs of fever, tachycardia, low blood pressure and pain. In addition, a foul smelling brown vaginal discharge was documented as being present. At this time, Savita Halappanavar was commenced on intravenous antibiotics, oxygen therapy, intravenous fluids and medication to manage her elevated temperature. In addition, blood tests, which included a full blood count, blood cultures, liver and renal function and a serum lactate test were taken.

On Wednesday 24 October, her condition continued to deteriorate and a diagnosis of sepsis, related to chorioamnionitis (an inflammation of fetal membranes due to a bacterial infection) was made. Following review by Savita Halappanavar's consultant obstetrician and the on-call anaesthetic team, she was transferred to the gynaecology theatre for insertion of a central venous catheter (a tube that is inserted into a vein in the chest, to convey fluid, nutrients and medicine into the body, and to take blood for testing) and a radial arterial line (a small, short plastic tube that is placed through the skin into an artery of the arm or leg). While in theatre, she suffered a miscarriage with the spontaneous delivery of the foetus. She was then transferred to the High Dependency Unit in the main Hospital.

Savita Halappanavar's condition continued to deteriorate, and she was subsequently transferred to the Hospital's Intensive Care Unit in the early hours of the morning of Thursday 25 October 2012. Savita Halappanavar died in the Intensive Care Unit on Sunday 28 October 2012 at 01:09hrs, seven days after her admission to the Hospital.

Following the death of Savita Halappanavar, the Hospital Group Clinical Director commissioned an investigation into the incident. This incident investigation was overseen by the National Incident Management Team (NIMT) of the HSE and was chaired by an independent external chair. The investigation looked at the factual circumstances leading up to the incident to identify key causal factors that

may have occurred and relevant contributory factors. The report of the incident investigation and recommendations were published by the HSE on 13 June 2013. The recommendations are included in Appendix 2.

While this incident investigation was ongoing, a coroner's inquest into the death of Savita Halappanavar commenced on Monday 8 April 2013 and continued over seven working days. On 19 April 2013, the inquest jury returned a verdict of medical misadventure. The Coroner has made nine recommendations (see Appendix 3).

1.2 Establishment of the HIQA investigation

On 14 November 2012, having learned of the death of Savita Halappanavar in the media, the Authority wrote to the Chief Executive of University Hospital Galway, seeking assurances that the care provided to Ms. Halappanavar was in line with the *National Standards for Safer Better Healthcare*. In addition, UHG was requested to provide assurances that there were controls in place to manage and mitigate similar risks to other patients; and details of how the Chief Executive was assured that these controls were effective.

On 15 November 2012, the Authority wrote to the HSE's National Director of Quality and Patient Safety seeking assurances that the HSE had controls in place to manage and mitigate risks to patients in receipt of obstetrics and gynaecology services provided on behalf of the HSE and details of how the HSE, as a service provider, was assured that those controls were effective.

This information was requested in order for the Authority to establish if there was a serious risk to the health or welfare of persons receiving maternity services provided by the HSE at the Hospital.

In parallel with the receipt of information from UHG and the HSE in response to the Authority's request, on 22 November 2012, the Chief Executive of the Authority received a letter from the then Director General Designate of the HSE outlining his belief that there may have been circumstances which gave rise to a potential serious risk to the safety, quality and standards of services provided such that it would be appropriate for HIQA to conduct an investigation (see Appendix 1). In the letter, the Director General Designate requested HIQA to consider undertaking an investigation in accordance with 9(1)(a) of the Health Act 2007.

Considering this request, together with the Authority's review of the information received from the HSE and the Hospital, in accordance with section 9(1) of the Health Act 2007 (the Act) and having formed the opinion required by sub-section 9(1)(a) of the Act, the Board of the Authority, believing on reasonable grounds that there was a serious risk to the health or welfare of persons receiving services provided by the HSE at UHG, made the decision to instigate an investigation. This investigation would consider the safety, quality and standards of services provided by the HSE to patients, including pregnant women, at risk of clinical deterioration

and as reflected in the care and treatment provided to Savita Halappanavar at the Hospital.

Following the announcement of the HIQA investigation, the Terms of Reference for the investigation were approved by the Board of the Authority on 27 November 2012. The Terms of Reference are detailed on the next two pages.

Terms of Reference

The Health Information and Quality Authority (the Authority) will investigate the safety, quality and standards of services provided by the Health Service Executive (HSE) to patients, including pregnant women, at risk of clinical deterioration, including those provided in University Hospital Galway (UHG) and as reflected in, among other things, the care and treatment provided to Savita Halappanavar. The Investigation shall be carried out on the basis of the following terms:

1. The Authority will review the safety, quality and standards of services provided by the HSE at UHG to patients, including pregnant women, at risk of clinical deterioration and as reflected in the care and treatment provided to Savita Halappanavar. This will include the diagnosis and management of patients with sepsis. Assessment of the services will be made against the *National Standards for Safer Better Healthcare* and relevant national and international evidence of what is known to achieve best outcomes.
2. The Authority will review the arrangements that the HSE has in place to ensure that clinically deteriorating pregnant women, including those at risk of sepsis, receive care which is compliant with the *National Standards for Safer Better Healthcare* and relevant national and international evidence of what is known to achieve best outcomes.
3. The Authority will review the arrangements that the HSE has in place to assure the delivery of high quality, safe and reliable services. This will be limited to those aspects of safety, quality and standards that the Authority considers are relevant and material to the Investigation and will include those arrangements relating to the reporting and management of patient safety incidents and the implementation of the prompt identification and management of clinically deteriorating patients.
4. If, in the course of the Investigation, it becomes apparent that there are reasonable grounds to believe that there are further or other serious risks to the health or welfare of any person receiving similar services, the Investigation Team may recommend to the Authority and/or the Minister for Health, that these terms be extended to include further investigation or that a new investigation should be undertaken, as appropriate.

5. The Authority shall, in good faith, prepare a report of the findings of the Investigation and make local and national recommendations as to the safety, quality and standards of services provided by the HSE, to the extent that the Authority considers appropriate. The report will be submitted to the Board of the Authority for approval. This report will be published in order to promote safety and quality in the provision of health services for the benefit of the health and welfare of the public.

This Investigation will be carried out in accordance with section 9(1) and other relevant provisions set out in the Health Act 2007, as the Authority believes that on reasonable grounds there is a serious risk to the health or welfare of persons receiving services following consideration of, amongst other things, information and correspondence received from the HSE.

The Investigation will be conducted by an Investigation Team appointed and authorised by the Authority in accordance with Part 9 of the Health Act 2007. The Team will carry out the Investigation and may exercise such powers as it has, pursuant to Part 9 of the Health Act 2007, including rights of entry, its rights to inspect premises, records and/or documents and its rights to conduct interviews and rights to require explanations in relation to documents, records or other information. In addition, the Authority (with appropriate Ministerial approval and in accordance with the Health Act 2007 where required) may engage such advisers as it considers necessary in the undertaking of this Investigation.

This published Report includes the Investigation Team's findings during the course of the investigation from the time the Terms of Reference of the Report were approved on 27 November 2012 to the date this Report was approved by the Board of the Authority, on 07 October, 2013.

2 Methodology

This chapter summarises the methodology used by the Authority in conducting this investigation.

2.1 Overall approach

The Authority conducted this investigation in line with the Terms of Reference and in the interest of wider service improvement. In keeping with the Authority's mission and corporate values, the Investigation Team has aimed to ensure fairness and due process throughout the investigation process.

Based on the Terms of Reference agreed by the Board of the Authority on 27 November 2012, the Authority designed the investigation approach to examine the arrangements in place at University Hospital Galway (UHG) for the provision of quality, safe services for patients, including pregnant patients, at risk of clinical deterioration. This included the diagnosis and management of patients with sepsis.

In parallel, the approach incorporated a review of the national arrangements that the HSE had in place to ensure that the care provided to clinically deteriorating patients is compliant with the *National Standards for Safer Better Healthcare* and relevant national and international evidence of what is known to achieve best patient outcomes. The dual approach allowed for the identification of opportunities for improvement in the arrangements that the HSE has in place locally and nationally to ensure the delivery of high quality, safe and reliable services.

The commencement of this investigation by the Authority came at a time when the HSE was undertaking its own incident investigation into the circumstances that led to the death of Savita Halappanavar. The Galway West Coroner's inquest for determining the cause of death also took place during the course of the Authority's investigation.

The Investigation Team was cognisant of these two concurrently running inquiry processes and therefore designed the methodological approach to avoid duplication and unnecessary burden on the service provider and specific staff who continued to deliver care to patients within the Hospital. This was particularly important when all inquiries shared the common goal of understanding what had happened to Savita Halappanavar and to minimise the likelihood of such an event happening again to other patients and to promote learning and improvement within the healthcare system.

2.2 Investigation Team

The Minister for Health, with the approval of the Minister for Public Expenditure and Reform, approved the appointment of members of the Investigation Team as authorised persons to conduct the investigation, in accordance with section 70(1)(b) of the Health Act 2007 (the Act).

The membership of the Investigation Team is set out in Appendix 4.

2.3 Advisory Panel

The Authority arranged for the provision of additional professional advice, in accordance with section 70(2)(b) of the Health Act 2007, through the establishment of an Advisory Panel. The role of the Advisory Panel was to advise the Authority in order to ensure an alignment of the recommendations with national and international best practice and to take account of the National Clinical Care Programmes.

The membership of the Advisory Panel is set out in Appendix 5.

2.4 Lines of Enquiry

Lines of Enquiry were developed by the Authority to guide the investigation approach and to provide the Investigation Team with a framework for the selection and gathering of information.

They reflect the *National Standards for Safer Better Healthcare* (the National Standards), national and international best evidence, the findings of previous reviews and investigations carried out by the Authority[4, 5, 6, 7,8] and the recommendations of the 2008 report of the Commission on Patient Safety and Quality Assurance, which had been established by the then Minister for Health and Children in January 2007[9].

The Lines of Enquiry were framed around the National Standards' themes of quality and safety. These themes reflect the essential components of a high quality, safe healthcare service and encompass the required capacity and capability of the service provider to deliver such services.

The quality dimensions are:

- Person-centred care and support
- Effective care and support
- Safe care and support
- Better health and wellbeing.

The capacity and capability themes are:

- Leadership, governance and management
- Workforce
- Use of resources
- Use of information.

2.5 Patients' and relatives' experience

At the outset of this investigation, the Authority invited Mr Praveen Halappanavar, the husband of Savita Halappanavar, through his legal representatives, to meet with the Authority in order to identify the questions that he may have liked answered and to hear about his experience and his account of the very sad events in relation to the care of his wife. In subsequent correspondence, the Authority provided Mr. Halappanavar with the Terms of Reference of this investigation, through Mr Halappanavar's legal representatives, for comment prior to publication. This correspondence was followed by five further invitations to Mr Halappanavar to meet with the Authority between November 2012 and August 2013. Mr Halappanavar did not wish to meet with the Authority during this investigation. Therefore, his experience of the care provided to Savita Halappanavar is not reflected in this investigation report.

Prior to and following the announcement of this investigation, the Authority was contacted, both in writing and by telephone, by nine individual members of the public who had received care themselves, or who had accompanied family members who had received care, at the Hospital in 2011 and 2012. In order to explore the provision of patient-centred care from a patient's perspective specifically, the Authority met with four patients and/or members of their families, seven individuals in total. These people reported their experience of receiving care provided to a clinically deteriorating patient at the Hospital, or when accompanying a relative who had experience of the care provided to a clinically deteriorating patient.

The Authority recognises that this is a very limited sample of the experience of all the patients who receive care at the Hospital and that it does not represent a statistically significant sample of patients. However, the aim of meeting these patients and/or members of their families was to encourage patients and family members to describe, in their own words, their experience of the care provided and their perspective of the service received.

2.6 Investigation findings

In line with the Terms of Reference, the investigation involved the review and evaluation of information derived from multiple sources including documentation and data, patient healthcare records, interviews, observation, and in line with these processes, outlines the conclusions and recommendations of the Authority.

2.7 Review of literature

The Authority conducted a literature review of national and international best practice, within the scope of the Terms of Reference, to inform the investigative process and to support the findings and recommendations that are made in this Report.

2.8 Documentation and data

In accordance with section 73 of the Act, the Authority issued formal documentation and data requirements to the Hospital, other public providers of maternity services, and the HSE at a national level (see Appendices 6 and 7).

The Investigation Team obtained approximately 1,360 pieces of documentation and data and covered areas such as the:

- corporate and clinical governance structure and management arrangements
- patient activity and patient outcome data in relation to maternity services
- risk management systems including reported adverse incidents
- arrangements for the dissemination and implementation of policies, procedures, guidelines and best available evidence
- workforce planning and staffing arrangements.

The Authority provided a timeframe of 10 working days for the return of documentation and data from the date that the information requests were issued.

2.9 Interviews

In accordance with section 73 of the Act, the Authority obtained information through interview with various individuals including staff working in the Hospital, the wider Hospitals Group and HSE staff at national level whose role related to aspects of the governance and quality and safety of services at the Hospital. The Authority interviewed selected individuals using a framework of areas of exploration related to the Lines of Enquiry. The interviews were used to clarify issues that may have been identified during the Investigation Team's review of documentation and data, gather information generally, consider any further information that was provided and to inform the investigation findings.

All individuals who were interviewed were provided with a minimum of 10 working days' notification of interview. Where an individual was unavailable on the allocated day, alternative arrangements were put in place to facilitate an interview at a later date, where possible.

Following the interview, individuals were provided with a copy of a summary note of their interview for their review and were invited to inform the Authority, within 10 working days, if they had any feedback in relation to their interview summary. Where commentary was received, it was considered by the Authority in the development of the investigation findings.

2.10 Group meetings

The Investigation Team also carried out group meetings with staff at University Hospital Galway. The group meetings were used to clarify issues identified during the Investigation Team's review of documentation and data. The discussions were facilitated by the Investigation Team and were framed around the investigation's Lines of Enquiry.

2.11 Observation

In order to obtain information about the environment and physical facilities for the delivery of safe, high quality care to patients at University Hospital Galway, members of the Investigation Team observed a number of the areas in the Hospital. This observation included the:

- Emergency Department (ED)
- St Monica's Ward (the gynaecology ward)
- St Catherine's Ward (the antenatal ward)
- Labour ward
- High Dependency Unit (HDU)
- Intensive Care Unit (ICU)
- Early Pregnancy Assessment Unit (EPAU)
- Outpatients Department (OPD).

2.12 Patient healthcare record review

To further inform the patient experience and understand the patient pathway, the Investigation Team selected healthcare records for review, in accordance with section 73 of the Act, for a number of patients who had received care at the Hospital from 2011 to 2013. The healthcare records of 16 medical, surgical and maternity patients were selected for review. These patients had been cared for between 2011 and 2012, and sepsis had been identified as a contributory factor in their diagnosis. This included a specific review of the healthcare record of Savita Halappanavar.

2.13 Due process feedback

The Authority provided a copy of the relevant excerpt(s) of the confidential draft report of the investigation findings to a wide range of identified interested parties, including those interviewed.

Those who received a copy of the relevant excerpt(s) were invited to offer their feedback and commentary generally on any matters in the draft report excerpt, as well as any further information that they considered pertinent to the investigation.

The Authority provided a timeframe for the return of any feedback and comments from the date of issue of the draft excerpt of the report. Every comment received was carefully considered by the Authority prior to the publication of the Report.

Part 2

Profile of Galway and Roscommon University Hospitals Group

3 Galway and Roscommon University Hospitals Group including University Hospital Galway

3.1 Introduction

Within this chapter, the Authority will briefly describe the service and activity profile of the Galway and Roscommon University Hospitals Group (GRUHG*) ('the Hospital Group') at the time of this Report, to include University Hospital Galway† (UHG). This chapter will also describe St Monica's Ward which is the gynaecology ward within UHG to which Savita Halappanavar had been admitted and cared for until her transfer to the High Dependency Unit. The supporting governance structure and systems will be discussed in Part 3, chapter 8 of this report.

3.2 Profile of Galway and Roscommon University Hospitals Group

At the time of the investigation, the Hospital operated within the HSE as an acute hospital as part of the Galway and Roscommon University Hospitals Group‡.

Together with Merlin Park University Hospital (MPUH) and operating as Galway University Hospitals (GUH), the Hospital provides a comprehensive range of services to emergency and elective patients on an inpatient, outpatient and

* Galway and Roscommon University Hospitals Group is referred to as 'the Hospital Group' throughout this Report.

† University Hospital Galway is referred to as UHG and 'the Hospital' throughout this Report.

‡ In December 2011, the Minister for Health, Dr James Reilly TD, announced that Galway University Hospitals (incorporating Merlin Park University Hospital) together with Portiuncula Hospital Ballinasloe and Roscommon General Hospital were to be placed within a single management structure led by a single chief executive with responsibility for group performance. This hospital group and the Mid Western Hospitals Group have been the first administrative hospital groups with increased autonomy established by the Government as a precursor to plans for a national network of hospital groups to be managed by trusts.

day case basis across the two sites. These two hospitals are part of the wider Galway and Roscommon University Hospitals Group. The Hospital Group includes Roscommon General Hospital in County Roscommon and Portiuncula Hospital Ballinasloe in County Galway. The Hospital Group predominantly serves the populations of Counties Galway, Mayo and Roscommon.

At the time of the investigation, the total number of beds within the Hospital Group was approximately 800 with staff numbers at 4,000 whole-time equivalents (WTEs). The Hospital Group operates under a single HSE corporate and clinical governance model, with one budget and one employment ceiling (an agreed number of whole-time equivalent employees set for a budgetary time period). Table 1 below indicates activity data for the Hospital Group.

Table 1: Activity data for the Galway and Roscommon University Hospitals Group in 2012*.

Areas of activity	Galway University Hospitals[1]	Portiuncula Hospital Ballinasloe General and Maternity	Roscommon County Hospital	Galway and Roscommon University Hospitals Group Total
Inpatient discharges	37,831	11,338	1,899	**51,068**
Day cases	74,770	8,775	5,129	**88,674**
Emergency presentations	66,327	22,892	0	**89,219**
Emergency admissions	28,164	7,502	1,384	**37,050**
ED attendances	64,919	22,119	N/A	**87,038**
Births	3,377	2,056	N/A	**5,433**
Inpatient average length of stay (ALOS) in days	5.4	4.1	8	-

* *Source: HSE Supplementary Report, December 2012*[(10)].

Savita Halappanavar attended University Hospital Galway, the larger hospital within the Hospital Group, for her maternity care. The Hospital is an acute general hospital for un-differentiated (all types of patients with any degree of seriousness or severity) patients. The Hospital has 664 beds in total: 558 inpatient beds and 106 day case beds, which includes adult and children's beds. There are 49 inpatient maternity beds. It provides elective and emergency adult and children's services on an inpatient, day case and outpatient basis. The Hospital services are listed in Table 2 on the following page.

Table 2: Services provided at University Hospital Galway

Acute and chronic pain management	Histopathology
Acute psychiatry	Immunology
Anaesthesia	Infectious diseases
Biochemistry	Microbiology
Cardiology	Neonatology
Cardiothoracic surgery	Neurology
Care of the elderly	Obstetrics and gynaecology
Clinical pharmacology	Oncology
Decompression chamber	Ophthalmology
Dermatology	Oral maxillofacial
Emergency medical admissions	Orthodontics paediatrics
Emergency surgical admissions	Palliative care
Emergency medicine	Plastic surgery
ENT (Ear, nose and throat)	Radiology
Fertility	Radiotherapy
Gastroenterology	Respiratory medicine
Gastro-intestinal surgery	Symptomatic breast care
General surgery	Trauma orthopaedic surgery
Haematology	Urology
Hepatology	Vascular surgery

University Hospital Galway and Portiuncula Hospital Ballinasloe provide the maternity services for the Galway and Roscommon University Hospitals Group. Together they reported 5,433 births (live and stillbirths) for 2012.

Based on information received from the public providers of maternity services by the Authority, University Hospital Galway and Portiuncula Hospital had 49 and 33 inpatient maternity beds respectively.

3.3 Profile of maternity services at University Hospital Galway

The Women's and Children's Directorate encompasses the Departments of Obstetrics and Gynaecology and Paediatrics.

In 2012, the Hospital reported 3,377 births within the maternity service. This number of births (both live and stillbirths) was slightly less than the previous year (2011) of 3,428 births. The Hospital reported a Caesarean section rate of 27.3% for 2012 which is in line with the national average rate in Ireland of 27%. The

birth-to-inpatient bed ratio at the Hospital in 2012 was 69:1. This is in line with the national average of the 19 public maternity hospitals/units as reported in the data received by the Authority from the HSE (the national range of births per inpatient bed was between 45:1 to 94:1 for the 19 public maternity hospitals/units). The model of maternity care was predominantly consultant led and hospital based.

It was reported to the Authority that the average length of inpatient stay in the postnatal ward is one to two days following a normal vaginal delivery, or three to four days following a Caesarean section. Early discharge midwifery-led support is provided to patients who live close to the Hospital. It was reported in the draft 2012 annual report for the Hospital that 408 mothers availed of this seven-day service.

3.3.1 Care environment

The maternity and gynaecology services in UHG are provided in the 'maternity unit'*. This two-story unit has a separate entrance and is linked to the main Hospital via a corridor. The ground floor includes:

- St Catherine's Ward, an 18-bed ward which provides antenatal care for expectant mothers (20 weeks to full term)
- St Angela's Ward, a 31-bed ward which provides 24-hour care for postnatal mothers and babies
- the labour ward which includes seven single delivery rooms
- Outpatient's Department
- Physiotherapy.

The first floor includes:

- Special Care Baby Unit, a 14-cot ward where care is provided to newborn babies who are unwell or premature
- Obstetrics and Gynaecology Operating Theatre
- parent craft classroom
- St Monica's Ward, a 15-bed inpatient ward that also has four day-trolleys.

At the time of the investigation, there was no day obstetric unit at the Hospital. In addition, there were no maternity high dependency beds in the 'maternity unit' or specific beds allocated in the High Dependency Unit (HDU) in the general Hospital. It was reported by staff at the Hospital that the antenatal ward and postnatal ward frequently had 100% bed occupancy and when either ward is full, antenatal and postnatal patients may be accommodated in St Monica's Ward.

* Source: http://www.guh.hse.ie/Wards_Units_/. Accessed at time of investigation.

3.3.2 St Monica's Ward

St Monica's Ward was identified as the gynaecology ward. The ward included a ward office/nurses' station, four trolley spaces allocated for day cases, a clinical examination room, an ultrasound scan room and 15 inpatient beds.

Hospital staff reported that they generally allocate the single rooms sensitively, for example, to patients who had miscarried, and that ill patients were usually moved as near to the nurses' station as is possible.

St Monica's Ward was used as the overflow to accommodate ante- and postnatal patients when St Catherine's and St Angela's wards were full. Consequently, the casemix of patients accommodated on St Monica's Ward and their care needs were significantly different. The types of patients cared for on St Monica's Ward included:

- antenatal patients
- postnatal women and their babies
- post-operative patients following, for example, dilatation and curettage (D and C), evacuation of retained products of conception (ERPC), laparoscopy, day surgery, hysterectomy, ovarian debulking and ovarian cystectomy
- gynaecology oncology patients (excluding patients receiving chemotherapy)
- patients undergoing infertility investigations
- patients who were being treated for miscarriage.

In addition to accommodating inpatient and day patients, prior to December 2012, all patients who presented, outside of core hours, with a gynaecology or maternity emergency were directed to St Monica's Ward for assessment. This had been identified as a risk by the Hospital and as a result all patients with a gynaecology or maternity emergency were required to be assessed initially in the Hospital's Emergency Department. However, all patients who required clinical examination continue to be transferred to St Monica's Ward. This is further discussed in section 6.2.2 of this Report.

Savita Halappanavar was initially assessed in the clinical examination room, and then admitted to be cared for on St Monica's Ward. Part 3 of this Report will describe the care pathway of Savita Halappanavar.

Part 3

Findings in relation to the care provided to Savita Halappanavar, other clinically deteriorating pregnant women (as reflected in the care and treatment of Savita Halappanavar), and other findings at University Hospital Galway

4 Findings in relation to the care provided to Savita Halappanavar and the quality of maternity services

This chapter of the Report identifies the Authority's findings in relation to the care provided to Savita Halappanavar at University Hospital Galway (UHG), the care of clinically deteriorating pregnant patients as reflected in the care and treatment of Savita Halappanavar and other concerning aspects of the maternity services at UHG.

4.1 Introduction

A positive safety culture includes open communication with patients, strong clinical leadership and professional accountability, effective multidisciplinary team working, appropriate behaviour, evidence-based practice, adherence to policies and guidelines and clinical audit. This must be delivered by a fully trained, competent workforce, accountable for their individual and collective practice, supported and managed within a strong corporate and clinical governance system.

As referenced in the HSE procedure for developing policies, procedure, protocols and guidelines (PPPG), each health professional/HSE employee is accountable for their practice[11].

This means being answerable for decisions he/she makes and being prepared to make explicit the rationale for those decisions and justify them in the context of, for example, evidence-based practice, and professional and ethical conduct. It should be recognised that policies, procedures, protocols and guidelines represent a statement reflecting an expected standard of care. There may be occasions when it is acceptable to deviate from a PPPG but clinical judgment in such a decision must be clearly documented. The Authority acknowledges the importance of clinical guidelines and guidance. However, their use should not replace clinical judgment and the provision of basic care.

Leadership and accountability are fundamentally important criteria for the delivery of a safe system of care. Ultimate accountability for the safe delivery of patient care lies with the named consultant in charge of that patient's care. Crucially, the delivery of safe, high quality patient care is not only the responsibility of a named individual, it is also the job of everyone who works in the multidisciplinary clinical team.

Corporate and clinical governance arrangements must ensure that all members of the workforce exercise their personal and professional responsibility, the workforce is competent at any given time, and that robust arrangements are in place to monitor the quality and safety of the services they are delivering. In addition, it is important that the organisation has strong clinical governance arrangements to, if appropriate, hold those to account whose competencies and performance has fallen below what is reasonably expected of them.

The Authority reviewed the pathway of care provided to Savita Halappanavar which is outlined throughout Part 3, Chapter 4 of this Report.

Chapter 5 of this Report outlines the Authority's findings in relation to a clinically deteriorating pregnant patient, as reflected in the care and treatment provided to Savita Halappanavar. In doing so, the Authority was cognisant that the HSE incident investigation was being conducted concurrently and was reviewing the events which took place between 21 October and 28 October 2012 relating to the tragic death of Savita Halappanavar.

During this investigation, the Authority identified concerning aspects of the care provided to pregnant women at the Hospital. These are related to the access arrangements, healthcare record management and workforce and are described in Chapter 6 of Part 3 of this Report. These findings include and extend beyond the pathway of care provided to Savita Halappanavar.

In addition, Chapter 7 describes the arrangements in place at UHG for the identification and management of the clinically deteriorating general adult patient.

4.2 Pathway of care provided to Savita Halappanavar

In line with the Terms of Reference of this investigation and in the interests of wider service improvement, the Investigation Team reviewed the care pathway of Savita Halappanavar through her healthcare record. These findings were supported through review and analysis of the findings of the Coroner's inquest and the HSE incident investigation into the death of Savita Halappanavar that had both been completed at the time of reporting of these findings.

Figure 1 on page 57 illustrates the timeline of the pathway of care provided to Savita Halappanavar from her initial attendance at St Monica's Ward in University Hospital Galway on the morning of Sunday 21 October 2012 at 09.35hrs to Wednesday 24 October, when Savita Halappanavar's condition had begun to significantly deteriorate and the critical care team became involved in her care.

It was from the time of the involvement of the critical care team that the Authority did not identify opportunities for learning and therefore this is not depicted in the time line below.

The timeline depicts a visual representation of 13 missed opportunities to intervene in the care provided to Savita Halappanavar which, had they been identified and acted upon, may have potentially changed the outcome of her care. The missed opportunities are denoted by the red **X** symbols. Each of these missed opportunities (**X** symbols) is numbered in square brackets, for example, [1] depicting the chronology of these missed opportunity events. Some of these missed opportunities occurred in clusters over a specific time frame and this timeframe is indicated on the timeline by green brackets.

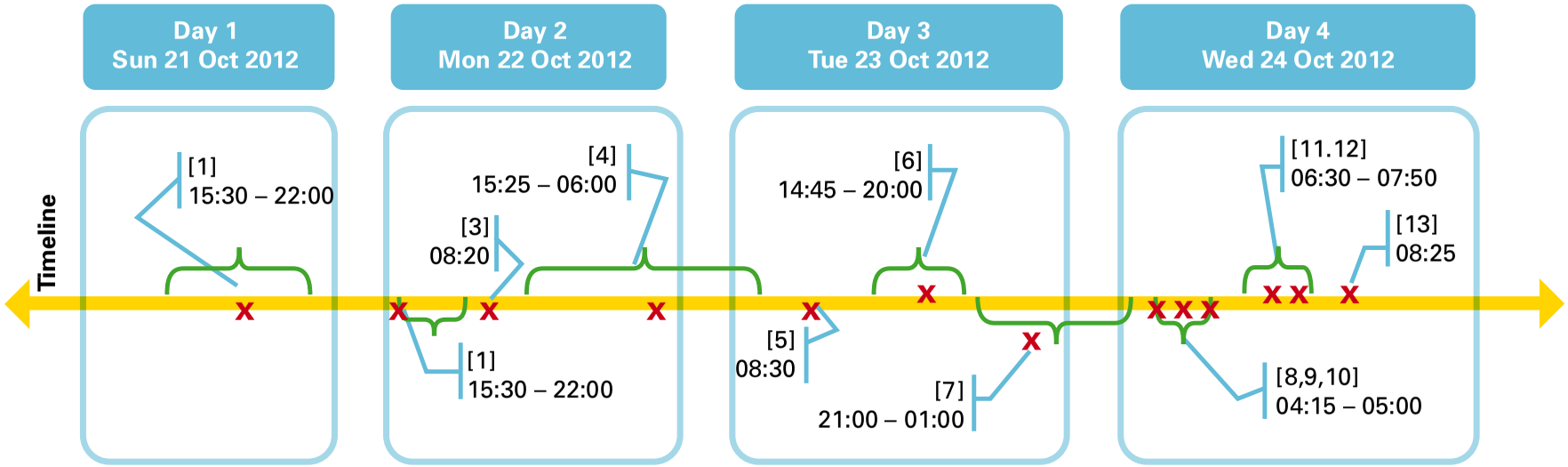
Table 3 on the following pages outlines the missed opportunity events illustrated in Figure 1 above and the timeline of these events from the time of Savita Halappanavar's initial attendance at St Monica's Ward at UHG on the morning of Sunday 21 October 2012 at 09.35hrs to Wednesday 24 October, when the critical care team became involved in her care following the diagnosis of septic shock. Table 3 demonstrates:

- the missed opportunity events (as numbered in Figure 1)
- the date and time that each missed opportunity event occurred
- a description of each missed opportunity event
- the Investigation Team's findings in relation to these missed opportunity events.

In addition, Table 3 includes a description of the outcome of her care in the days following the significant deterioration in her clinical condition when a diagnosis of septic shock was made on Wednesday 24 October 2012 to the time of her death on Sunday 28 October 2012 at 01:09hrs.

The identified missed opportunity events – which primarily signified deterioration in her clinical condition – must be used as learning opportunities for application both locally at the Hospital and across all maternity units/hospitals nationally.

Figure 1: Missed opportunities to intervene in the care pathway of Savita Halappanavar



Key to Figure 1:

- X = indicates a missed opportunity event
- [#] = indicates a number depicting the chronology of missed opportunity events along the timeline
- ⌒ = indicates a specific time frame during which one or more missed opportunity events occurred.
- Times are shown in 24-hour clock format.

Table 3: Care pathway of Savita Halappanavar at University Hospital Galway from Sunday 21 October 2012 to Sunday 28 October 2012

Sunday 21 October 2012

Event	Time	Initial attendance at UHG
	09:35hrs	On Sunday morning, 21 October 2012, Savita Halappanavar self referred to St Monica's Ward University Hospital Galway with a complaint of lower backache radiating to her lower pelvic region and urinary frequency. She was a 31-year-old woman who was 17 weeks pregnant and in her first pregnancy. A provisional diagnosis of Symphysis Pubis Dysfunction (SPD) was made. Savita Halappanavar was advised to take medication for the lower back pain. She was referred for a physiotherapy appointment and discharged home.
Event	**Time**	**Missed opportunity**
1	15:30hrs – 22:00hrs	*The healthcare record indicated:* Savita Halappanavar re-attended St Monica's Ward. Internal gynaecological examination showed that the fetal membranes were bulging and could be felt almost at the entrance of the vagina (that is, the water sac around the baby was visible and bulging). The fetal heart rate was detected using a handheld ultrasound device. Based on these clinical findings a diagnosis of inevitable/impending pregnancy loss was made by the obstetrics and gynaecology registrar. Savita Halappanavar was admitted to an inpatient room on St Monica's Ward. Blood tests were taken.
Findings		The blood results showed an elevated white cell count of $16.9x10^9$/litre (normal range in second trimester pregnancy is 6.2 – $14.8x10^9$/litre[12]). The initial blood test results were not reviewed by the consultant, NCHDs or midwives/nurses caring for Savita Halappanavar. The elevated white cell count should have alerted staff to investigate the cause of this raised white cell count further.

Monday 22 October 2012

Event	Time	Missed opportunity
2	00:30hrs – 06:30hrs	*The healthcare record indicated:* Spontaneous rupture of membranes occurred at 00:30hrs.
Findings		Four-hourly observations to include temperature, heart rate and respiration and blood pressure were not recorded. The Hospital's Maternal Obstetric Early Warning Score (MOEWS*) chart was not in use on St Monica's Ward at the time of Savita Halappanavar's care. Prophylactic antibiotics to minimise the risk of infection were not prescribed.
Event	**Time**	**Missed opportunity**
3	08:20hrs	*The healthcare record indicated:* Savita Halappanavar was reviewed by the consultant obstetrician in charge of her care. The team was aware that she had suffered a spontaneous rupture of membranes overnight. This review took place at Savita Halappanavar's bedside and was part of the consultant's routine morning ward round.
Findings		Savita Halappanavar's plan of care, following this consultant ward round, was that a fetal ultrasound scan would be taken with instructions to – 'Await events'† The Investigation Team is of the opinion that a more comprehensive plan of care should have been developed and documented following this clinical review. The plan of care in particular should have contained elements to address and investigate the following clinical facts: ■ Infection was the most probable cause of Savita Halappanavar's inevitable miscarriage. ■ The risk of infection was increasing following Savita Halappanavar's spontaneous rupture of membranes.

* Early Warning Scores facilitate early detection of deterioration in clinical condition by categorising a patient's severity of illness and prompting nursing staff to request a medical review at specific trigger points, utilising a structured communication tool while following a definitive escalation plan. A National Early Warning Score (NEWS) was introduced in Ireland in 2012. This did not incorporate the specialty of obstetrics. However, local maternity hospitals/units had introduced a local form of a Modified Obstetric Early Warning Score for use for maternity patients in their own maternity hospital/unit, including UHG, during 2012.

† Await events refers to the conservative (expectant) management of miscarriage as opposed to the surgical or medical management of miscarriage.

Monday 22 and Tuesday 23 October 2012

Event	Time	Missed opportunity
4	15:25hrs – 06:00hrs	*The healthcare record indicated:* Over a 15-hour period, three recordings of low blood pressure and two of an elevated heart rate were documented in Savita Halappanavar's Observation Chart by nursing/midwifery staff.
Findings		The clinical significance of these signs, over this 15-hour period was not recognised by the clinical staff. Savita Halappanavar's clinical observations, taken together with other clinical indicators, indicated signs of clinical deterioration, for which infection would be a likely cause.

Tuesday 23 October 2012

Event	Time	Missed opportunity
5	08:30hrs	*The healthcare record indicated:* Savita Halappanavar was reviewed by the consultant obstetrician in charge of her care. This review took place at Savita Halappanavar's bedside as part of the consultant's routine morning ward round.
Findings		The clinical staff in charge and looking after Savita Halappanavar did not recognise, document or manage the risks in relation to her changing clinical state, for example: ■ at this time, it was 24 hours since Savita Halappanavar had a spontaneous rupture of membranes. The risk of infection in the uterus increases after 24 hours following a rupture of membranes. ■ Prophylactic antibiotic cover (Erythromycin), was commenced 21 hours after the spontaneous premature rupture of membranes ■ Savita Halappanavar's vital signs up to this time were indicative of clinical deterioration as a result of infection.

Tuesday 23 October 2012

Event	Time	Missed opportunity
6	14:45hrs – 20:00hrs	*The healthcare record indicated:* Over a five-hour period, Savita Halappanavar had three recordings of an increasingly elevated heart rate documented in her healthcare record. The pulse rate recorded in Savita Halappanavar's medical note of 114 beats per minute at 19:00hrs.
Findings		The nursing/midwifery staff did not recognise the significance of these recordings along with other clinical indications as an important indicator of clinical deterioration.

Tuesday 23 and Wednesday 24 October 2012

Event	Time	Missed opportunity
7	21:00hrs – 01:00hrs	*The healthcare record indicated:* Savita Halappanavar complained of weakness. Nursing/midwifery staff contacted the senior house officer (SHO) at 21:00hrs.
Findings		When the nursing/midwifery staff caring for Savita Halappanavar contacted a non-consultant hospital doctor (NCHD), the doctor was not immediately available to come and review the patient. Given the seriousness of Savita Halappanavar's condition, the nursing/midwifery staff caring for her did not appear to have recognised the urgent need to escalate her care and request that she be reviewed by another doctor.

Wednesday 24 October 2012

Event	Time	Missed Opportunity
8, 9, 10	04:15hrs – 05:00hrs	*The healthcare record indicated:* Savita Halappanavar had a raised temperature, was shivering and had vomited.
Findings		The nursing/midwifery staff did not recognise the significance of these clinical symptoms, for example, the change in Savita Halappanavar's clinical symptoms, shivering and vomiting with a raised temperature were a sign of sepsis. Vomiting in a patient who was presenting clinical symptoms similar to Savita Halappanavar could potentially suggest sepsis[13].
11, 12	06:30hrs – 07:50hrs	*The healthcare record indicated:* There was significant deterioration in Savita Halappanavar's condition. Her temperature and pulse rate were elevated and her blood pressure was low. She was complaining of feeling weak, general body aches and had an offensive smelling vaginal discharge. The junior NCHD was contacted at 06:30hrs by nursing/midwifery staff caring for Savita Halappanavar.
Findings		The junior NCHD reviewed Savita Halappanavar, made a diagnosis of "chorioamnionitis with probable sepsis", took blood for tests and commenced intravenous antibiotics at 07:00hrs. Following this, the junior NCHD discussed her case with a more senior NCHD – however, at this time the evidence shows that her treatment plan was not changed.

Event	Time	Missed Opportunity
13	08:25hrs	*The healthcare record indicated:* Savita Halappanavar was reviewed by the consultant obstetrician in charge of her care. This review took place at her bedside as part of the consultant's daily routine ward round. Her pulse rate and temperature were elevated – additional antibiotics were prescribed by the consultant. Blood cultures and blood tests were noted as pending and a vaginal swab and a urine test were taken to be tested for evidence of infection.
Findings		Women with maternal infection can deteriorate rapidly from sepsis, to severe sepsis and then into septic shock. The doctors in charge of and caring for Savita Halappanavar, despite a diagnosis of chorioamnionitis with probable sepsis being made, did not appear to recognise the significance of this diagnosis and the continuing deteriorating clinical signs. In line with local guidelines, this should have prompted contact with a consultant microbiologist and other senior members of the multidisciplinary team, including critical care personnel who should be involved early in the process, if sepsis is suspected or diagnosed to discuss ongoing management. Entries in her healthcare record – describing her clinical status, treatment plan, and care delivered – were not all contemporaneously entered. The Investigation Team noted a number of retrospective notes (clearly labelled as retrospective notes) which were written by nursing/midwifery staff in the Savita Halappanavar healthcare record two weeks following her death. These retrospective entries were placed in various areas of the existing notes meaning that the timeline of actual events documented at the time was difficult to follow.
Outcome	13:00hrs	Diagnosis of septic shock, most likely secondary to chorioamnionitis was made.

Findings		At 13:00hrs on Wednesday 24 October the midwife/nurse working on St Monica's Ward contacted the consultant obstetrician in charge of Savita Halappanavar as her blood pressure was low, her pulse rate was elevated and she was complaining of low back pain. The consultant obstetrician reviewed the patient and noted her clinical deterioration. The consultant's impression was that the patient was suffering from septic shock most likely secondary to chorioamnionitis and subsequently discussed her case with the microbiology consultant with further instructions to administer additional intravenous antibiotics.
Outcome	14:15hrs	Savita Halappanavar was reviewed by the anaesthetic clinical staff.
Findings		The consultant obstetrician contacted the anaesthetic team to urgently review Savita Halappanavar. A High Dependency Unit (HDU) bed was not available at 14:15hrs when the anaesthetic team first reviewed Savita Halappanavar. While awaiting a HDU bed to become available, she was transferred to the operating theatre to continue her treatment and monitoring from the anaesthetic and obstetric teams. While in theatre, Savita Halappanavar spontaneously delivered her baby and placenta. She was transferred to the High Dependency Unit on Wednesday 24 October at 16:45hrs*.

Thursday 25 October to Sunday 28 October

Outcome	Savita Halappanavar's clinical condition continued to deteriorate with an increasing oxygen requirement and she was transferred to the Intensive Care Unit (ICU) at 03:00hrs on Thursday 25 October. Throughout Thursday, Savita Halappanavar continued to have a high temperature, an elevated heart rate and remained critically ill throughout Friday and Saturday. She suffered a cardiac arrest at 00:45 on Sunday 28 October 2012, and died at 01:09hrs.

* The healthcare record of Savita Halappanavar indicated that the results of blood tests taken identified a particular strain of *Escherichia coli* (*E. coli*) called ESBL-(Extended-Spectrum Beta-Lactamase) producing *E. coli*. ESBL-producing *E. coli* are antibiotic resistant and consequently make the infections harder to treat. Antimicrobial resistance is described in more detail in Chapter 12 of this Report.

4.3 Summary of findings in relation to the care provided to Savita Halappanavar and the quality of maternity services

The Authority identified, through a review of Savita Halappanavar's healthcare record, a number of missed opportunities which, had they been identified and acted upon, may have potentially changed the outcome of her care. For example, following the rupture of her membranes, four-hourly observations including temperature, heart rate, respiration and blood pressure did not appear to have been carried out at the required intervals. At the various stages when these observations were carried out, the consultant obstetrician, NCHDs and midwives/nurses caring for Savita Halappanavar did not appear to act in a timely way in response to the signs of clinical deterioration: increased heart rate, decreasing blood pressure, raised temperature with shivering and an episode of vomiting.

In summary, of the care provided there was a:

- general lack of provision of basic, fundamental care, for example, not following up on blood tests as identified in the case of Savita Halappanavar
- failure to recognise that Savita Halappanavar was at risk of clinical deterioration
- failure to act or escalate concerns to an appropriately qualified clinician when Savita Halappanavar was showing the signs of clinical deterioration.

The consultant, NCHDs and midwifery/nursing staff were responsible and accountable for ensuring that Savita Halappanavar received the right care at the right time. This did not happen. The most senior clinical decision maker involved in the provision of care to Savita Halappanavar at any given time should have been suitably experienced to interpret clinical findings and act accordingly. Ultimate accountability rested with the consultant obstetrician who was leading Savita Halappanavar's care. In addition, the clinical governance arrangements within the Hospital failed to recognise that vital hospital policies were not in use nor were arrangements were in place regarding assurance on the provision of basic patient care on St Monica's Ward.

The evidence reviewed by the Investigation Team suggests that a number of the Hospital's guidelines were not complied with. These included guidelines relating to the observation of obstetric patients through the use of a maternal early warning score chart and the management of sepsis and pre-term pre-labour rupture of membranes. While clinical guidelines and guidance are important, their use should not replace clinical judgment or the provision of basic care. Furthermore, the healthcare record documentation of Savita Halappanavar's care lacked detail in relation to her clinical status and the potential risk of clinical deterioration at identified times throughout her care pathway. In addition, the infrastructure of St Monica's Ward did not support the delivery of safe care and was not designed to effectively identify, monitor and treat patients at risk of clinical deterioration. In particular, piped oxygen was not available at seven of the 15 bed-spaces and the location of the nurses' station did not facilitate appropriate observation of all patients.

5 Findings in relation to the clinically deteriorating pregnant patient, as reflected in the care and treatment provided to Savita Halappanavar

5.1 Introduction

The Authority reviewed documentation and data received from the Galway and Roscommon University Hospitals Group. It also conducted an on-site observation at University Hospital Galway (UHG) to inform the investigation as to the arrangements in place at UHG for the provision of care to clinically deteriorating pregnant women, as reflected in the care and treatment provided to Savita Halappanavar. These findings are reported below in line with the Authority's findings of the review of the pathway of care provided to Savita Halappanavar.

5.2 Care of the clinically deteriorating pregnant patient

The Investigation Team categorised the findings associated with the missed opportunities to intervene in the care provided to Savita Halappanavar into four main themes:

- insufficient monitoring to facilitate the early identification of a clinically deteriorating maternity patient
- insufficient early intervention and escalation to and by a senior clinical decision maker and access to critical care facilities
- insufficient identification and management of maternal sepsis
- ineffective and insufficient clinical handover.

For each theme, the Investigation Team outlines its findings at local level. The Authority has made recommendations both specifically in relation to the Hospital and nationally for the purpose of wider system learning.

5.3 Monitoring to facilitate the early identification of a clinically deteriorating pregnant patient

Once a maternity patient has been admitted to hospital and has had her initial healthcare needs assessed and addressed, it is important that healthcare services have continuous assessment processes in place to facilitate the early identification of, and response to, any clinical deterioration. The most basic means of identifying any patients at risk of clinical deterioration is to observe the patient and regularly monitor and track their clinical observations. This should be a basic component of caring for such patients.

Clinical observations include observing the patient, measuring blood pressure, heart rate, temperature, rate of respiration, oxygen saturation*, level of consciousness and urinary output. The use of an early warning score to record these observations is known to assist in achieving the best outcomes for the identification and management of a patient who is clinically deteriorating.

Notwithstanding the usefulness of an early warning score, care must be provided by an effective workforce which has the composite skills and training at any given time to recognise the clinical signs and symptoms of a clinically deteriorating patient in a timely manner and initiate the appropriate treatment plan.

5.3.1 What the Authority found

In 2009, the Hospital developed a local Modified Obstetric Early Warning Score (MOEWS) chart based on the chart used in the 2007 Savings Mothers' Lives report in the United Kingdom (UK)[14]. Local guidance to accompany the use of this Modified Obstetric Early Warning Score (MOEWS) chart was also developed by the Hospital and published in July 2012. The guidance stated that this chart should be used for any maternal obstetric patients who require observation.

However, the Authority found that this guidance was not adhered to on St Monica's Ward. The Hospital's local Maternal Obstetric Early Warning chart, despite being published and operationally effective from July 2012, was not in use on St Monica's Ward in October 2012 at the time of Savita Halappanavar's care.

It is imperative that all organisations have the appropriate arrangements in place to ensure that new processes, like a MOEWS chart being introduced, is supported by training and monitoring mechanisms to ensure effective compliance. At the time of the investigation there was no apparent corporate or directorate quality

* Oxygen saturation is a measure of how much oxygen the blood is carrying as a percentage of the maximum it could carry. It is measured by a small sensor which is placed over the patient's fingertip.

assurance process to ensure that the Hospital's MOEWS chart was implemented on St Monica's Ward. This was of concern to the Authority. A well governed clinical service continuously monitors its service to ensure that the quality and safety of patient care is compliant with local and national guidance, and this appears to have not been the case in the Women's and Children's Directorate in October 2012.

It was reported during the investigation that the National Maternal Obstetric Early Warning System (I-MEWS) chart had been introduced for patients receiving obstetrics care on St Monica's Ward following an interim recommendation made on 30 November 2012 by the HSE's National Incident Management Team, in its review into the death of Savita Halappanavar. The implementation of this I-MEWS chart at the Hospital was confirmed at interview.

Notwithstanding the importance of using an I-MEWS chart, it is critical that all clinical staff involved in the multidisciplinary provision of care to maternity patients are trained in the recognition and subsequent management of a clinically deteriorating maternity patient and have a duty to perform and interpret the basic components of their role as would be expected with any patient.

5.4 Early intervention and escalation (including access to critical care)

With the increasing complexity of maternity cases, there is an increasing requirement to ensure that there is a clearly defined adequately resourced critical care pathway in place.

An early warning score is a valuable tool to support decision making in relation to the timely and effective care and treatment of a clinically deteriorating maternity patient. However, timely and effective care and treatment depends on observation of the patient with regular monitoring and recording of a patient's clinical observations, recognising their significance and the triggering of an appropriate response to abnormal clinical observations[15]. Accordingly, a clear escalation protocol is required detailing the response required by the relevant clinical grade and type of healthcare professional within the team who are deemed appropriate and clinically competent to deal with different levels of abnormal clinical measurements and observations recorded. In addition, the escalation protocol should include an accepted mechanism for other members of the clinical team to act on a significant patient safety concern that they may have relating to a patient's clinical management as directed by a senior clinical decision maker, including the consultant responsible for the patient's care.

5.4.1 What the Authority found

At the time of Savita Halappanavar's care, the maternity service did not have a formal clinical escalation protocol in place. However, at the time of this

investigation and with the implementation of the I-MEWS in November 2012, it was reported that an aligned escalation protocol is now in place across the Hospital Group.

There is a transfer protocol in place for the transfer of obstetric patients to ICU/HDU. Once the critical care team assess and accept the patient, the critical care team working in collaboration with the patient's consultant obstetrician takes overall clinical responsibility for the patient.

It was reported that maternity patients could experience a delay in accessing a HDU/ICU bed. This was evidenced, for example, in Savita Halappanavar's case where she was initially transferred to the operating theatre for therapeutic intervention while awaiting transfer to a HDU bed. In other cases, staff at the Hospital reported that a delay in accessing an ICU or HDU bed was managed by either temporarily transferring the patient to the labour ward, where midwifery staff had critical-care-specific training, or stabilising and maintaining the patient on the ward, where ward clinical staff were clinically supported by anaesthetist staff.

In 2012, there were nine obstetric patients admitted to critical care, six patients were admitted to ICU and three to HDU. It was reported at interview in February 2013 that due to an insufficient number of critical care nursing staff, three of the 12 ICU beds were closed, while all six HDU beds were open. However, at the time of the investigation, the Hospital Group had completed a successful recruitment process with the remaining ICU beds scheduled to be fully operational before the end of 2013.

At the time of the investigation there was no emergency response team in place at the Hospital. Such a team would include critical care clinicians or teams located within the Hospital who would provide initial emergency assistance at ward level in an outreach capacity. It was reported by the Hospital that it planned to have these arrangements in place before the end of 2013.

5.5 Identification and management of maternal sepsis

Mortality due to maternal sepsis has increased in the UK and is now the leading cause of direct maternal death in the UK[16]. Substandard clinical care was identified in many of these cases of maternal death from sepsis. In particular, these reports noted a lack of recognition of the signs of sepsis and a lack of guidelines on the investigation and management of maternal sepsis. Furthermore, these reports recommend that all clinical staff must undertake regular, written, documented and audited training for the identification and initial management of serious obstetric conditions or emerging potential emergencies, such as sepsis, which need to be distinguished from commonplace symptoms in pregnancy.

In April 2012, the Royal College of Obstetricians and Gynaecologists in the UK published guidelines on the recognition and management of bacterial sepsis in pregnancy[13]. The guidelines highlight that the signs and symptoms of sepsis

in pregnancy may be less distinctive than in the non-pregnant population and therefore a high index of suspicion among healthcare professionals is necessary.

5.5.1 What the Authority found

The Hospital had a guideline in place on the management of 'Suspected sepsis and sepsis in obstetric care'. This guideline covered, throughout its stages of development, the clinical identification of sepsis. However, the guideline did not include an escalation/referral pathway to include clinical, legal and ethical guidance for staff at critical clinical points. The guideline also lacked information that enabled patient consultation and consent in respect of their treatment and associated interventions.

The Investigation Team identified a number of times that Savita Halappanavar exhibited a number of clear signs of systemic inflammatory response as outlined within the Hospital guideline. These included a raised heart rate and low blood pressure which did not appear to have been promptly recognised or acted upon by the consultant, NCHDs or midwives/nurses caring for her in line with that guideline. Prophylactic antibiotic cover (Erythromycin) to minimise the risk of infection was not commenced at the time that Savita Halappanavar had a premature spontaneous rupture of membranes – antibiotic cover commenced 21 hours later. The Investigation Team is of the opinion that these were missed opportunities to intervene in her care that had they been identified and acted upon, may have potentially changed the outcome of her care.

Blood test results taken on her admission showed an elevated white cell count of $16.9x10^9$/litre (normal range in second trimester pregnancy is 6.2 – $14.8x10^9$/litre[12]). The Investigation Team reviewed the Hospital's guidelines on the management of suspected sepsis and sepsis in obstetric care which states that a white cell count of greater than $12x10^9$/litre is a sign of suspected sepsis. However, these blood tests were not reviewed by the consultant, NCHDs or midwife/nurses involved in the provision of her care, nor was there any quality control arrangements in place to ensure that a patient's blood test is followed up by the responsible clinician – this was a failure in the most basic quality and duty of care provided to Savita Halappanavar. In addition, prophalytic antibiotic therapy (erythromycin) to minimise the risk of infection was not commenced at the time Savita Halappanavar had a premature spontaneous rupture of membranes - the first dose being administered 21 hours later.

In addition, there was no evidence available to suggest that prior to October 2012, clinical staff involved in the provision of maternity care in the Women's and Children's Directorate had undergone specific sepsis training in relation to the application of this policy and/or the specific management of a maternity patient with sepsis. Similarly, it was reported at interview that there was no formal audit process in place to monitor the implementation and adherence to Hospital policies to include sepsis.

5.6 Clinical handover

It is an essential part of the care of any patient that relevant, up-to-date information relating to the patient is handed over from shift to shift and between different clinical teams and departments. This is a basic duty of care incumbent on healthcare professionals. Failure to do so can result in patients not receiving the appropriate care they require which can result in adverse outcomes for patients[17,18].

Communication at all times should follow a structured format so that there is no confusion over exactly what is required of each team or individual. Effective multi-disciplinary and multi-professional team working is an essential component of reliable, safe care and the contemporaneous transfer of information between individual professionals and teams – both documented in the notes and verbally, is essential.

5.6.1 What the Authority found

At the time of Savita Halappanavar's care, there was no formal hospital guidance in place at the Hospital regarding effective verbal handover of patients to new cohorts of staff coming on duty nor was there any hospital policy for written handovers to take place. However, even without formal guidance, this should be expected to take place as a basic duty of care by healthcare professionals for the purpose of care continuity. It was reported at interview that verbal handover was formally given by the senior house officer (SHO) on call to the consultant obstetrician each morning at the time that Savita Halappanavar was cared for on St Monica's Ward, with nursing staff on St Monica's giving a verbal handover to their nursing colleagues at the change of each shift.

For the purpose of this Report, out-of-hours is defined as hours outside of the historical core hours of Monday to Friday and between 09:00hrs and 17:00hrs. Outside of core hours, when the staff on St Monica's Ward required the on-call obstetric team to review Savita Halappanavar, the practice was to initially page the senior house officer (SHO). The SHO is a junior team member, usually with less than two years' obstetrical experience. If the SHO required a more senior clinical decision maker, the SHO would then contact the on-call obstetric registrar. If the senior clinical decision maker, as was evidenced in the case of Savita Halappanavar, was unavailable because of other clinical commitments to clinically review the patient, the SHO would, for example, communicate the clinical details over the telephone.

It was reported at the Coroner's inquest and in the HSE's incident investigation into the death of Savita Halappanavar that there was disparity in staff's recollection of what was communicated and what was heard at that time of her care in relation to her clinical symptoms, particularly her lowered blood pressure recording[19]. The Investigation Team is of the view that the implementation of a structured communication process may have averted such a discrepancy. It was

subsequently reported that the Hospital Group had introduced the ISBAR tool at the end of 2012 to facilitate communication and to be used as the basis for clinical handover. The ISBAR tool structures the communication process under five headings:

1. I – Identify yourself.
2. S – Situation.
3. B – Background.
4. A – Assessment.
5. R – Recommendation.

It was too early for the Authority to assess the implementation and impact of this tool.

At the time of the investigation, it was reported that formal consultant ward rounds took place each day in the maternity service with a multidisciplinary clinical handover taking place verbally at the change of each shift in the maternity unit at the Hospital. It was reported that consultant teams meet with the on-call SHO and registrar before they go off duty on the labour ward each morning (Monday to Friday). At this time the on-call team update the consultant and his/her team on the status of their patients.

Each evening (Monday to Friday) the consultants' team hand over their patients to the team on call for that night. Weekend cover arrangements include the consultant on call conducting a full ward round including all maternity and gynaecological patients.

These arrangements were further explored by the Investigation Team while on site at the Hospital. The findings from interview raised concerns in relation to the robustness of these clinical handover arrangements with some staff identifying that the full clinical team complement was not always available at handover time. Others reported that midwives participated in consultant-to-consultant only and registrar-to-registrar only clinical handovers. This is of concern to the Authority as this may mean that the full team caring for a patient may not be fully informed of a patient's condition and treatment plan.

5.7 Summary of findings in relation to the clinically deteriorating pregnant patient, as reflected in the care and treatment provided to Savita Halappanavar

In examining the care and treatment provided to Savita Halappanavar and clinically deteriorating pregnant patients, the Authority has identified a range of concerns regarding deficits in the most fundamental aspects of clinical care. Key among these findings was the fact that despite the endorsement and dissemination of key protocols within the Hospital Group on the use of an early warning score and the identification and management of pregnant women with developing sepsis,

'Suspected Sepsis and Sepsis in Obstetric Care', it was clear that these protocols were not in use on St Monica's Ward at the time of Savita Halappanavar's care. This finding is indicative of a failure in clinical governance arrangements within the Hospital Group.

At the time of the investigation, the Authority acknowledges that a number of key policies, protocols and practices have been put in place at the Hospital since the death of Savita Halappanavar to ensure the identification and subsequent care of clinically deteriorating pregnant patients.

The preceding sections of this Report outline a series of missed opportunities in relation to the care provided to Savita Halappanavar and conclude that it would have been expected that clinical staff involved in her care should have had the skills, knowledge and expertise to recognise the signs of clinical deterioration as a result of developing sepsis.

In examining the case of Savita Halappanavar the Authority identified a lack of safe and basic care manifested by:

- a failure to follow up on diagnostic blood tests and act on results
- generalised failure in the routine monitoring of patient observations, detection and recognition of clinical deterioration and of the signs of developing sepsis
- a failure to recognise and manage the risks associated with spontaneous rupture of membranes and inevitable miscarriage in the second trimester of pregnancy and, additionally, the relationship of such events with the risk of sepsis
- poorly documented patient healthcare records with little evidence of comprehensively documented care planning
- ineffective communication of vital clinical information through clinical handover and the absence of arrangements in place to ensure that that relevant up-to-date information was handed over between different clinical teams
- failure to escalate and involve other relevant clinical specialties in a timely way
- compromised organisational governance arrangements manifested by:
    - an absence of formal staff training on the recognition and management of sepsis and the clinically deteriorating obstetric patient
    - failure to implement and adhere to Hospital policies and guidelines
    - absence of formal quality assurance arrangements in place to ensure Hospital policies/guidelines were adhered to
    - absence of a formal clinical escalation pathway in place
    - failure to adequately maintain a healthcare record that reflected the plan of care and care received.

The Authority has made recommendations in respect of these findings.

6 Findings in relation to the maternity services at University Hospital Galway

During this investigation, the Authority identified other concerning aspects in relation to the care that may be provided to pregnant women at University Hospital Galway. These are related to patient access arrangements, patient healthcare record management and workforce. These findings include and extend beyond the pathway of care provided to Savita Halappanavar.

This chapter of the Report describes the Authority's findings and recommendations for improvement in relation to these arrangements. While these are local findings, the recommendations have national applicability for the provision of care in line with best practice across the other 18 public maternity hospitals/ units in Ireland.

6.1 Access arrangements for any pregnant woman attending University Hospital Galway

The Authority identified weaknesses in the access arrangements relating to the care pathway of any pregnant woman attending the Hospital, not directly reflected in the care pathway of Savita Halappanavar. The Authority was of the view that these aspects of the care pathway need to be addressed locally and that all maternity services nationally should consider these findings in light of the services they provide in order to support the delivery of an equitable service where all service users have access to the right care and support at the right time, based on their assessed needs.

6.2 Pathways and environment

The Investigation Team reviewed the patient pathway for pregnant women, booked* and unbooked, attending the Hospital as an emergency during core hours and outside of core hours to determine the access arrangements in place.

* The term 'booked pregnant women' is used to describe pregnant women who have attended their first antenatal appointment, while the term 'unbooked pregnant women' is used to refer to pregnant women who have not attended their first antenatal appointment, as reflected in documentation received from University Hospital Galway.

6.2.1 Core hours

For the purposes of this Report, historical core hours are defined as Monday to Friday and between 09:00hrs and 17:00hrs. During core hours these patients attend the Hospital's Maternity Admissions Department, where the Hospital's obstetric medical chart is used. Patients are initially reviewed by a senior midwife and obstetric senior house officer and referred to the obstetric registrar or consultant on call if necessary. If maternity patients require inpatient admission then patients over 20 weeks' gestation are admitted usually to the antenatal ward or labour ward and maternity patients under 20 weeks are admitted to the gynaecology ward.

6.2.2 Outside core hours

In reviewing the minutes of meetings and as reported at interview, there appeared to have been prolonged discussions between Hospital maternity staff and staff of the Emergency Department at the Hospital in agreeing an out-of-hours pathway for a maternity patient attending as an emergency. In September 2012 the Women's and Children's Directorate in the Hospital identified risks to patients who presented out of hours to St Monica's Ward and proposed that all such patients were seen and triaged in the Emergency Department. At the time of the investigation, a memorandum issued by the Women's and Children's Directorate on 4 November 2012 stated that from 5 November 2012 unbooked maternity and gynaecology patients were to be initially assessed in the Emergency Department by the on-call obstetric SHO. Staff from the Emergency Department suggested that they did not have the appropriate infrastructure in the context of privacy to carry out, for example, a vaginal examination. Consequently and following the SHO's initial assessment, the patient may have to be transferred to an examination room located on the gynaecology ward (St Monica's). The distance between the two areas was estimated to take 10 minutes by wheelchair.

The Investigation Team was concerned about an arrangement that necessitated a patient being transferred 10 minutes by wheelchair for a clinical examination, which was unsatisfactory and contrary to the notion of a seamless patient-centred service and an avoidable risk in the patient's pathway. It was reported that the Emergency Department was to undergo refurbishment.However, at the time of reporting there were no definite timelines for completion. The Authority was concerned that such a patient-centred risk required discussions between clinical teams over a prolonged period of time and that these access arrangements remained a live issue under review for the duration of this investigation, as evidenced in the minutes of the Women and Children's Directorate meetings as late as April 2013.

When implementing any revised patient pathway, or indeed any change process, it is imperative that all relevant stakeholders are informed about and understand the change. It was of concern to the Investigation Team that the pathways for booked and unbooked maternity patients presenting as an emergency both during

and outside of core working hours were not formally documented by the Hospital. It was also apparent from group interviews and during the observation process that there was confusion amongst clinical staff regarding the exact pathway for these different patient presentations. It was also not evident that clear information was available to general practitioners (GPs) or pregnant women and their families regarding these pathways and how they can refer a patient or how a patient self referring can access care should they become acutely ill.

6.2.3 Antenatal access

Up until 5 November 2012, as in the case of Savita Halappanavar, maternity patients who were less than 20 weeks' gestation and gynaecology patients attending as an emergency were admitted directly to the gynaecology ward, St Monica's Ward.

Best practice guidelines for antenatal care recommend that all antenatal patients should be seen at 10 weeks and have an ultrasound scan carried out to determine gestational age and detect multiple pregnancies between 10 and 14 weeks' gestation[20]. Any delay in this could potentially lead to a later risk assessment in pregnancy and consequently to problems both for the mother and baby manifesting later in pregnancy.

It was initially reported to the Investigation Team that maternity patients have their first antenatal visit where they are seen by their named consultant obstetrician and have their ultrasound at 20 weeks' gestation. However, the timeframe of 20 weeks was subsequently reported in June 2013 as having been met and that all antenatal patients were now having their initial antenatal visit and ultrasound at 12 weeks' gestation.

The Investigation Team reviewed the key performance indicator reports submitted as evidence by the Hospital which showed that in May 2013 the Women's and Children's Directorate reported that only 24% of women who had an anomaly scan in March 2013 had also received an early ultrasound scan at the Hospital. Hospital staff reported at interview that all antenatal patients have their first ultrasound scan at 12 weeks. The Authority was unable to ascertain what the situation was at the time of the investigation and recommends that the Hospital ensures all antenatal patients are seen and have their first ultrasound before 10 to 14 weeks' gestation.

The Authority acknowledges the choices offered to pregnant women at UHG whereby following the first antenatal visit, the pregnant woman's antenatal care can be jointly managed by their general practitioner (GP) and consultant obstetrician. Alternatively, maternity patients at the Hospital can choose to attend a midwife-led antenatal clinic. In 2012, 27.7% of all antenatal patients attended the midwives' outpatient antenatal clinic. It was reported that these numbers will increase in 2013 with an outreach midwives' clinic having reopened in Gort, County Galway, in November 2012.

Maternity patients considered at risk of complications during their pregnancy, for example, patients with diabetes, with a history of previous maternity complications or multiple pregnancies, attended high-risk antenatal outpatient services at the Hospital. It was reported that, when appropriate, these patients were jointly managed by their obstetrician and other in-house clinical specialities. This inter-specialty approach was evidenced in a number of the patient's healthcare records which were reviewed by the Investigation Team.

In the 2007 Safer Childbirth report (UK), it was recommended that guidelines should be available to obstetricians and midwives on conditions requiring antenatal referral to the obstetric anaesthetist, and a system should be in place to ensure that any such referral happens in a timely fashion[21]. At the time of the investigation it was reported that the Clinical Lead for Obstetric Anaesthesia Services ran a weekly high-risk antenatal clinic. However, there were no detailed referral criteria for this clinic, rather the Clinical Lead worked directly with the outpatient nurse-in-charge. The Authority acknowledges the commencement of this service but is concerned that the quality and safety of the services provided to high-risk obstetric patients may be compromised by the informal arrangements described above.

6.2.4 Access to obstetric ultrasound

In the Hospital, both routine and emergency obstetric ultrasound scans are completed by the Hospital's Scanning Department located close to the Early Pregnancy Assessment Unit. The Investigation Team found that there was limited access to obstetric ultrasound scanning out-of-hours at the Hospital. At the time of the investigation two of the six registrars working at the Hospital were reported as having received the appropriate training in ultrasound scanning.

It was reported that if an emergency scan is required out-of-hours, then the registrar on duty (if appropriately qualified) will perform it. If the registrar has not completed sufficient ultrasound training then the on-call consultant will be contacted to perform the scan. For the patient this would mean that if they required an ultrasound out of hours and the on-call registrar was not trained to perform it, then the patient would have to wait for a consultant to be called in to perform the scan. Minutes of the meeting of the Women's and Children's Directorate of April 2013 indicated that access to ultrasound scanning outside of core hours remained an issue. However, the Directorate did not identify how it planned to address the issue or what actions it was taking to mitigate any associated risk.

It is recognised that the use of emergency ultrasound imaging in the pregnant patient is appropriate in certain clinical situations such as where there is a suspected ectopic pregnancy or major ante partum haemorrhage. Ultrasound imaging enhances a clinician's ability to evaluate, diagnose and treat emergencies in a timely and focused manner and its use should be considered optimal for patient care. It was reported that training in ultrasound is not a core component of

the national curriculum for obstetrics and gynaecology registrar training provided at the Hospital. Because the most senior on-site clinician outside core hours is at registrar level, the Authority is concerned that this deficit may potentially compromise the evaluation, diagnosis and subsequent timely management of an ill obstetric patient or patients with other obstetric complications. The Authority was of the opinion that ultrasound imaging is within the scope of practice of obstetricians and gynaecology registrars and that this should be considered an essential skill locally and nationally before appointment to a registrar post.

6.3 Healthcare records management

Healthcare professionals require access to all relevant information about the patient at the point of clinical decision making in order to make the most informed decision regarding the patient's clinical condition. Therefore, the effective completion and management of healthcare records* is essential in ensuring that all relevant parts of the healthcare record are up to date, sufficiently detailed, accurate and available in a timely and appropriate manner at these critical points of clinical decision making and this is the responsibility of healthcare professionals.

The Investigation Team carried out a review of selected healthcare records to review the quality and safety of services specifically in relation to arrangements around the clinical care of critically ill patients. This care encompasses the diagnosis and management of patients with sepsis, timely response to diagnostic test reports and the structure of the clinical handover system. The healthcare records of 16 medical, surgical and maternity patients who had been cared for between 2011 and 2012 and where sepsis was identified as a contributory factor in their diagnosis were selected for review. The Authority recognises that the volume of charts selected for review is small and that the healthcare record review did not involve a consistently representative sample of the healthcare records of all patients at UHG.

6.3.1 Healthcare record review findings

The Investigation Team found the maternity healthcare records to be cumbersome and the chronology of events was difficult to follow. Clinical entries were dated but rarely timed and the clinician's job title was not always documented. Therefore the Investigation Team could not adequately assess the arrangements in place for the clinical care of critically ill patients, such as timeliness of clinical review, the level of senior clinical decisions and the timeliness of review and transfer to ICU/HDU.

A gynaecological-specific healthcare record was used for all unbooked maternity patients on St Monica's Ward. As in the case of Savita Halappanavar, an obstetric

* Healthcare records refer to all the information in both paper and electronic formats relating to the individual care of a patient or service user. This includes (but is not limited to) demographics (such as name, address, date of birth), medical history, social history, findings from physical examination, X-rays and specimens, the results of diagnostic tests, prescriptions, procedures and all communication relating to the care of the service user.

chart was used for all booked maternity patients. This was a multidisciplinary chart which meant that all clinical disciplines documented notes on the same page. The Authority supports the use of a multidisciplinary healthcare record provided that all entries are documented, signed, dated and entered appropriately and contemporaneously. However, the Authority found during its review of healthcare records at UHG that some signatures and titles were illegible, the healthcare records were difficult to follow and were not always in chronological order.

It was also reported that pregnant women booked at the Hospital do not carry their own obstetric healthcare record for the duration of their antenatal care at the Hospital. It was noted that this practice differs across the Galway and Roscommon University Hospitals Group given that the maternity patients at Portiuncula Hospital Ballinasloe do carry their own healthcare record. This inconsistency across the Hospital Group was of concern to the Authority which recommends that a standardised practice in relation to healthcare record management be in place across the Hospital Group.

Furthermore, the Authority was of the view that this practice of maternity patients carrying their own obstetric chart throughout their antenatal care should be standardised across all 19 public maternity units. This would facilitate patient and staff communication and help significantly with both the transfer of patients throughout the country and patients presenting as an unexpected or emergency attendance at emergency departments in other hospitals. Additionally, international standards in maternity services also recommend this practice as it provides an opportunity for women to be 'partners in maternity care' and to inform parents and share information[20,22,23].

The Investigation Team reviewed minutes from the Hospital from June 2012 and found that the Women's and Children's Directorate had identified a risk in the administration of an anaesthetic to gynaecological and/or obstetric patients without having full knowledge of their medical history, as a result of the patient's healthcare record not always being available. This was further explored at interview where staff outlined the difficulties and delays in accessing patient healthcare records, particularly outside office hours. This represents a most basic and dangerous gap in the provision of safe care for patients. In addition, staff reported that the room used to store patients' healthcare records was located in the basement and was not suitable as it was prone to flooding and had insufficient space. On exploring this further, the Investigation Team identified that no interim arrangements had been put in place to mitigate these identified risks.

The HSE's *Standards and Recommended Practices for Healthcare Records Management* are intended to define correct healthcare records management and promote service-user safety and apply to both the general and maternity healthcare records[24]. The HSE's recommended practice includes a National Maternity Healthcare Record. The development of this National Maternity Healthcare Record followed recommendations made in the report of the Lourdes Hospital Inquiry in 2006. It was evidenced in the healthcare records reviewed at

University Hospital Galway, and was reported at interview, that the Directorate had consciously decided not to implement the National Maternity Healthcare Record as it planned to introduce an electronic patient record during 2013. The date for roll-out of the electronic patient record was not confirmed at the time of reporting. It was subsequently reported by the HSE that the National Maternity chart is being introduced to University Hospital Galway and will be completed by the end of 2013.

At the time of the investigation, it was reported that only 5 of the 19 maternity hospitals/units had implemented the National Maternity Healthcare Record. This inconsistency across maternity services nationally raised concern for the Authority, which recommends that a standardised practice in relation to healthcare record management should be in place across all maternity services in order to improve documentation, communication and patient safety.

6.4 Maternity Services Workforce – University Hospital Galway

6.4.1 Clinical leadership within the Women's and Children's Directorate in University Hospital Galway

The maternity services at the Hospital are part of the Women's and Children's Directorate, within the Galway and Roscommon University Hospitals Group. The Clinical Director of the Directorate is a consultant obstetrician. The 2008 consultants' contract sets out that the primary role of a clinical director is to deploy and manage consultants and other resources, plan how services are delivered, contribute to the process of strategic planning and influence and respond to organisational priorities[25]. The Clinical Director of the Women's and Children's Directorate continued a full clinical commitment and receives payment for three additional sessions (1.5 days) to fulfil the role of clinical director.

At the time of the investigation, it was reported at interview that this arrangement worked well and that the Clinical Director did not have difficulty managing this additional workload. However, the Authority was of the view that the arrangements within the Hospital in respect of the allocation of clinical sessions for the Clinical Director of the Women's and Children's Directorate were not conducive to the achievement of strong leadership and management at this critical time. In subsequent information provided by UHG in September 2013, it was reported that the Hospital Group was in the process of redefining the role of the group-wide Clinical Director for the Women's and Children's Directorate. It was reported that this Post will have 50% protected time for the Directorate/managerial business and a 50% backfill arrangement in place to maintain clinical service provision. This is in line with HSE national guidance with regards to the appointment of clinical directors, which was published in June 2012[26]. The Authority considers this as a positive development.

6.4.2 Consultant obstetricians in University Hospital Galway

At the time of the investigation there were seven permanent consultant obstetricians and gynaecologists working at University Hospital Galway, which equates to five whole-time equivalents and two consultants holding joint clinical and academic posts at the Hospital and National University of Ireland, Galway. There were also 15 non-consultant hospital doctors (NCHDs) in the Maternity Unit: three specialist registrars, three registrars, eight senior house officers (SHOs) and one intern in obstetrics and gynaecology (see Table 4 below).

Table 4: Consultants and NCHD staff at University Hospital Galway as of January 2013

Consultants and NCHDs in obstetrics and gynaecology UHG	Number of staff	Number of whole-time equivalents(WTE)
Consultants in obstetrics and gynaecology	7 as follows: ■ 3 full-time permanent ■ 3 part-time permanent ■ 1 part-time temporary	5
Specialist registrars	3	3
Registrars	3	3
Senior house officers	8	8
Interns	1	1

6.4.3 Consultant obstetrician's on-call

Outside of core hours, medical care was provided by one obstetric registrar and one senior house officer. It was reported that the majority of patients outside of core hours would initially be clinically assessed by the midwifery staff and senior house officer (SHO) and then referred to the registrar. However, staff recounted that there could be delays in the patient being seen by the obstetric registrar given that they could be working in, and unable to leave, the labour ward or the emergency theatre. In these circumstances it was reported and evidenced in the case of Savita Halappanavar that the SHO would contact and update the registrar of the patient's condition by phone and take any subsequent instructions from them.

There is a consultant obstetrician assigned to be on call for obstetrics and gynaecology from home. It was reported that before leaving the Hospital that the on-call consultant would call to each clinical area for an update on any clinical

concerns or new admissions. All staff reported that they would readily contact the on-call consultant if they had any concerns in relation to a patient's clinical condition. At the time of the investigation, there was no formal guideline in place at the Hospital to direct staff as to when it was appropriate to contact the on-call consultant obstetrician. Such guidelines would provide all staff, and particularly assist less experienced staff, with a clear pathway of referral to ensure patients are seen by a senior clinical decision maker in a timely manner and with clear guidance as to when a senior clinical decision maker should be contacted at any time. In addition, it would potentially facilitate the Hospital to audit the efficacy of the referral processes.

The Authority supports the HSE incident investigation recommendation that 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)[27] should be developed, implemented and compliance with them audited. In July 2013, the Hospital reported that it was working with the HSE national implementation team to agree a national approach to this recommendation and that a local policy would be generated for implementation at the Hospital within a time frame of six months.

The Authority recommends that interim arrangements are put in place to ensure that patients are seen by the senior clinical decision maker in a timely manner and that contingency arrangements are in place to support a more junior doctor when a registrar is unavoidably delayed.

6.4.4 The labour ward in University Hospital Galway

The labour ward is a critical location for the pregnant patient and this area must involve direct supervision and care by consultant staff and have 24-hours seven-days-a-week senior midwifery cover. It was reported that the consultant obstetricians conducted morning ward rounds in the labour ward. The labour round primarily consisted of the midwife and on-call obstetric registrar verbally updating the consultant on the clinical status of their patients in the labour ward – this update did not always include the consultant going to see each patient at that time.

In addition, the Authority found that consultants on call for the labour ward were not solely dedicated to the labour ward for that session. It was noted that they also may be running outpatient and private and public antenatal and postnatal clinics or in theatre when they were on call. However, maternity staff reported that all these services were in close proximity to the labour ward and that this arrangement was not problematic in that the other consultants responded quickly to being called when the on-call consultant was not immediately available. Obstetric registrars would contact the labour ward periodically throughout the day either in person or by telephone for updates on the progress of women on the labour ward.

Notwithstanding these arrangements, the labour ward is the highest risk area in obstetric care and the practice of the consultant obstetrician not being physically present on the labour ward – but rather engaged in other clinical activities – is at variance with recommendations from the UK's Royal College of Obstetrics and Gynaecologists' report, *Safer Childbirth: Minimum Standards for the organisation and delivery of care in labour*[21]. The Authority acknowledges the absence of nationally endorsed guidelines on maternity services workforce in Ireland. Therefore, the Investigation Team references the UK's Safer Childbirth Report as a framework which has the potential to be used as an opportunity to inform improvements in the quality and safety of maternity services' provision in Ireland.

In addition, it is important that every opportunity to train and develop junior medical and midwifery staff competencies in obstetrics is availed of and that junior doctors are supervised by senior consultant staff at every opportunity. The labour ward is the optimum environment for this to happen.

The Authority did not formally review the matter of consultant presence and the availability and or frequency of on-site simulation programmes, in all 19 maternity hospitals/units but information reported throughout the investigation would suggest that there is varied practice across the 19 units. The Investigation Team was concerned that in the absence of complete information on consultant labour ward cover and on the levels and quality of on-site training and support across the country, there may be a potential risk to the quality and safety of care received by women in these maternity services.

At the time of the investigation, it was reported that there were no formal skills training or simulation programmes (for example PROMPT – Practical Obstetric Multi-professional Training, skills and drills) in place to assess the clinical, communications and multidisciplinary team-skills competencies functioning in the maternity services. However, it was subsequently reported that multidisciplinary team members had attended PROMPT training.

6.4.5 Midwifery staffing in obstetrics and gynaecology in University Hospital Galway

From data reviewed by the Authority, and from interviews with the Hospital's managerial and clinical staff, the Authority confirmed that maternity services were staffed with qualified midwives. At the time of the investigation, there were approximately 150 staff with midwifery qualifications working at the Hospital. The Hospital is affiliated to the National University of Ireland and provides on-site clinical placements to 32 student midwives also working at the Hospital. These midwives and students provide care on the labour ward, gynaecology ward (St Monica's), antenatal ward (St Catherine's) and the postnatal ward.

Young, fit, pregnant women have significant physiological reserve, which disguises the early warning signs of illness. Therefore, pregnant women can appear to remain well until quite late into the clinical deterioration process[28]. Consequently, the Investigation Team explored the arrangements in place on the labour ward,

as a high-risk area, and St Monica's Ward where Savita Halappanavar was an inpatient, to ensure the midwifery/nursing staff had the appropriate skills and competencies to care for pregnant, postnatal and clinically deteriorating maternity patients and to assess what workforce arrangements were in place to respond to surges in clinical activity or increased patient acuity.

Qualified midwives worked in the labour ward with a senior midwife in charge of each shift. In addition to the delivery suites, and at the time of the investigation, on the labour ward in the Hospital there was a dedicated room for pregnant women who require a higher level of nursing care than usual in order to receive one-to-one midwifery care.

Such women included those who:

- have experienced a very large amount of bleeding during their pregnancy or after delivery
- experience very high blood pressure during their pregnancy and require administration of certain drugs directly into their bloodstream to control this
- require their blood pressure to be monitored very closely using a line placed directly in their blood vessel.

It was reported that 44 women required this type of care on the labour ward in 2012. Midwives caring for these patients receive training from critical care educators at the Hospital. It was reported that it was mandatory for these midwives to complete this training on an annual basis. However, it was also reported that approximately 70% of them had completed it over the last two years. The Investigation Team was informed that nursing staff rosters were managed to include the presence of midwives trained to care for high dependency patients at all times. It is imperative that all staff working in the labour ward are competent to manage all patients in their care.

6.4.6 St Monica's Ward, University Hospital Galway

The gynaecology ward (St Monica's) had 15 inpatient beds with four trolleys allocated for day cases. St Monica's Ward included a nurses' station, a clinical examination room, and an ultrasound scan room. This environment did not support the delivery of safe care and was not designed to effectively identify, monitor and treat patients at risk of clinical deterioration. In particular, piped oxygen was not available at seven of the 15 bed-spaces and the location of nurses' station did not facilitate appropriate observation of all patients.

As previously identified, the Investigation Team found St Monica's Ward was used as an overflow to accommodate antenatal and postnatal patients when the ante and post natal wards were full. Consequently, the casemix of patients accommodated on St Monica's Ward and their care needs were significantly diverse. It was reported that patients cared for on this ward included post-operative gynaecology patients, gynaecology oncology patients (excluding patients

receiving chemotherapy), women receiving fertility treatments, antenatal patients up to 20 weeks' gestation, and on occasion antenatal patients over 20 weeks' gestation and postnatal women and their babies. It was reported that all nursing staff caring for patients on this ward were qualified midwives.

However, it was also reported that although the nursing staff had midwifery qualifications they may not have actually worked in the antenatal, postnatal or labour ward environments for many years. This could potentially mean that, in the absence of a continuous professional development and competency-based maternity care learning, these staff may not have maintained their midwifery competencies and therefore may not have been suitably experienced to provide the appropriate type and level of care required to best meet the needs of the diversity of patient mix, including the recognition of a clinically deteriorating pregnant patient.

The HSE reported that at the time of Savita Halappanavar's care the wards on which she was cared for at University Hospital Galway had been adequately staffed and no consultant obstetrician was on leave. On St Monica's Ward, the staff numbers per shift on average ranged from four nurses in the day time, three nurses in the evening, and two nurses at night time. There was a senior nurse in charge on each shift. It was reported that a ward attendant was available on some of the shifts. It was also reported that as a result of the national staffing moratorium, there were three staff vacancies since 2012, primarily related to maternity leave.

At interview and in the group meetings between UHG staff and the Investigation Team, staff reiterated the challenges associated with the staffing embargo and the high levels of maternity leave requiring replacement at the Hospital. It was reported that the Assistant Director of Nursing in charge of the Maternity Unit reviewed the staffing levels per shift and allocated additional staff if required. However, it was also reported that there were not always additional staff readily available to re-allocate to St Monica's Ward.

At the time of the investigation, maintaining adequate nurse staffing levels on St Monica's Ward remained an issue of concern at the Hospital. The Group Executive Council meeting of March 2013 identified the staffing shortage relating to maternity and sick leave as an operational issue, particularly in the context of opening additional gynaecology day beds. The minutes of the Executive Council Group meeting indicated that the issue was being monitored by the Nurse Management team. The following month, in April 2013, the staffing shortage was identified as a safety concern, with plans to continue to monitor any associated risks.

The Investigation Team reviewed the April, May and June 2013 reports of the Women's and Children's Directorate which had been sent to the Executive Council Group. These identified a nurse staffing shortage of approximately seven whole-time equivalents (WTEs).

On 16 July 2013, the Authority wrote to the Chief Executive of the Hospital requesting the details of the assurances and measures currently in place to ensure the safety and quality of services on St Monica's Ward (see Appendix 8). On 19 July 2013, the Hospital replied to the Authority detailing that nursing staff levels on St Monica's Ward were being monitored daily by both the Assistant Director of Nursing and Midwifery and the Director of Nursing and Midwifery. In addition, the Hospital reported that the Women's and Children's Directorate Team was monitoring the situation at its team meeting on a weekly basis. The Hospital reported that when service demand required additional staff support the following measures were taken: redeployment from other areas in the Hospital to St Monica's Ward, engagement of agency staff when necessary and the sanctioning of overtime to supplement staffing needs as required (see Appendix 9).

The Investigation Team explored the arrangements in place at the Hospital to ensure that staff competencies were being maintained. Ward staff reported a good attendance rate at mandatory training which included basic life support and infection prevention and control. The Clinical Nurse Manager maintained a record of attendees. Following the death of Savita Halappanavar, the Hospital had reviewed its training, supporting guidelines and local recommendations in relation to the recognition and management of a clinically deteriorating patient and had implemented changes which included formal training and the use of early warning scores (to detect the clinical deterioration of maternity patients).

At the time of the investigation, midwifery and nursing staff did not rotate between clinical areas. A rotation scheme enables midwives/nurses, through experiential learning, to maintain their clinical competencies. For example, a midwife could work in a labour ward to enhance their midwifery competencies. The Hospital Executive and clinical staff reported at interview that there were plans in place to rotate midwifery staff through the various wards at the Hospital as a means of keeping their acute care and midwifery competencies up to date. It is of concern to the Authority that during the period of the investigation, this rotation practice had not yet been implemented at the Hospital.

In addition and as outlined above, the response received from the Hospital on 19 July 2013 in relation to staffing arrangements on St Monica's Ward indicated that staff may be redeployed to St Monica's, or agency staff recruited to the ward, when service demand required. The Authority recommends that this redeployment or use of agency staff must be cognisant of, and meet the needs of, the complexity and diversity of patient casemix on St Monica's Ward. Accordingly, in redeploying staff or allocating agency staff to St Monica's Ward, the Hospital must ensure that these staff have the necessary skills and competencies to care for this complex caseload.

6.4.7 Critical care workforce, University Hospital Galway

As part of the Terms of Reference the Authority also reviewed the safety, quality and standards of services provided by the HSE at the Hospital to both general patients and pregnant women at risk of clinical deterioration.

A key step involved in the care for any clinically deteriorating patient, be they pregnant or not, is the early notification and involvement of the local critical care team.

In reviewing the care of Savita Halappanavar, it was evident that once the critical care team was notified, they immediately reviewed her and were then actively involved in the management of her care. However, the Authority identified through a review of her healthcare record – and confirmed at interview – that the original referral to the critical care team was at a late stage in her clinical deterioration.

The critical care workforce at the Hospital delivers care to both pregnant and general patients. The Directorate responsible for the delivery of critical care is called the Theatre Anaesthetics and Critical Care Directorate. There were 23 consultant anaesthetists working in the Theatre Anaesthetics and Critical Care Clinical Directorate who covered both University Hospital Galway and Merlin Park University Hospital, both located in Galway City.

Of these 23 consultant anaesthetists, three had completed additional training in obstetric anaesthesia and three of the 23 consultant anaesthetists had also completed additional training in paediatric anaesthesia.

6.4.8 On-call arrangements, anaesthesia, University Hospital Galway

Within maternity services there is a need to recognise that emergencies happen frequently and often with rapidity, with a requirement to respond quickly in order to save mothers' or babies' lives. The Association of Anaesthetists of Great Britain and Ireland and the Obstetric Anaesthetists' Association (OAA/AAGBI) recommended in its 2005[29] and 2013[30] guidelines that a duty anaesthetist should be immediately available for the delivery suite 24 hours-per-day and that there should be a clear line of communication from the duty anaesthetist to the supervising consultant at all times*.

At the time of the investigation, anaesthetic on-call cover in the Hospital consisted of three non-consultant hospital doctors (NCHDs) on site. This consisted of:

- one junior NCHD who covers general theatre, obstetric theatre and labour ward (primarily for patients requiring epidurals)

* The term 'duty anaesthetist' denotes an anaesthetist who has been assessed as competent to undertake duties on the delivery suite under a specified degree of supervision.

The duty anaesthetist should be immediately available to attend the obstetric unit 24 hours-per-day, and must therefore have no other responsibilities outside obstetrics. In all units offering a 24-hour epidural service, the duty anaesthetist must be resident on site.

- one registrar who covers the Intensive Care Unit (this registrar acts as the link doctor for all deteriorating patients in the Hospital)
- one on-call senior registrar who covers all areas
- a fourth NCHD on call for orthopaedic trauma who is scheduled to work until 10pm.

There were three consultant anaesthetists on call out-of-hours in the Hospital. These consultants are not on site. This means that if a patient becomes acutely ill and requires consultant-provided care, then the consultant would be paged/ telephoned and requested to come in to the Hospital.

This consultant on-call cover consisted of:

- one consultant who covered general theatre (one general theatre is run at night and frequently two at the weekend) and the Women's and Children's Directorate (labour ward)
- one consultant who covered orthopaedic trauma (one orthopaedic trauma theatre is run at night and two at the weekend)
- one consultant who covered the Intensive Care Unit.

While anaesthetic availability for the labour ward during core hours was reported as being essentially immediate in that the location of the gynaecology theatre was in very close proximity to the labour ward, it was reported that there was no consultant anaesthetist dedicated solely to the labour ward either during core working hours or on call periods. It was also reported that the consultant on call for orthopaedic trauma would only very rarely be called in to the Hospital mid-week and more frequently at weekends as this was when the majority of orthopaedic emergency cases occurred. The Investigation Team queried the effectiveness of this roster arrangement and whether arrangements could be made to redeploy consultant cover, particularly to obstetric care. It was reported that discussions had taken place within the Theatre Anaesthetics and Critical Care (TACC) Directorate in relation to changing this rota. However, a solution had not been reached at the time of the investigation.

The Safer Childbirth Report recommends that for any obstetric unit there should be 10 consultant anaesthetic programmed activities or sessions per week (that is five days), to allow full 'working hours' of consultant cover[21]. This was increased to 12 consultant anaesthetist sessions allocated for every maternity unit in the OAA/AAGBI's 2013 guidelines[30].

In addition to this, the Safer Childbirth Report recommended that there should be a separate consultant anaesthetist for each formal elective Caesarean section list and additional clinical time should be made available each week for antenatal referrals, especially when a formal clinic is provided[21]. The Hospital has a clinical lead for obstetric anaesthesia services, who is a consultant anaesthetist. This clinical lead has one session (a half day) dedicated to the labour ward. This session is primarily educational in nature.

6.5 Summary of findings in relation to maternity services at University Hospital Galway

The Investigation Team reviewed the patient pathway for pregnant women, booked* and unbooked, attending the Hospital as an emergency during core hours and outside of core hours to determine the access arrangements in place. The Authority found that the care pathway for patients who required routine access during core hours to maternity services, including access to ultrasound, was not always timely or appropriate. Best practice guidelines for antenatal care recommend that all antenatal patients should be seen at 10 weeks and have an ultrasound scan carried out to determine gestational age and detect multiple pregnancies between 10 and 14 weeks' gestation. The Authority was unable to clarify if antenatal patients were receiving timely access to maternity services in line with best available evidence. In addition, there was no formal clinical pathway in place to refer high risk obstetric patients to the antenatal high-risk service operated by an obstetric anaesthetist.

The care pathway for patients who required emergency access to maternity services outside core hours, including access to assessment in the Emergency Department, ultrasound, and clinical examination, was not always appropriate and effective. The Women's and Children's Directorate identified risks to patients who presented out of hours to St Monica's Ward and proposed that all such patients were to be seen and triaged in the Emergency Department. The Authority was concerned that such a patient-centred risk required discussions between clinical teams over a prolonged period of time and that the access arrangements remained a live issue under review for the duration of the investigation, as evidenced in the minutes of the Women's and Children's Directorate meetings as late as April 2013.

The National Maternity Healthcare Record was not in use in UHG, and maternity patients did not carry their own records. Patient healthcare records were not managed in line with the HSE's Standards and Recommended Practices for Healthcare Records Management. In particular, there was evidence of retrospective entry of information and in the case of Savita Halappanavar, retrospective notes were entered two weeks following her death. There were delays in accessing patient healthcare records, particularly outside office hours, while records were stored in a basement area that was prone to flooding.

The labour ward is a critical location for the pregnant patient and best practice is that patients being cared for on the labour ward have direct supervision and care by consultant obstetric staff with 24-hours seven-days-a-week senior midwifery cover. The Authority found that consultants on call for the labour ward were not present on the labour ward but rather were engaged in other clinical activities. This is at variance with national and international best evidence. In addition, the

* The term 'booked pregnant women' is used to describe pregnant women who have attended their first antenatal appointment, while the term 'unbooked pregnant women' is used to refer to pregnant women who have not attended their first antenatal appointment, as reflected in documentation received from University Hospital Galway.

Authority found that there were no guidelines or clear pathway of referral to ensure patients were seen by a senior clinical decision maker in a timely manner. There was no evidence that UHG facilitated or had in place arrangements to ensure that medical and nursing staff had the necessary competencies and skills to provide care to patients at risk of clinical deterioration. The Authority found that the arrangements to redeploy anaesthetic consultant cover, particularly to obstetric care, were not always effective.

While anaesthetic availability for the labour ward during core hours was reported as being essentially immediate in that the location of the gynaecology theatre was in very close proximity to the labour ward, it was reported that there was no consultant anaesthetist dedicated solely to the labour ward either during core working hours or on-call periods. It was also reported that the consultant on call for orthopaedic trauma would only very rarely be called in to the Hospital mid-week and more frequently at weekends as this was when the majority of orthopaedic emergency cases occurred. The Authority was concerned about the effectiveness of this roster arrangement and whether arrangements could be made to redeploy consultant cover, particularly to obstetric care. It was reported that discussions had taken place within the Theatre Anaesthetics and Critical Care (TACC) Directorate in relation to changing this rota. However, a solution had not been reached at the time of the investigation.

The Investigation Team found St Monica's Ward was used as the overflow to accommodate ante- and postnatal patients when St Catherine's and St Angela's wards were full. Consequently the casemix of patients accommodated on St Monica's Ward and their care needs were significantly different. In addition, this included the unscheduled presentations, out-of-hours, of patients with gynaecological and obstetric emergencies. There was no evidence that the organisation of the workforce took account of the complexity and diversity of the patient casemix on St Monica's Ward.

The Authority has made recommendations in respect of these findings.

7 Findings in relation to the clinically deteriorating general adult patient

In accordance with the Terms of Reference, the Authority reviewed the safety, quality and standards of services provided at University Hospital Galway (UHG) to general adult patients (non-maternity) at risk of clinical deterioration.

This was reviewed under the following headings:

- Monitoring to facilitate early identification of clinical deterioration.
- Early intervention and escalation to and from a senior clinical decision maker and access to critical care facilities.
- Identification and management of sepsis in general patients.

7.1 Monitoring to facilitate early identification of clinical deterioration

Once a patient has been admitted to hospital and has had their initial healthcare needs assessed and addressed, it is essential that healthcare services have continuous assessment processes in place to facilitate the early identification of and response to any clinical deterioration[31].

As previously discussed, the basic means of identifying patients at risk of clinical deterioration is to observe the patient and regularly monitor and track their physiological (clinical) observations. Clinical observations include measuring blood pressure, heart rate, temperature, rate of respiration, oxygen saturation* and level of consciousness.

7.2 National Early Warning Score implementation at University Hospital Galway

It was reported that the National Early Warning Score (NEWS) was introduced to all general adult areas in UHG on 5 November 2012 and pre-planning for its

* Oxygen saturation is a measure of how much oxygen the blood is carrying as a percentage of the maximum it could carry. It is measured by a small sensor which is placed over the patient's fingertip.

roll-out had commenced in June 2012. Guidelines to support the implementation of the NEWS were launched nationally in February 2013 by the National Clinical Effectiveness Committee (NCEC) and the Minister for Health[32]. It was reported that UHG was in the process of implementing these guidelines.

Training in the use of the NEWS guideline for clinical staff is essential for its effective implementation and use. It was reported that there was approximately 2,000 clinical staff to be trained across both the University Hospital Galway and Merlin Park University Hospital sites. At the time of the investigation, approximately 1,200 staff had received training. The training was being rolled out on a prioritised basis commencing with the Medical Division and Acute Medical Division in UHG.

The official education programme for the NEWS Project is called the National Early Warning Score COMPASS© training[33]. At the time of the investigation, it was reported that approximately 50% of non-consultant hospital doctors (NCHDs) had undertaken the training (it is a mandatory requirement in the specialty of surgery), with 25 to 30 out of a total of 110 consultants at UHG having received the training. This equated to only 23-27% of UHG consultant staff trained in the use of the NEWS.

In addition, it was reported that the Theatre and Critical Care (TACC) Directorate was not involved in the roll-out of the Early Warning Score and had not been involved in local decisions with regard to the appropriate interventions and escalation in response to NEWS scores. Subsequent information provided by Hospital management indicated the involvement of TACC staff in this roll-out. However, the Authority is concerned that key clinical staff from the multidisciplinary team reported that they were not directly involved in this development.

The Authority recommends that the Hospital Group Executive as a priority review these arrangements and ensure that all relevant clinical staff are immediately trained in the use of NEWS and all other similar patient safety initiatives.

7.3 Early intervention and escalation (including access to critical care)

The effectiveness of an early warning score (EWS) depends not only on the accurate recording of patient observations, but also, crucially, on the triggering of an appropriate response to abnormal clinical observations. This is important in order to ensure that the clinically deteriorating patient receives timely, safe and effective treatment. Accordingly, a clear escalation protocol is required detailing the response required in dealing with different levels of abnormal clinical measurements and observations recorded.

The Investigation Team found that UHG was implementing the NEWS guideline, had an escalation protocol in place and was using the ISBAR communication tool, as per the national guidelines. These initiatives were in the early stages of implementation.

As previously discussed in Part 3 of this Report, UHG was scheduled to introduce an Emergency Response Team in the third quarter of 2013.

7.4 Identification and management of sepsis in general patients

Severe sepsis and septic shock are major healthcare problems, affecting millions of people around the world each year, leading to a mortality rate of one in four (and often more), and is increasing in incidence worldwide[34,35]. Studies have found that survival rates following sepsis are related to early recognition and initiation of treatment. Therefore, it is essential that healthcare organisations have effective systems to recognise and treat patients who may be at risk or be developing sepsis.

The Hospital reported that 167 general patients required ICU care as a result of sepsis in 2011 and 139 general patients in 2012. The Hospital also reported that 70 general patients required HDU care as a result of sepsis in 2011, while 89 general patients required such care in 2012.

The National Early Warning Score which, as discussed above, had been implemented in the Hospital includes 'sepsis prompts' on the accompanying patient observation chart. These prompts are prominent on the chart and aim to promote the early detection of sepsis in all patients and detail steps to guide the initial treatment of sepsis. The inclusion of these prompts on the NEWS observation chart will potentially increase staff awareness of sepsis in general and the need to consider it as a diagnosis in any clinically deteriorating patient. In addition, there was a flow chart on the management of sepsis in use in the Intensive Care Unit and in the Emergency Department and it was reported that the Surviving Sepsis Campaign guidelines[34] are also available in the ICU and HDU.

However, the Authority is concerned that at the time of the investigation the Hospital did not have a hospital-wide guideline in place for the management of sepsis in adult patients. Furthermore, it was reported that there was no consistent definition of sepsis, severe sepsis and septic shock across UHG.

The absence of clear hospital-wide sepsis guidelines and definitions could potentially result in inconsistencies in the provision of care and the recording, collection and reporting of sepsis-related morbidity data.

7.5 Summary of findings in relation to the clinically deteriorating general adult patient

The Investigation Team found that UHG was implementing a National Early Warning Score (NEWS) guideline and ISBAR communication tool, as per the national guidelines. These initiatives were in the early stages of implementation. However, the Authority is concerned that the early implementation of these initiatives at UHG had lacked multidisciplinary input and involvement and has made recommendations accordingly.

The Authority was concerned that at the time of the investigation, the Hospital did not have a hospital-wide guideline in place for the management of sepsis in adult patients and recommends that this should be implemented without delay.

The absence of clear hospital-wide sepsis guidelines could potentially result in inconsistencies in the provision of care. Furthermore, the absence of clear hospital wide definitions for sepsis can result in inconsistencies in the recording, collection and reporting of sepsis-related morbidity data posing a potential shortcoming to improving the quality and safety of services for pregnant women, management of the service and the implementation of learning. The Authority is of the opinion that these arrangements should be reviewed.

The Authority has made recommendations in respect of these findings.

Part 4

Findings in relation to the Governance of Galway and Roscommon University Hospitals Group and University Hospital Galway

8 Governance of Galway and Roscommon University Hospitals Group and University Hospital Galway

8.1 Introduction

This chapter of the Report provides an overview of the corporate and clinical governance and reporting arrangements in place within the Galway and Roscommon University Hospitals Group (GRUHG*) when care was provided to Savita Halappanavar and at the time of the investigation. In doing so, the Authority has reviewed the corporate and clinical governance arrangements within the Hospital Group as they apply to the provision of a safe quality maternity service at University Hospital Galway (UHG), as reflected in the care and treatment of Savita Halappanavar.

This chapter of the Report includes an account of the arrangements in place for the management of incidents during 2012 and the course of action taken following the death of Savita Halappanavar on Sunday 28 October 2012 at UHG. It also includes an overview of the Authority's findings in relation to the Women's and Children's Directorate and the governance structure for the provision of maternity services in the Hospital.

8.2 Galway and Roscommon University Hospitals Group corporate and clinical governance structure

Since 2011, in line with Government policy, there has been significant re-organisation of services in order to prepare the way for the wider introduction of the principal of 'Money Follows the Patient'[36] and the ultimate introduction of 'Universal Health Insurance'[37,38].

* For the purposes of reporting, Galway and Roscommon University Hospital Group is referred to as 'the Hospital Group'. University Hospital Galway is referred to as 'UHG' or 'the Hospital'.

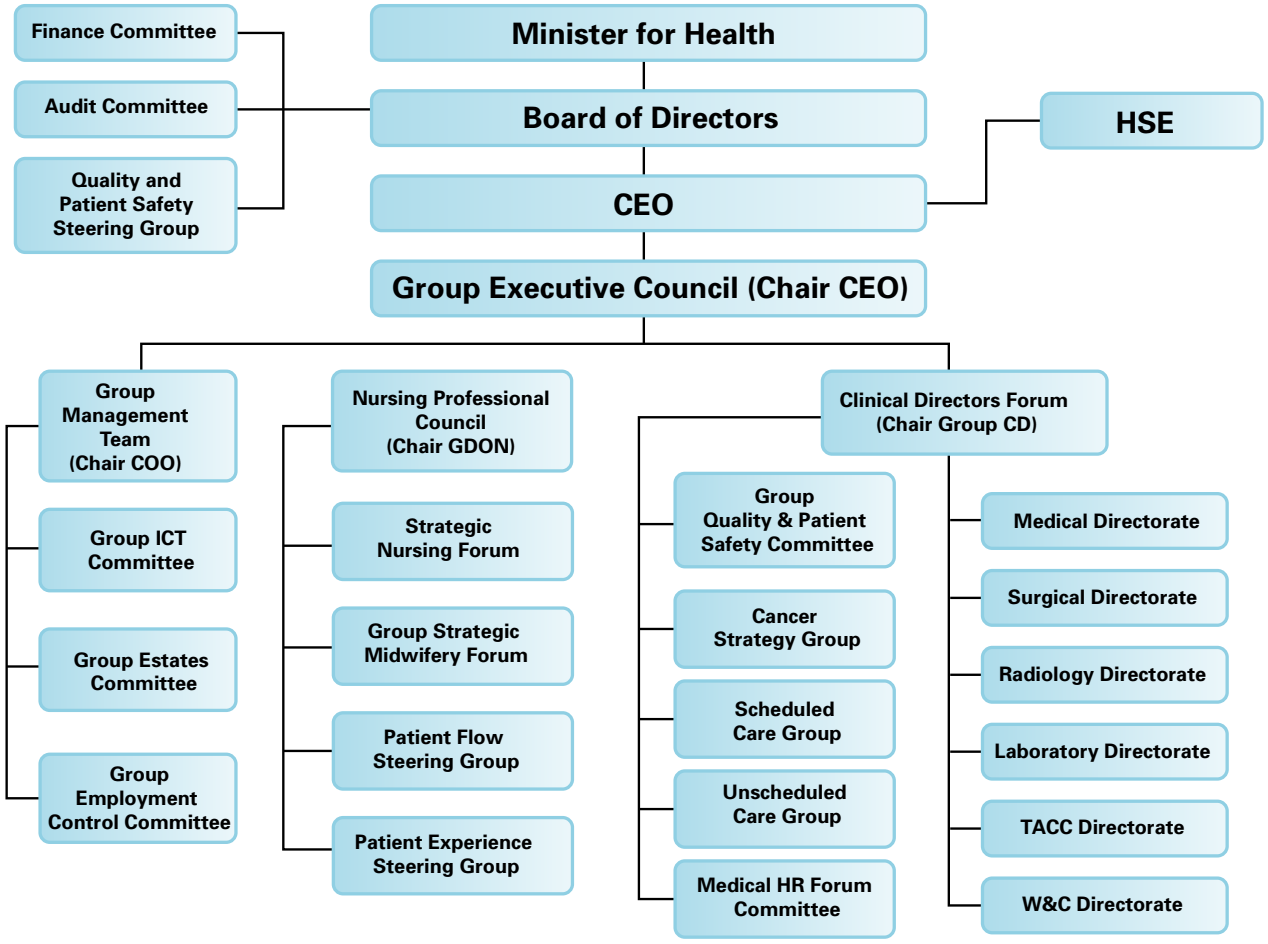
Consequently, the governance, leadership and management structures and arrangements of the health services are changing on a phased basis.

In December 2011, the Minister for Health announced that new management arrangements were being put in place for the groups of hospitals in the HSE West. Galway University Hospitals (incorporating Merlin Park University Hospital and University Hospital Galway) together with Portiuncula Hospital Ballinasloe and Roscommon General Hospital were placed within a single management structure led by a single chief executive, reporting to a board of directors. At this time, it was stated that the Hospital Group would have a single clinical governance model, one budget and one employment ceiling and that the chief executive would be responsible for group performance.

In January 2012, a new Chief Executive for the Hospital Group was appointed to lead the changes necessary for these new arrangements. The Authority is aware that the corporate and clinical governance structures and arrangements at UHG were undergoing significant changes prior to and during the course of this investigation. However, the Authority has not reviewed the efficacy of all of these arrangements, given that many of these were at an early stage of development and transition.

The Authority was provided with a diagram of the proposed final governance structure (see Figure 2 on the following page). However, many of these arrangements were not in place in October 2012.

Figure 2: Galway and Roscommon University Hospitals Group Corporate Clinical Governance Structure



Source: Galway and Roscommon University Hospitals Group.

8.3 Corporate governance arrangements

8.3.1 Introduction

Galway University Hospitals (incorporating Merlin Park University Hospital and University Hospital Galway) together with Portiuncula Hospital and Roscommon General Hospital were combined, on an administrative, non-statutory basis, into one Hospital Group in January 2012. The Group has one overall group management team, one financial budget and one whole-time equivalent (WTE) ceiling in January 2012. The new Chief Executive took up post and a programme to establish the change in governance arrangements was commenced.

In reviewing the governance arrangements at University Hospital Galway, the Authority acknowledges the substantial changes underway at the Hospital Group at the time of this investigation as it moves towards becoming the West/North West Trust to further include Sligo Regional Hospital, Letterkenny General Hospital, County Donegal, and Mayo General Hospital. When the Hospital Group moves to trust status incorporating the staff of the additional hospitals, it is estimated that staff numbers will increase to approximately 7,730 WTEs with an estimated 103,211 inpatient cases, 138,248 day cases, 10,996 births and 181,921 emergency attendances each year. The new trust will provide acute clinical services to an estimated population of 700,000.

8.3.2 Board of Directors, Galway and Roscommon University Hospitals Group

In line with the Government's reform programme and as a step in the move towards the formation of hospital trusts and the proposed governance arrangements, in June 2012 the Minister for Health, appointed a Chairperson to the Group.

The Hospital provided the Investigation Team with the Corporate and Clinical Governance Framework for the Hospital Group. This included terms of reference for the Hospital Group's Board of Directors.

At the time of Savita Halappanavar's death, the Board was not in place. The first meeting of the Interim Board of Directors took place in February 2013. As part of the investigation the Authority examined the governance arrangements and structures that had evolved in the months following her death.

The stated objectives of the Board are to provide strategic direction and leadership to the Hospital Group in the attainment of its goals by establishing effective corporate and clinical governance arrangements and obtaining assurance, by holding executives to account, that the Group is being well managed and providing a high quality, safe clinical service within the allocated resources. Public accountability is to be achieved by holding five of the 10 Board meetings in public which the Authority acknowledges is a positive development.

The terms of reference identified that the strategies and policies developed by the Board of Directors would be consistent with the standards of HIQA and the Department of Health.

The composition of the Board, as identified in the terms of reference, includes 11 directors, including the Chairperson, six non-executive directors and four executive directors. The non-executive directors are to be selected and appointed through an independent selection process on the basis of having the necessary skills, experience and competencies required to fulfil the role effectively. The term of their appointment is up to a maximum of three years. The remaining four directors are executive and include the Hospital Group's Chief Executive, Chief Financial Officer, Clinical Director and Director of Nursing and Midwifery, with the Group's Chief Financial Officer acting as the Board Secretary.

The appointment by the Chairperson of the four executive directors is not in line with the Authority's recommendations in its 2012 investigation report into the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (Tallaght Hospital) or best available international evidence[4].

In September 2013, the Director General of the HSE advised the Authority that the members of the Board were appointed in line with extant arrangements. Consequently, the Authority requested the Hospital Group to re-submit the Terms of reference as of September 2013, for the Hospital Group Board. Documentation submitted at this time also included an organisational structure chart of the Hospital Group that reflected the Group Chief Executive having a dual reporting line to the HSE and to the Hospital Board with the Hospital Board having a reporting line to the Minister of Health. However, the Board's Terms of Reference received and reviewed by the Authority did not reflect any change to ensure alignment with the recommendations of the Tallaght Hospital report*. It is now critical that the HSE, in conjunction with the Hospital Group and its Board, convey jointly clarity on the composition of the Hospital Group Board, in line with the recommendations of the Authority's Tallaght Hospital report.

It was confirmed at interview, and through review of the documentation received, that the Board would seek its assurances in relation to the safety and quality of services provided to patients through a sub-committee structure and corporate

* Boards should be of a sufficient size (up to a maximum of 12) and expertise to effectively govern the organisation. The board should be selected and appointed through an independent process established by the State and on the basis of having the necessary skills, experience and competencies required to fulfil the role effectively. The board should comprise non-executive directors and a chairperson and, in keeping with good governance, individuals with conflicts of interest, including employees of the hospital and those with other relevant conflicts of interest, should not be appointed to the board. The chief executive, and other designated executive officers (to include as a minimum, the equivalent of the director of finance, medical/lead clinical director and director of nursing) should be formally in attendance at the board with combined shared corporate accountability for the effective governance and management of the hospital.

In advance of such an independent process being established, the members of boards with the necessary knowledge, skills, competencies and experience should be appointed by the Minister for Health.

performance reporting. The proposed assurance arrangements included a Board Quality and Patient Safety Steering Group, chaired by a non-executive director of the Board. However, at the time of reporting, the steering group had not met. The first meeting was scheduled to take place in Quarter 4 of 2013.

Patients and members of the public are entitled to expect the highest level of healthcare. When the delivery of care falls below that level, they are entitled to ask why and be assured that measures have been taken to protect them and future patients from harm. The HSE with the Hospital Group Board must consider the findings of this investigation and seek assurances that the Chief Executive – as the person ultimately accountable for the safety and quality of services – ensures that the recommendations of this investigation and that of the HSE incident investigation into the death of Savita Halappanavar are implemented.

In addition, the Chief Executive of the Hospital Group, as the HSE delegated officer, should consider the actions, omissions and practices of the professional's involved in the care of Savita Halappanavar, and make appropriate referral(s) to the relevant professional regulatory body/bodies.

8.3.3 The Group Executive Council

The Group Executive Council (GEC) has responsibility to ensure the Hospital Group's clinical activities are governed under a single robust structure. The primary focus is to inform the Board of key performance indicators (KPIs) and other activity level measures in the clinical directorates. The GEC is chaired by the Group Chief Executive and membership includes Hospital Group executives, clinical directors and general managers, and the Ex Officio Dean of the National University of Ireland, Galway.

It was confirmed at interview and in the documentation reviewed that the Executive Council is well attended with a structured agenda and schedule. The Group Executive Council reviews the Group's national and local KPIs and clinical directorate's activity levels. The minutes of the Group Executive Council reviewed confirmed that the GEC was updated on all aspects of the HSE's incident investigation into the death of Savita Halappanavar and the implementation of the resultant recommendations. In addition, the minutes of May 2013 identified that the Group Board had commissioned a management consultancy review of its current maternity service model which was to include a desktop review of integrated best practice to include midwifery-led clinics.

The following sections briefly outline the core elements of the governance structure. As outlined the governance structure and arrangements were at an early stage of development at the time of the investigation and as a result the Authority was unable to determine their effectiveness.

8.3.4 The Group Management Team

It was reported that a Group Management Team (GMT) was established in 2012 with the responsibility for ensuring that the hospitals within the Hospital Group are managed in an efficient and effective manner enabling it to provide the highest quality care to the public. Its functions include the development of corporate key performance indicators, strategic planning, service planning, and budget and resource management. The management team is chaired by the Group Chief Operations Officer and membership includes Hospital Group executives and the general managers from all the other group hospitals.

8.3.5 Risk Management and Continuous Quality Improvement

Up to the end of 2012, there was a Risk Management Committee and Continuous Quality Improvement (CQI) Steering Group in place at the Hospital. The Committee reported to the then Board of Governance and the CQI Steering Group.

The terms of reference of the Risk Management Committee demonstrated that the purpose of the Committee was to ensure that systems and processes were in place to minimise risk to patients, staff and visitors and to protect the assets of the organisation. Responsibilities included development and monitoring of the implementation of the Hospital's Risk Management Strategy, reviewing high level reports on complaints, critical incidents and near misses, and reviewing the progress of the Hospital's risk registers including the escalation of high level risks.

The Risk Management Committee reported to the then Board of Governance and the CQI Steering Group and met every two months. Membership of the Risk Management Committee included the Clinical Director, representatives of the clinical directorates, the Clinical Risk Advisor, the Quality and Risk Manager and representatives of various sub-committees, for example, infection control. The agendas and minutes of the 2012 meetings of the Risk Management Committee were provided to the Investigation Team. There was a standard agenda which covered Matters Arising, Medical Healthcare Records, Risk Management/Patient Safety and other Committee reports.

The Continuous Quality Improvement Steering Group was chaired by a consultant endocrinologist and was meeting monthly. The purpose of this Steering Group was to oversee the performance and management of the Hospital's compliance with HSE and HIQA national standards, and it reported to the then Board of Governance. The terms of reference for the committee group demonstrated that the committee group's responsibilities included reviewing, on a regular basis, the systems of governance relating to healthcare quality and performance and to ensure that clinical services were being delivered on the basis of best available evidence and practice with appropriate clinical policies, protocols and guidelines in use. Membership of the committee group included a representative of the clinical directorates, Chairperson of the Risk Management Committee, the Director of Nursing and Midwifery, Quality and the Risk Manager.

The Hospital provided the agendas and minutes for the Continuous Quality Improvement Steering Group meetings for five meetings that took place during 2012, which reflected updates on the developments in the clinical and corporate governance arrangements for the Hospital Group and compliance with the *National Standards for Safer Better Healthcare*. The functions for clinical audit and guidelines development were demonstrated through a review of the minutes of the committee sub-groups. The aim of the clinical audit activities was to embed clinical audit within the corporate and clinical governance structure of UHG. The evidence submitted demonstrated that each specialty conducted two audits annually and that audit presentation days were taking place four times annually. The policies and procedures sub-group reviewed and approved guidelines and policies.

The minutes of the meetings demonstrated that the above arrangements were in the process of being reviewed during 2012 with the creation of the Galway and Roscommon University Hospitals Group. The minutes also showed that the risk management arrangements were to be integrated into a new clinical governance structure through the Clinical Directors Forum and the Group's Quality and Patient Safety Committee (QualSec), both of which are described in more detail below.

8.3.6 The Clinical Directors Forum

The Hospital Group's Clinical Director is the Chairperson of the Clinical Directors Forum, established in 2012. It was indicated through review of the terms of reference submitted and through interview that the primary function of the Clinical Directors Forum is to drive good clinical governance across the Group, implement national standards, guidance and policy, review clinical activity and ensure that the Hospital Group prioritises patient safety and provides the highest quality care to all patients.

The Clinical Directors Forum is accountable to the Group Executive Council and the Group Hospital Board. Membership includes the Group's clinical directors for each of the six clinical directorates, including the Women's and Children's Directorate and Group executives. The Clinical Directors Forum meets monthly and receives reports from the Group Quality and Patient Safety Committee. It also receives reports from each of the clinical directorates in relation to their risk register and their performance against key performance indicators (KPIs).

The Authority noted that key performance indicators are important in identifying opportunities for improvement in the delivery of services, and internationally the development of clinical care KPIs is focusing more directly on clinical outcome measurements. In addition, there is increasing international evidence that service providers without robust arrangements to measure the standard of care delivered to patients, and the patient experience while in their care, are at increased risk of failing to identify poor care. The Authority found that the majority of the key performance indicators in use by the Hospital Group are related to the structure of care provision rather than the process of care provision or the outcome of the care

received. This was further explored during the on-site visit by the Investigation Team. It was reported at interview that using key performance indicators as a management tool was a new development within the Hospital Group and that it was hoped to increase the number of patient outcome key performance indicators in the future.

The Hospital reported that, similar to many other hospitals in the Group, the Hospital's information management systems required considerable investment to meet the demands of the service. The Hospital Group's Board has approved an information management strategy and at the time of the investigation the Group was seeking funds from the HSE to implement this strategy.

The clinical directors are full-time clinicians, and the strategic and managerial component of their role, for many, is a new and challenging function. It was reported that a number of clinical directors are attending a national training programme, the Diploma in Quality and Leadership in Healthcare – a joint programme provided by the Royal College of Physicians of Ireland and the Quality and Patient Safety Directorate in the HSE. It was also reported that there are a number of national educational initiatives underway including National Clinical Director Forum meetings.

It is imperative that the Galway Roscommon University Hospitals Group Board recognises in this time of unprecedented change that its clinical directors will need to have excellent leadership, communication, change management and strategic competencies. The significant changes under way include the Group's transition to trust status, working towards compliance with the *National Standards for Safer Better Healthcare*, implementing the National Clinical Care Programmes, the integration of additional clinical services and the implementation of learning from local and national adverse events and investigations. This was further reinforced at interview nationally, where it was reported that clinical directors who had completed their term of office had identified key challenges within the role of clinical director which included managing change, prioritising work, managing their time effectively and unclear lines of accountability.

Consequently, it is critically important that the Clinical Directors Forum and its members, are well supported in the context of resources and that they have scheduled protected time to fulfil their clinical director role. Furthermore, effective arrangements must be in place to ensure that clinical leaders are supported on site by the Group's Board and Executive through formal and informal education and mentoring programmes, management training and support programmes both at local and national level. The Authority recommends that the Board and Executive have formal corporate assurance mechanisms in place to monitor the performance of all clinical and non-clinical leaders and managers.

8.3.7 Quality and Safety Executive Group

As described above, all quality and safety functions across the Hospital Group had been reviewed in 2012 with a view to integrating these functions within a single governance structure.

The Quality and Safety Executive Group (Qualsec) is chaired by the Group Clinical Director who reports monthly to the Board's Quality and Patient Safety Sub-committee and to the Group Chief Executive. At the time of the investigation, this Board Sub-committee had not yet convened and was due to hold its first meeting in Quarter 4, 2013.

At the time of the investigation, the Qualsec had only recently been formed and had held two meetings. Membership included the Group Director of Nursing and Midwifery, clinical directors, general managers, patient representatives, general practitioner and clinical representatives, Clinical Audit Lead, and the Quality and Patient Safety Manager. The purpose of this Group is to develop, deliver and oversee the implementation of a comprehensive quality, patient safety and risk management programme and also includes ensuring that the organisation meets appropriate national and international best practice standards. It is expected to provide assurances to the Group Executive Council and the Board in relation to risk management, incident reporting and compliance with national standards. All quality and safety related internal Hospital committees are required to submit monthly reports to the committee which includes risk management, risk register and clinical audit activities. The Group Clinical Director is also tasked with overseeing a process of self-assessment and evaluation of the committee's performance and operations.

In February 2013, it was reported at the group meetings between UHG staff and the Investigation Team that in addition to this forum, the Group Chief Executive was meeting regularly with the National HSE Director for Integrated Services Directorate in relation to quality and patient safety issues within the Hospital Group.

8.3.8 Nursing Professional Council

With the appointment of the Group Director of Nursing and Midwifery in 2013, the Nursing Professional Council was established. This group is chaired by the Group Director of Nursing and reports to the Group Executive Council (GEC). The membership includes the Hospital GroupopsitalsH 's Directors of Nursing, Assistant Directors of Nursing and Practice Development, a representative from the Centre for Nursing Education and ex officio (by right of office) membership that includes members of the Executive.

The Nursing Professional Council provides professional leadership, monitors and evaluates nursing services and ensures robust nursing governance arrangements. The Nursing Professional Council meets monthly and has a fixed agenda which includes quality and risk, nursing development and evaluation of services.

8.3.9 Public and patient involvement

At the time of the investigation, the Hospital Group had a three-year strategic plan (2013 to 2015) for public and patient involvement. It aims to provide the Galway and Roscommon University Hospitals Group with a framework and practical methodologies to develop patient partnerships, thus increasing communication involvement. The Group strategy is founded on increasing evidence that public and patient participation in the provision of healthcare leads to better health outcomes and better quality of care.

In addition, it was reported that 45 quality improvement projects had been implemented across the Hospital based on patient satisfaction surveys. It was also reported at interview that service-user feedback is discussed at local weekly team management meetings.

At the time of the investigation, the Hospital was in the process of recruiting a Patient Advocacy and Liaison Service (PALS) Officer with responsibility for the implementation of the public and patient involvement strategy. This post was to report to the Group Director of Nursing and Midwifery.

8.4 Governance arrangements for incident management and the implementation of recommendations of the investigations following the death of Savita Halappanavar

The Authority explored the arrangements in place for the management of incidents during 2012 and considered the course of action taken following the death of Savita Halappanavar on Sunday 28 October 2012.

At the time of the investigation, the Hospital provided the Authority with an algorithm (a step-by-step procedure for solving a problem in a finite number of steps) for the reporting of incidents, which included a clear structure of internal reporting and escalation of a serious incident with risk-rating applied and decision-to-escalate as appropriate to external agencies (for example, the HSE's National Incident Management Team). The need for an investigation or review would be identified and initiated as necessary according to this algorithm, followed by a report and implementation of an improvement plan.

Following the death of Savita Halappanavar, the Hospital advised the relevant coroner of the case on 28 October 2012 and verbally informed the Confidential Maternal Death Enquiry (MDE) Ireland on 1 November 2012. Details of the case were also escalated for the attention, support and oversight of the HSE National Incident Management Team by the Hospital on 1 November 2012. Incident report forms were completed both by the Gynaecology Department and the Intensive Care Department.

On 13 November 2012, the Hospital established a local Investigation Team in line with HSE practice for the review of serious incidents. This was subsequently stood down following the announcement by the HSE on Monday 19 November

that the National Incident Management Team (NIMT) was to conduct an incident investigation, led by an external chair. No additional local, internal review was undertaken by the Hospital in parallel to the HSE's incident investigation. However, the Hospital established an internal team, the Maternal Death Review Team, which was subsequently renamed the Local Incident Management Team (LIMT), involving members of the Hospital Group Executive Team and the Quality and Risk Manager, to manage the Hospital's response to the incident and to assist in the coordination of the subsequent investigations.

Following the completion of the Coroner's inquest and the HSE incident investigation into the death of Savita Halappanavar, the Hospital established an Implementation Team for the implementation of the recommendations of the inquest and of the HSE incident investigation.

This Team held its first meeting on 5 July 2013. The functions of this Team, as evidenced by the terms of reference, included:

- review of recommendations from the Coroner's inquest
- review of recommendations from the HSE's incident investigation review
- development and audit of quality improvement plans – liaison with the HSE national implementation team for implementation of the recommendations.

This Implementation Team reported to the Local Incident Management Team (LIMT), the Executive Quality and Safety Team (QualSec), the Executive Council and the Patient Safety Committee of the Board. At the time of this Report, this Team was in the process of implementing the recommendations of the HSE incident investigation and the Coroner's inquest at local level. An action plan reported to the Authority's Investigation Team demonstrated that implementation of one recommendation in relation to the implementation of an Irish Maternity Early Warning System (I-MEWS)[39] was complete with all others in progress with implementation timelines of six to 12 months.

In addition, the findings of the three investigative processes, including this HIQA investigation, have highlighted a number of issues of non-compliance with the *National Standards for Safer better Healthcare*. In parallel with any action plan for the implementation of these recommendations, the Hospital Group Board, together with the Executive, should assure itself of the actions needed to bring the maternity services into compliance with those National Standards. This is reiterated later in this report in Chapter 14 to include the assurances required at national level with supporting appendices. (See Appendices 14 and 15).

8.5 The Women's and Children's Directorate at University Hospital Galway

The Directorate is led by a Clinical Director who is accountable to the Clinical Director's Forum and Executive Management Council. The Clinical Director formally reports to these two groups on a monthly basis. It was reported at

interview that the maternity unit, as part of the wider Hospital governance structure, is accountable for the delivery of maternity services at the Hospital. It was also reported at interview that the Clinical Director of the Women's and Children's Directorate delegates accountability for the safety and quality of clinical services to each individual consultant in their delivery of individual patient care.

The Authority found evidence that the Women's and Children's Directorate was actively implementing the recommendations made by the HSE incident investigation into Savita Halappanavar's death, including the introduction of PROMPT (Practical Obstetric Multi-professional Training), counselling training and implementation of I-MEWS for pregnant women across the maternity unit and gynaecology ward. The Clinical Director is a member of the Group-wide implementation committee.

8.5.1 Governance and reporting structure

It was indicated through review of the terms of reference, dated May 2012, submitted to the Investigation Team, that the primary functions of the Women's and Children's Directorate are to determine, review, implement and monitor the agreed key performance indicators, priorities and cost containment plans for the Directorate; monitor staffing levels within the Directorate and identify and recommend key critical positions for filling/replacement and to monitor and review any specific risk issues. It was reported that the governance arrangements to support the implementation of the terms of reference is managed through three structured meetings:

1. A monthly Full Directorate Group (committee).
2. A weekly Core Directorate Group.
3. Meetings every two months between the Clinical Director and the consultant obstetricians and paediatricians.

The Authority reviewed the agenda, minutes and schedule of the three structured meetings. The minutes reviewed confirmed that the monthly full directorate committee meetings are held in accordance with the term of reference. Membership of this committee includes consultant obstetricians and gynaecologists, and senior nursing and midwifery staff, while the monthly committee meeting is also attended by a consultant obstetric anaesthetist.

The Hospital provided minutes of the weekly Core Directorate Group meetings. However, these minutes did not demonstrate that these meetings were taking place on a weekly basis. In addition, there was no evidence available to the Investigation Team to determine whether or how often the bi-monthly meetings with the Clinical Director and consultant obstetricians and paediatricians occur in practice as it was reported that minutes for these meetings are not recorded. It is of concern to the Authority that the evidence submitted by the Hospital suggests that the governance arrangements, as determined in the terms of reference for the Women's and Children's Directorate, are not adhered to and the Authority recommends that the Hospital's Executive urgently reviews this situation.

8.5.2 Quality and safety performance monitoring

The Women's and Children's Directorate monitored 12 key performance indicators on a monthly basis in 2012. These indicators look at:

- routine ultrasound scanning
- theatre list interruptions
- budget
- non-attendance rates for clinics
- staff absenteeism
- neonatal infant temperature on arrival to the Neonatal Intensive Care Unit
- critical neonatal interventions
- neonatal sepsis
- Emergency Department waiting times for children with medical complaints
- radiology waiting times for children
- outpatient appointment waiting times for children
- children's waiting times for inpatient treatment.

These 12 key performance indicators were presented at the monthly Core Directorate Group meetings and Executive meetings in 2012 using a dashboard template. This dashboard highlighted indicators in red, amber and green depending on the degree to which they were achieving the targets set.

At the time of the investigation, two new key performance indicators had been set for 2013 and the responsibility for recording and reporting each key performance indicator to the full Directorate committee had been assigned to a number of individuals within the committee. Ten of these indicators were the same as those that were collected in 2012. The indicators monitoring children's waiting times for inpatient treatment and Emergency Department times for children with a medical complaint are no longer included in these 12 indicators. This was because, as evidenced in the committee minutes, the Directorate had met its targets and achieved green status for these indicators in 2012.

There was evidence from the monthly Core Directorate Committee minutes that the Directorate was conducting clinical audits and using the results of these audits to inform the selection of their key performance indicators. For example, as a result of clinical audit, two new 2013 indicators have been developed: one monitoring whether women in the region delivering at less than 32 weeks' gestation are transferred to the Hospital and the second monitoring whether all eligible women receive antibiotics during labour for the prevention of Early Onset of Group B Streptococcal (EOGBS) infection in babies.

While acknowledging the use of key performance indicators as a tool to measure performance, it was of concern to the Authority that predominantly the key

performance indicators used did not specifically focus on measuring outcomes for maternity patients, maternity patients' experience or standards of care provided.

There was evidence that patients' feedback was sought and used to inform service development. The Investigation Team noted that the Women's and Children's Directorate had conducted a review of all comment cards submitted by patients and/or their families or friends to the Directorate between September to December 2012 and found a 93% overall satisfaction rate (good or excellent rating) of 121 cards submitted by service users.

There was a monthly mortality and morbidity meeting. However, these meetings and findings were not minuted or formally reported. It was reported that learning from events was shared at these meetings. Nonetheless, this forum did not appear to be supported by a formal structured process which, if in place, would assist in the dissemination of findings and learning.

8.5.3 Strategic Planning

The evidence reviewed confirmed that the Women's and Children's Directorate had identified 16 priorities for implementation in 2013. These priorities were identified and approved by the Core Directorate Committee. Each priority has an associated time frame for implementation and a named individual assigned as Lead Officer for their implementation.

8.5.4 Risk management and learning

There was evidence that risks identified and reported in the Risk Register in the Women's and Children's Directorate were reviewed at the monthly meeting of the Directorate Group. It was noted in the May 2013 minutes that a new hospital-wide risk management and complaints process had been introduced. It was reported that the new process had given responsibility to manage risk and complaints to the business manager in each directorate. However, it was concerning to note that the minutes recorded that the majority of staff now in charge of risk had no formal training in risk management. It was reported in the May 2013 minutes of the Women's and Children's Team weekly meeting that the Business Manager of the Women's and Children's Directorate had not received risk management training. It was further noted in the May 2013 Women's and Children's Directorate Committee meeting that the majority of staff who were in charge of risk had no formal training in risk management. There was no resultant action assigned at the meeting to refer this issue to the Group Executive Council. The Authority subsequently reviewed the Women's and Children's Directorate's May and June 2013 reports to the Executive Council Group and again the Authority was concerned to note that this training deficit had not been escalated within the Group governance structures. However, it was subsequently reported in September 2013 by the Hospital Group that all business managers, clinical directors and members of the directorate teams have had training in the management of risk and complaints.

Furthermore, it was also reported in the May 2013 minutes of the Women and Children's Directorate weekly team meeting that STARSWeb has not been populated since the changeover to the new incident management system. The Hospital Group subsequently reported in September 2013 that STARSWeb was being populated. However, they acknowledged the challenges associated with two systems in use that were not being directly linked and required double entry to record incidents. At the time of reporting the Hospital Group reported that they were seeking a solution with the Clinical Indemnity Scheme (CIS) to address this deficit.

Effective risk management is a critical component in ensuring a safe, high quality service. Therefore, ongoing training for the workforce on the identification, management, response to and reporting of patient safety incidents and clinical risk is imperative. The Group must ensure that the efficacy of the arrangements in place to support and train all staff responsible for managing risk, adverse incidents, near misses, claims and complaints are continuously monitored and evaluated.

8.5.5 Multidisciplinary team working

Pregnant women receive their care from multidisciplinary and multi-professional teams. These teams are made up of different types of healthcare professionals with different skills, knowledge, levels of experience and expertise. The focus of each multidisciplinary team is to work together to achieve the best outcomes for the patients they are caring for and each member of the team has a responsibility in achieving this.

It was reported at interview that there were good informal multidisciplinary team working and communication processes within the Directorate. This was further explored during the on-site part of the investigation. The Authority found evidence to suggest that opportunities to improve multidisciplinary team working existed within the Women's and Children's Directorate. For example, from the documentation submitted and information gathered at interview, it was apparent that there was limited involvement of all disciplines in the development of local obstetric policies and guidelines. For the most part the majority of policies were developed under the guidance of the Midwifery Practice Development Coordinator. The Authority considers the lack of multidisciplinary involvement a missed opportunity, particularly when non-consultant hospital doctors (NCHDs) on training programmes would potentially enhance the process, and as such an approach would help in generating directorate-wide policy awareness. It was reported at interview that draft policies are reviewed by individual consultants and discussed at the Directorate meeting.

Multidisciplinary and multi-professional involvement in the development of clinical guidelines and policies is paramount for the successful implementation of such guidelines and policies[40]. It was reported at the group meetings between UHG staff and the Investigation Team that new guidelines or revised guidelines are made available for all staff on the local IT system for storing documents. All staff

have access to and receive training on this IT system. It was reported by staff that new guidelines are discussed at ward meetings and that staff sign a check-sheet when they have read the new guidelines.

The Authority is of the opinion that the development of clinical policies and guidelines should be within a formal governance structure led by a named clinical lead. The clinical lead is ultimately responsible and accountable for the prioritisation, development, dissemination and monitoring of compliance with directorate policies and guidelines.

8.6 Summary of governance of Galway and Roscommon University Hospitals Group and University Hospital Galway

The Investigation Team reviewed the governance arrangements at Galway and Roscommon University Hospitals Group, where, since the inception of the Group on 9 January 2012, a significant reorganisation of its corporate and clinical governance structure and quality assurance processes had been undertaken. This reorganisation – as identified in the 2012 Group Annual Report – placed the clinical directorate structure at the heart of this reorganisation, with one of its key priorities to improve the quality of care provided.

It was confirmed at interview, and through review of the documentation received, that the Board's assurance structure on the safety and quality of patient services was monitored through a sub-committee structure and through corporate and directorate performance reporting. The Quality and Safety Executive Group was primarily responsible for the safety and quality of patient services throughout the Group, and at the time of the investigation was a recent development which would take a period of time to become fully established.

Corporately and at Directorate level, the Group monitored its performance monthly against key performance indicators. These key performance indicators cover a diversity of performance areas. However, at the time of the investigation there were few specific-patient-outcome and standard-of-care metrics currently being measured and the Authority has made recommendations in relation to this.

At the time of the death of Savita Halappanavar, there was a Risk Management Committee and Continuous Quality Improvement (CQI) Steering Group in place within the Group. At the time of this Report, this function has been subsumed into a revised group corporate and clinical governance structure. Structures were in place for the implementation of the recommendations of the HSE incident investigation and the Coroner's inquest through a local implementation team. The implementation of the recommendations was a standing item at all Group Board and corporate committee meetings.

There were a number of corporate and clinical governance committee structures, all with clear terms of reference. A review of their minutes confirmed a good attendance rate by all members. However, the Investigation Team was unable to

determine from the minutes of most committees/groups whether actions were being followed up and closed off at subsequent meetings.

While acknowledging the work that has been undertaken by the Group to establish these governance arrangements and assurance mechanisms, the Authority is concerned at the complexity of these structures and the large number of committees in place, with a number of these involving the same members, many of whom also have full-time clinical responsibilities. While the Authority is aware of the dependency of the Group's corporate and clinical governance committees on the involvement of these clinical staff, it will be important that strong arrangements are in place to ensure sustainability for that level of contribution while also ensuring that the provision of their clinical services are not compromised. It is equally important that all clinical leaders are supported in developing the composite management competencies to lead and manage their respective clinical directorates in achieving the Group's strategic plan with a particular emphasis on the quality and safety of patient services. In addition, it is imperative that an effective communication system is in place to ensure buy-in by all front-line staff. Therefore, it is incumbent on the Executive to ensure that the appropriate supporting and monitoring arrangements through the Group's clinical directorate structures are effective and that the organisational structures to support these are less complex.

Finally, patients and members of the public are entitled to expect the highest level of healthcare quality. When the delivery of care falls below that level, they are entitled to ask why and be assured that measures have been taken to protect them and future patients from harm. The Hospital Group Board and Executive, with ultimate responsibility for the delivery of a safe quality service for patients, must consider these findings, in particular those that relate to the care pathway of Savita Halappanavar. The HSE with the Hospital Group Board and Executive must ensure that the recommendations of this investigation and the HSE incident investigation into the death of Savita Halappanavar are implemented.

The Authority has made recommendations in respect of these findings.

Part 5

Profile and findings of Maternity Services Nationally

9 Profile and governance arrangements for maternity services nationally

9.1 Introduction

This chapter of the Report provides an overview of the Authority's findings in relation to the current profile and governance arrangements for the provision of maternity services in Ireland.

9.2 National governance and reporting arrangements for maternity services

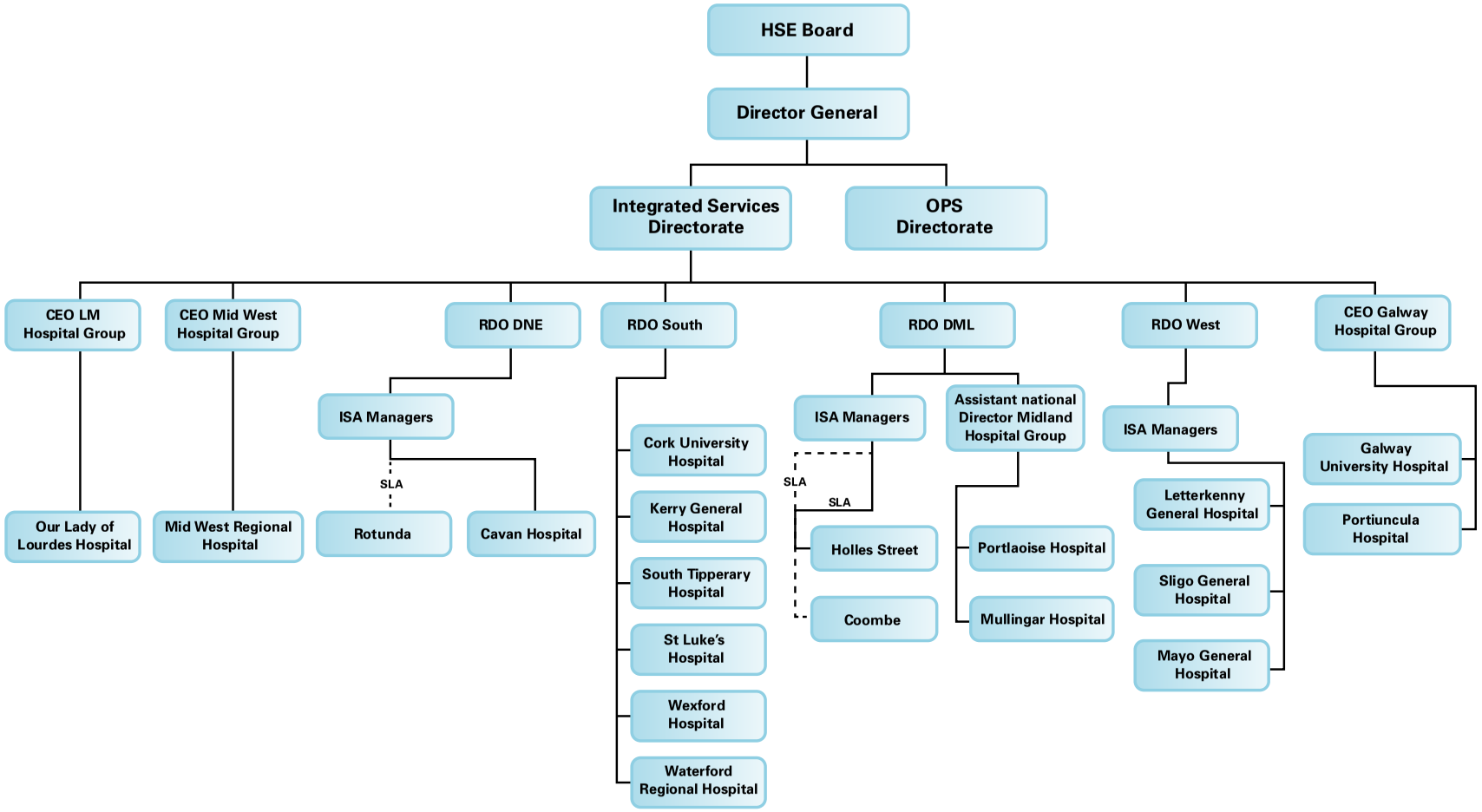
All pregnant women who are resident in Ireland are entitled to receive public maternity care under the 1954 Maternity and Infant Scheme[41]. This service is provided by general practitioners (GPs) registered with the scheme and hospital obstetricians and midwives working within the public maternity services.

In response to a document request by the Authority, the HSE submitted an organisational chart illustrating the governance and accountability structure for the delivery of maternity services nationally within the HSE at the time of the investigation. See Figure 3 on the following page.

At a national level, the HSE's Director of Integrated Services is responsible for the delivery of maternity services in Ireland. This post reports directly to the Director General* of the HSE. It was reported at interview that the HSE Office of the Director of Integrated Services reports quality and safety concerns directly to the Director, Quality Patient Safety Directorate (QPSD). The role of the QPSD, as described at interview, was mainly focused on supporting and helping the services and investigating patient quality and safety events.

* As part of Future Health, the Government's reform programme for the Irish health service, the Minister for Health, Dr James Reilly TD, signed into effect a number of changes to the governance arrangements of the Health Service Executive, effective from Thursday 25 July 2013. These changes included the formal establishment of the Health Service Directorate to replace the existing Board of the HSE and the formal appointment of Tony O'Brien as Director General of the HSE.

Figure 3: Governance and accountability for delivery of maternity services nationally in the HSE.*



*Source: HSE.January 2013. Note: SLA = service level agreement; QPS = Quality and Patient Safety; LM = Louth Meath; RDO = Regional Director of Operations; DNE = Dublin North East; DML = Dublin Mid Leinster; ISA = Integrated Service Area. It was subsequently reported by the HSE that ISA managers exist in the HSE South and this had not been included in the figure above when submitted to the Authority.

9.3 Governance arrangements for public providers of maternity services

At a local level, at the time of the investigation, public maternity services were being provided through a myriad of governance structures and arrangements in 19 maternity hospitals/units around the country.

For example, at the time of the investigation, there were three stand-alone maternity hospitals in Dublin, each with its own 'clinical master' who combines the role of senior clinician and chief executive. There was a service level arrangement in place between these hospitals and the HSE through section 38 of the Health Act 2004, whereby these hospitals are funded through the HSE. These three hospitals were linked to acute general hospitals for gynaecology services and act as local tertiary and national sub-specialty referral centres for other obstetric units.

At the time of the investigation, it was reported that these hospitals were being managed through service level arrangements with the Integrated Service Area (ISA) managers for their respective HSE region and they report through the Regional Director of Operations who reports to the HSE's National Director for Integrated Services for their respective HSE region. There is also one independent hospital, Mount Carmel Hospital, providing private maternity services in Dublin*.

Outside Dublin, maternity services are provided through statutory HSE hospitals, mostly within the structure of an acute hospital. However, some are provided in stand-alone hospitals on the campus of the main general hospital (for example in Cork University Hospital Group) or located off-site (as in the case of the Mid-Western Regional Hospital Group, Limerick). The governance arrangement for the majority of these maternity hospitals/units is through the hospital general manager and respective ISA manager to the Regional Director of Operations (RDO) or the Chief Executive (as in the case of the Louth Meath Hospital Group), up to the National Director for Integrated Services.

The Mid-Western Regional Hospital Group and the Galway and Roscommon University Hospitals Group have different governance and reporting structures as they move towards becoming hospital trusts under Government reforms. They both have a chief executive, a hospital group board chairperson, and a group board. The Group Chief Executive reports to the HSE through the National Director for Integrated Services. It was reported by the HSE in September 2013 that the Group Chief Executive reports to the National Director for Quality and Patient Safety in relation to patient safety issues.

* At the time of the investigation, the Authority's remit in healthcare includes services provided or funded by the Health Service Executive (HSE). It does not include mental health services (which are regulated by the Mental Health Commission) or private healthcare providers.

Based on evidence reviewed and reported to the Investigation Team at interview, it is clear to the Authority that there is a range of local governance structures and oversight arrangements in place for the delivery of public maternity services in Ireland. The Authority is of the opinion that, where such inconsistencies in governance structures exist, and given the Authority's concerns in relation to the lack of accessible, consistent and reproducible data relating to the quality of the service covered later in this Report, it is impossible to assess the performance and quality of the maternity service nationally. The establishment of hospital groups in Ireland, as a step to creating independent hospital trusts, proposes a reorganisation of maternity services in the context of the integration of services and the supporting governance arrangements.

Notwithstanding these plans, it is imperative that the HSE immediately conducts a review of the current governance arrangements for the provision of maternity services at local level. This review should be led by a named accountable person to ensure that any corporate and clinical risks are identified, mitigated and managed in the context of current services and the proposed changes. The Authority has made recommendations accordingly.

9.4 Activity data: public providers of maternity services

The HSE has conducted a number of national and regional reviews related to workforce planning for midwifery services. However, the Authority was unable to find evidence of a national review of multidisciplinary maternity workforce arrangements, or national population-based needs assessment, undertaken to demonstrate the appropriate allocation of resources for the provision of maternity services in Ireland. Consequently, to gain a better understanding of the size and profile of the national maternity service, the Authority requested information from the HSE regarding activity levels within the 19 public providers of maternity services which included the number of births and the number of maternity beds.

Table 5 on the following page illustrates these figures for 2012.

Table 5: Population, births, birth rate, inpatient beds and birth:bed ratio, in 2012*

HSE region	Births	Population (million)	Birth rate (births per 1,000)	In-patient beds	Birth: bed ratio	Obstetrics and gynaecology consultants[42], *
HSE West	15,606	1.081	14.4	260	60:1	27
HSE South	17,740	1.140	15.5	279	63:1	31
HSE Dublin North East	14,551	1.019	14.2	190	72:1	27
HSE Dublin Mid Leinster	22,445	1.319	17	291	74:1	41
Total/ overall	**70,342**	**Approx. 4.5 million**	**15.2**	**1,020**	**69:1**	**126**

* *Data sources: HSE.*

Based on information provided by the HSE, the number of births by HSE region ranged from 14,551 in the HSE Dublin North East (DNE) to 22,445 births in the HSE Dublin Mid Leinster (DML) region with the birth rate for these regions ranging from 14.2 to 17 per thousand respectively. In addition to the aforementioned disparity in governance arrangements, there was also a variance in the number of births per inpatient bed in the public maternity services nationally-evidenced through data received from the 19 maternity hospitals/units in January 2013. The ratio of births to inpatient maternity beds ranged from 60:1 in the HSE West to 74:1 in HSE DML.

Table 6 on the following pages provides a further breakdown of these figures by local maternity service as provided by the maternity hospitals/units. The total number of live births was reported as 70,342 for 2012. The number of births by maternity hospital/unit ranged from 1,179 births in South Tipperary General Hospital to 9,109 in the National Maternity Hospital, Dublin. The number of births per inpatient bed ranged from 45:1 in South Tipperary General Hospital to 94:1 at Wexford General Hospital (WGH), a difference of almost 109%. The Authority was cognisant that there was a wide variation in the number of inpatient beds for birth per maternity hospital/unit, with the average birth to inpatient bed ratio being 69:1. This finding suggests that the access arrangements within the maternity services

* Number of consultants in obstetrics and gynaecology by HSE region as defined by the HSE's Report on Approved Consultant Establishment and trends as at 31st Dec 2012.

are variable and the Authority recommends that these arrangements should be reviewed.

Table 6: Number of births in 2012 and number of maternity inpatient beds*

Public provider of maternity services	Number of live births 2012	Number of maternity inpatient beds	Birth to in-patient bed ratio
HSE West region			
University Hospital Galway	3,377	49	69:1
Portiuncula Hospital Ballinasloe	2,027	33	61:1
Mayo General Hospital	1,819	30	61:1
Sligo Regional Hospital	1,601	28	57:1
Letterkenny General Hospital	1,881	37	51:1
Mid Western Regional Maternity Hospital Limerick	4,901	83	59:1
Total	**15,606**	**260**	**(Average) 60:1**
HSE South region			
Cork University Maternity Hospital	8,531	134	64:1
South Tipperary General Hospital	1,179	26	45:1
Kerry General Hospital	1,676	30	56:1
Wexford General Hospital	2,175	23	94:1
Waterford Regional Hospital	2,250	36	62:1
St Luke's Hospital, Kilkenny	1,929	30	64:1
Total	**17,740**	**279**	**(Average) 63:1**
HSE Dublin North East region			
Rotunda Hospital, Dublin (a voluntary hospital funded by the HSE)	8,999	109	82:1
Our Lady of Lourdes Hospital, Drogheda	3,636	50	73:1
Cavan General Hospital	1,916	31	62:1

* *Data source: Health Service Executive*

Public provider of maternity services	Number of live births 2012	Number of maternity inpatient beds	Birth to in-patient bed ratio
Total	**14,551**	**190**	**(Average) 72:1**
HSE Dublin Mid Leinster region			
Coombe Women and Infants University Hospital, Dublin (a voluntary hospital funded by the HSE)	8,563	120	71:1
National Maternity Hospital, Dublin (a voluntary hospital funded by the HSE)	9,109	101	90:1
Midland Regional Hospital Mullingar	2,712	40 (rooms)	68:1
Midland Regional Hospital Portlaoise	2,061	30	69:1
Total	**22,445**	**291**	**(Average) 74:1**
Total across all HSE regions	**70,342**	**1,020**	**69:1**

★ *Data source: Health Service Executive*

It was reported at interview, and supported in documentation reviewed, that the predominant model of maternity care throughout Ireland is the hospital-based consultant-led model of service which was defined by the 1954 Maternity and Infant Care Scheme, in place some 59 years at the time of the investigation.

It was also reported at interview that there are differences in the model of maternity care provided to pregnant women in different parts of the country. For example, in the HSE Dublin Mid Leinster region, the model of care has a stronger focus on midwifery-led care with the availability of a midwifery-led DOMINO scheme* while there are midwifery-led units based in the HSE Dublin North East region, in comparison to many other maternity hospitals/units in the country which are predominantly consultant-led.

Currently, there is no recommended birth to inpatient bed ratio for the model of maternity care provided in Ireland. However, based on the data submitted by the 19 maternity hospitals/units, there appears to be a significant variation in the number of births taking place in each hospital/unit against the number of inpatient beds available in that hospital/unit. This raises questions as to the sustainability

* A number of hospitals are operating a DOMINO/Community Midwives Scheme. This scheme enables women who are deemed at 'low risk of complications' to see members of a dedicated midwives team for their antenatal visits and to have a member of this team deliver their baby, either in hospital (Domino Scheme) or at home.

in the provision of services in some areas. Furthermore, it was emphasised at interviews with the Investigation Team that there are many areas where maternity service needs were not being fully met at the time of the investigation. This reinforces the Authority's concerns in relation to the inconsistency in the provision of maternity services and the need to ensure that all pregnant women have appropriate choice, access to the right level of care and support at the right time. The Authority has made recommendations accordingly on this issue.

9.5 Summary of the findings in relation to profile and governance arrangements for maternity services nationally

All pregnant women who are resident in Ireland are entitled to receive public maternity care under the 1954 Maternity and Infant Scheme.

At a national level, the HSE's National Director of Integrated Services is responsible for the delivery of maternity services in Ireland. At the time of the investigation, the organisational structure for HSE maternity services, as submitted to the Authority, did not indicate any direct reporting arrangement to the HSE's Quality Patient Safety Directorate. It was reported at interview that the HSE Office of the Director of Integrated Services reports quality and safety concerns directly to the Quality Patient Safety Directorate.

However, it was reported that the HSE's Director of Quality Patient Safety does not have any line management accountability for patient quality and safety. The role, as described at interview, was mainly focused on supporting and helping the services and investigating patient quality and safety events. In addition, it was confirmed at interview that there was no formal support structure in place nationally to support the escalation of risk.

The Investigation Team also noted a wide variation in the local clinical corporate governance arrangements across the 19 maternity units/hospitals nationally. The Authority is of the opinion that, where such inconsistencies in governance structures exist, and given the Authority's concerns in relation to the lack of accessible, consistent and reproducible data relating to the quality of the service, it is impossible to assess the performance and quality of the maternity service nationally. The establishment of hospital groups in Ireland, as a step to creating independent hospital trusts, proposes a reorganisation of maternity services in the context of the integration of services and the supporting governance arrangements.

One further concern is the lack of evidence of any national review, or national population-based needs assessment, undertaken to demonstrate the appropriate allocation of resources, including multidisciplinary workforce arrangements, for the provision of maternity services in Ireland. These concerns are further reinforced by the wide variation in births to inpatient maternity beds which ranged from an average of 60:1 in the HSE West to an average of 74:1 in HSE Dublin Mid Leinster.

The Investigation Team was cognisant of the variation in models of maternity care with predominance of consultant-led care. This raises questions as to the sustainability in the provision of maternity services in some areas. It was also noted that there are many areas where maternity service needs were not being fully met at the time of the investigation. This finding reinforces the Authority's concerns in relation to the inconsistency in the provision of maternity services in Ireland and the need to ensure that all pregnant women have appropriate choices and access to the right level of care and support at the right time.

The Authority has made recommendations in respect of these findings.

10 Findings in relation to National Maternity Services

10.1 Introduction

This chapter of the Report describes the Authority's findings in relation to the provision of maternity services nationally to include workforce arrangements for the provision of maternity services, use of information, sepsis, Healthcare Associated Infection and antimicrobial resistance.

10.2 Maternity services workforce

When a service sets its objectives for the provision of sustainable high quality, safe care and support, it must determine the workforce requirements needed to meet these objectives. The individual doctors, midwives and nurses must be skilled and competent and the workforce as a whole must be planned, configured and managed to achieve these objectives on an ongoing basis. Service providers must be able to assure the public, service users and their workforce that everyone working in the service is contributing to a high quality, safe service. It should be noted that as a result of the current fiscal situation in Ireland, significant reductions in both budget and staffing headcount in the HSE, including maternity services, have been widely reported in recent years and pose significant and understandable challenges to maintaining services.

In this chapter of the Report the Authority has outlined the findings in relation to the workforce responsible for the provision of maternity services nationally. These findings are presented in the context of what international and national studies, other investigations, relevant professional clinical research organisations and the *National Standards for Safer Better Healthcare* recommend as being necessary to deliver a safe quality national maternity service. The Authority has made a series of recommendations for improvement in this aspect of service provision.

10.2.1 Maternity services workforce and the clinically deteriorating patient

High quality, safe maternity services rely on having an appropriate workforce with the leadership, skill-mix and competencies to provide excellent and reliable care

at the point of patient delivery. Maternity patients are looked after in hospital by a number of different healthcare professionals including midwives, obstetricians and anaesthetists and it is essential that multidisciplinary working is at the core of every maternity unit.

Maternity services have come under increasing pressure in Ireland given the general rise in the birth rate over the past decade. Other factors that contribute to an increased workload include a generally older population of mothers[43], given that increased maternal age can lead to higher rates of complication in pregnancy; increased use of human assisted reproduction which has led to a higher rate of multiple births; and higher rates of co-morbid* disease[44].

Additionally, the numbers of babies born to women who themselves were born outside Ireland have risen, and these mothers may experience communication difficulties and other social and clinical challenges in accessing and receiving maternity care. Significantly, the Confidential Maternal Death Enquiry (MDE) Ireland report for the triennium 2009 to 2011 identified that 40% of all maternal deaths occurred in women who were not born in Ireland (5 out of 6 direct deaths; 4 out of 13 indirect deaths; and 1 out of 6 coincidental deaths respectively)[45]. This was also reflected in the National Perinatal Epidemiology Centre's Severe Maternal Morbidity Audit 2011 which reported the incidence of severe maternal morbidity† was disproportionately higher among non-Irish national ethnic minorities[46].

Caring for a clinically ill pregnant woman is further complicated by the fact that the body's physiological reserves increase during pregnancy. This means that a pregnant woman's physiological capacity to manage and compensate for clinical deterioration is at a very high level which may disguise the early warning signs of an illness[28]. Therefore, a clinically deteriorating pregnant woman can appear to remain well until quite late into the deterioration process. Consequently, although pregnancy and birth are normal physiological processes, unexpected emergencies can occur and can occur rapidly. It is therefore incumbent on all maternity service providers to ensure that all clinical staff caring for pregnant women are competent in, and complete regular training on, the identification and management of obstetric emergencies.

This issue has been previously highlighted in reports into serious adverse and untoward incidents. For example, in 2009, the report of the HSE investigation into the death of Tania McCabe at Our lady of Lourdes Hospital in Drogheda, Co Louth[47, ‡], recommended that:

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* Two or more coexisting medical conditions or disease.

† Morbidity can be described as the incidence of ill health.

‡ This was an investigation, commissioned by the Hospital Network Manager, HSE North East, into the circumstances pertaining to a maternal death: the death of Tania McCabe and her son Zach at Our Lady of Lourdes Hospital, Drogheda, Co Louth on Friday 9 March 2007. The investigation was conducted to identify learning for the service so as to assist in the prevention of future possible tragedies and to improve the quality of care.

- (Recommendation 8§) 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).
- (Recommendation 9) The HSE must streamline its processes in order to respond effectively to ensure safe staffing levels in known critical areas.
- (Recommendation 9) Hospitals should have a programme of continual assessment of staffing levels, skill-mix and workload and the HSE should strive to achieve flexibility and reduce response time to resource issues so as to effectively support front-line staff.

The report into the circumstances pertaining to the death of Tania McCabe and her infant son Zach was of particular relevance to this investigation given that Tania McCabe died after developing septic shock following premature rupture of the membranes. In January, 2013, the Authority received information from the HSE, in relation to the status of the implementation of the workforce recommendations of the Tania McCabe investigation and it was reported that progress in relation to the upgrade of medical and midwifery staffing was 'complete and ongoing'. The Authority's analysis of the implementation status of the other recommendations of the Tania McCabe investigation are contained in Part 7 of this Report.

10.3 Maternity services staffing: international and national literature review and recommendations from investigations

Those providing maternity services increasingly need to focus on developing new ways of working in order to maintain, monitor and increase levels of patient safety and quality within the resources available. One of the key elements in achieving this is ensuring that there are sufficient numbers of suitably qualified healthcare professionals to safely deliver the service. In order to determine best workforce planning practices for maternity services the Authority conducted an international and national literature review which primarily focused on the workforce levels required in obstetrics, obstetric anaesthesia and midwifery, clinical leadership and team working. In addition, the Authority reviewed the learning and recommendations from a number of maternity-related inquiries in Ireland.

10.3.1 Obstetrics

The medical specialty that provides acute maternity care is obstetrics, but nearly all obstetric doctors in Ireland combine their practice with a gynaecology practice. The UK's Healthcare Commission highlighted that this is an important consideration in establishing staffing levels. One of the key findings from its investigation into 10 maternal deaths which occurred at Northwick Park Hospital between 2007 and 2008 was that the consultant doctors – who split their time between obstetrics and gynaecology, were spending insufficient time in obstetrics[48].

§ These recommendations are numbered according to the Tania McCabe investigation report.

The labour ward is a critical high-risk area for the pregnant patient. This area must involve direct supervision and care by hospital consultant staff and have 24-hours-a-day, seven-days-a-week senior midwifery cover. In 2007, the Royal College of Obstetricians and Gynaecologists (RCOG) in the UK identified an increasing rate of interventions in labour and increased infant mortality at night, and identified evidence from the NHS Litigation Authority which all signalled the need for an increased consultant obstetrician presence on the labour ward[21]. The RCOG recommended that all units with more than 2,500 births a year should move to a 40-hour dedicated consultant presence on the labour ward per week and for those with 6,000 or more births a year to have at least a 60-hour consultant presence per week[21].

In Ireland, the Report of the National Task Force on Medical Staffing[49] (The Hanly Report) published in June 2003 had concluded that there was a clinical need for a consultant obstetrician and gynaecologist to be present on-site in each regional obstetric unit on a 24-hour basis. To achieve this they recommended that 191 Consultant posts in Obstetrics and Gynaecology would be needed by 2013.

In 2006, the professional body for the specialty, the Institute of Obstetricians and Gynaecologists, produced a report, entitled *The Future of Maternity and Gynaecology Services in Ireland 2006 – 2016*[50]. This report included a series of recommendations and standards for Irish maternity services. In relation to consultant staffing of labour wards, the report recommended that there should be 24-hour on-site, on-call consultant obstetric cover on the labour ward of units handling 6,000 deliveries per annum or more – or a dedicated consultant presence on the labour ward. This report also recommended that by 2016 there should be at least one consultant per 350 births in order to allow maternity units with between 3,000 and 4,500 births to provide dedicated consultant cover on the labour ward for 40 hours per week.

The Authority reviewed a published position paper produced by the HSE's Obstetrics and Gynaecology Clinical Care Programme on consultant workforce planning for obstetrics and gynaecology in the Republic of Ireland 2012-2022 (dated 2011)[51]. This position paper again reported that there are a relatively low number of consultant obstetricians and gynaecologists in Ireland and that action should be taken to increase the numbers of trainees into the national system. The position paper highlighted that failure to address this issue could potentially lead to serious adverse consequences for the provision of healthcare services in the medium and long term which could be associated with poorer outcomes for women and children.

At the end of 2012, the HSE reported that there were in total 126 consultant obstetricians and gynaecologists in Ireland. The breakdown of these consultants per HSE region is shown in Table 7 on the following page.

Table 7: Current consultant staffing levels in Ireland per HSE region

HSE region	Consultant obstetrician and gynaecology consultant numbers*	No. of live births 2012*
Dublin and Mid Leinster	41	22,445
Dublin North East	27	14,551
South	31	17,740
West	27	15,606

Data Source: HSE

This table shows a small variation in the consultant-to-live birth ratios in the existing four HSE regions. It also shows that all the regions fall significantly short of the one consultant per 350 births recommended by *The Future of Maternity and Gynaecology Services in Ireland 2006 – 2016* report (50 as necessary for the provision of dedicated consultant cover on the labour ward for 40 hours per week. The HSE must now consider the findings of these national reviews and the national and international evidence base in its workforce planning in order to resource safe maternity services. If it identifies significant risks in this review it must outline and implement measures to mitigate these.

10.3.2 Midwifery

In 2008, the Kings Fund (an independent charity in the UK that works to improve healthcare by providing research and health policy analysis) conducted an independent inquiry into the safety of maternity services in the UK[52].

It recommended that maternity units should review demand and capacity regularly and ensure that they deploy sufficient staff, with the right mix of skills, effectively during peak and other times. It highlighted that the planning of both employment and deployment needs should be informed by a broader set of factors than solely staffing ratios. It must also take account of standards for the organisation and processes of care, definitions of roles, experience levels and availability of support staff. It concluded that without suitable systems to ensure that maternity teams are effectively deployed to care for women and their babies, employing larger numbers of midwives, consultants, or both, may not improve safety.

* Number of consultants in obstetrics and gynaecology by HSE region as defined by the Report on Approved Consultant Establishment and trends as at 31 December 2012.

In its 2006 report on the future of maternity and gynaecology services in Ireland, the Institute of Obstetricians and Gynaecologists found clear variations in the quantum and mix of midwifery/nursing staff across the 22 maternity hospitals/units in existence in Ireland at that time and no national references for setting staffing level standards[50]. The Royal College of Obstetricians and Gynaecologists in the UK recommended in 2008 that each woman should receive one-to-one midwifery care during established labour and childbirth by a trained midwife or trainee midwife under supervision. The Royal College of Midwives, UK, recommends a ratio of 28 births: one whole-time equivalent (WTE) midwife for hospital births to enable one-to-one care to be offered. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists also recommended in 2011 that all women should receive one-to-one midwifery care during established labour and childbirth by a trained midwife or trainee midwife under adequate supervision[53].

The Kings Fund followed its 2008 report with a report that looked specifically at maternity staffing levels in the UK in 2011[54]. This report focused on the intrapartum period (the time relating to childbirth or delivery). It found that midwife-led models of care in particular appear to offer positive outcomes and experience and a potential for cost savings. It also identified a potential for certain competency-based tasks to be redeployed from doctors to midwives or from midwives to support workers.

As part of the investigation, the Authority requested the HSE to provide copies of any recent national reviews of midwifery workforce planning carried out by or on behalf of the HSE. The HSE provided the Authority with five reports that had been conducted either nationally or regionally between the period 2008 to 2012. Two of these were national reports regarding workforce planning for midwifery services.

The first of these national reports was conducted in 2009 and involved a national review of skill-mix in maternity services[55]. That review found the numbers of healthcare assistants employed by many of the 19 maternity hospitals/units were low and there was an under-utilisation of healthcare assistants in maternity services in general. It concluded that the role of the healthcare assistant should be part of any workforce planning or reconfiguration of the maternity services to enable midwives to realise their full potential in clinical practice.

The second report was conducted in early 2012 and was a review of the midwifery service workforce[56]. This review reported that the total number of midwife WTEs in post on 30 November 2011 was 2249.84 and the national number of vacant posts on this date was 123.88 WTEs, equating to a rate of 5.2%. The primary purpose of this review was to evaluate whether there was an ongoing need to continue the provision of the post-registration midwife education programme over the next five years. This report concluded that a more in-depth analysis of skill-mix needed to be undertaken in order to more accurately determine the requirements for all staff who work in the maternity services in the future. The report highlighted that this future analysis would need to take place after models of care for maternity services are agreed for implementation by the HSE. It was concerning to note that in subsequent information provided to the Investigation Team, it was

apparent that there was limited connectivity between the HSE's National Clinical Care Programme for Obstetrics and Gynaecology and the HSE's office responsible for nursing and midwifery services in respect of reviews of the midwifery service workforce, and therefore the development of overall models of maternity care.

The HSE must now consider the findings of these national reviews and the national and international evidence base in its workforce planning as they relate to the objectives of the HSE's National Clinical Care Programme for Obstetrics and Gynaecology.

10.3.3 Obstetric anaesthesia

Successive confidential enquiries into maternal deaths in the UK have stressed the importance of a dedicated obstetric anaesthesia service and the timely involvement of the anaesthetic team in the management of the sick obstetric patient. Obstetric anaesthetists play an important role in the maternity team. They are responsible not only for the provision of the epidural (a form of pain relief) service for women in labour but also the provision of anaesthesia for women who require Caesarean delivery and other theatre care. They are also required to assist with the resuscitation and care of pregnant women who become seriously ill as a result of haemorrhage (severe bleeding), pre-eclampsia* and other major complications.

The Association of Anaesthetists of Great Britain and Ireland and the Obstetric Anaesthetists' Association (OAA/AAGBI) recommended in its 2005[29] and 2013[30] guidelines that a duty anaesthetist should be immediately available for the delivery suite 24 hours-per-day and there should be a clear line of communication from the duty anaesthetist to the supervising consultant at all times. The term 'duty anaesthetist' is defined as an anaesthetist who has been assessed as competent to undertake the duties of the delivery suite. If this duty anaesthetist has other responsibilities outside the delivery suite these should be of a nature that would allow the activity to be delayed or interrupted should obstetric analgesia (pain relief) or anaesthesia demands rise.

Furthermore, the OAA/AAGBI's 2013 guidelines state that there should be a nominated consultant in charge of the obstetric anaesthesia service and as a basic minimum there should be 12 consultant anaesthetist sessions allocated for every maternity unit[30]. This is two more than the 10 consultant anaesthetist sessions it recommended in 2005 guidelines[29] and Safer Childbirth recommended in 2007[21]. The 2013 OAA/AAGBI guidelines also recommend that an agreed system for the antenatal assessment of high-risk mothers should be in place to ensure that the obstetric anaesthetist is given sufficient advance notice of all potential high-risk patients[30].

* A medical condition pregnant women may develop resulting in high blood pressure and protein in the urine. This condition can lead to the development of eclampsia which may be life threatening.

Notably, the Report of the National Task Force on Medical Staffing (The Hanly Report), published in Ireland, in June 2003, recommended that there is a clinical need for a consultant anaesthetic presence in each Major Hospital 24 hours a day and that at any one time, there should be a consultant on-site with primary responsibility for obstetric anaesthesia and a second consultant on-site with primary responsibility for the ICU[49]. A third consultant should be on-call off-site for theatre after scheduled activity ceases. The Hanly report did stress that implementation of this recommendation is dependent on volume and complexity of emergent workload.

The HSE must now review the arrangements it has in place to ensure it has sufficient consultant staffing levels to provide safe obstetric anaesthesia services in line with the Association of Anaesthetists of Great Britain and Ireland and the Obstetric Anaesthetists' Association's Guidelines in this area. If it identifies significant risks in this review it must outline and implement measures to mitigate these.

10.4 Summary of findings in relation to National Maternity Services

High quality maternity services rely on having an appropriate workforce with the leadership, skill-mix and competencies to provide proactive, excellent and safe care at the point of delivery on a 24 hour basis.

There have been a number of national and international reports and recommendations in relation to maternity services that have explored the workforce requirements and arrangements for the delivery of safe care. Nationally, these have included the Institute of Obstetricians and Gynaecologists' report on *The Future of Maternity and Gynaecology Services in Ireland 2006 – 2016*, the Association of Anaesthetists of Great Britain and Ireland and the Obstetric Anaesthetists' Association's (OAA/AAGBI) 2005 and 2013 guidelines and the HSE's report into the circumstances pertaining to the death of Tania McCabe and her infant son Zach at Our Lady of Lourdes Hospital, Drogheda on 9 March 2007.

However, the Authority was unable to find evidence of any national review, or national population-based needs assessment, undertaken to demonstrate the appropriate allocation of resources, including multidisciplinary workforce arrangements, for the provision of maternity services in Ireland.

The Authority reviewed a published position paper produced by the HSE's Obstetrics and Gynaecology Clinical Care Programme on consultant workforce planning for obstetrics and gynaecology in the Republic of Ireland 2012-2022 (dated 2011). This position paper reported that there are a relatively low number of consultant obstetricians and gynaecologists in Ireland and that action should be taken to increase the numbers of trainees into the national system. The position paper highlighted that failure to address this issue could potentially lead to serious adverse consequences for the provision of healthcare services in the medium and long term which could be associated with poorer outcomes for women and children.

At the end of 2012, the HSE reported that there were in total 126 consultant obstetricians and gynaecologists in Ireland. There is a small variation in the consultant to live birth ratios in the existing four HSE regions. However, the report shows that the regions fall significantly short of the one consultant per 350 births as recommended by *The Future of Maternity and Gynaecology Services in Ireland 2006 – 2016* report as being necessary for the provision of dedicated consultant cover on the labour ward for 40 hours per week, a figure supported by international evidence.

In respect of midwifery staff, the Authority reviewed a range of reports produced by or on behalf of the HSE. The HSE provided the Authority with five such reports that had been conducted either nationally or regionally between 2008 and 2012. Two of these were national reports regarding workforce planning for midwifery services.

The first of these national reports was conducted in 2009 and involved a national review of skill-mix in maternity services. It concluded that the role of the healthcare assistant should be part of any workforce planning or reconfiguration in the maternity services to enable midwives to realise their full potential in clinical practice.

The second report was conducted in early 2012 and was a review of the midwifery service workforce. This review reported that the total number of midwife whole-time equivalents (WTEs) in post on 30 November 2011 was 2249.84 and the national number of vacant posts on this date was 123.88 WTEs, equating to a rate of 5.2%. The primary purpose of this review was to evaluate whether there was an ongoing need to continue the provision of the post-registration midwife education programme over the next five years.

The report highlighted that future analysis would need to take place after models of care for maternity services are agreed for implementation by the HSE. It was of concern to the Authority to note that, in subsequent information provided to the Investigation Team, there was limited connectivity between the National Clinical Care Programme for Obstetrics and Gynaecology and the HSE office responsible for nursing and midwifery services in respect of reviews of the midwifery service workforce, and therefore the development of overall models of maternity care.

Successive confidential enquiries into maternal deaths in the UK have stressed the importance of a dedicated obstetric anaesthesia service and the timely involvement of the anaesthetic team in the management of the sick obstetric patient. Obstetric anaesthetists play an important role in the maternity team. They are responsible not only for the provision of the epidural (a form of pain relief) service for women in labour but also the provision of anaesthesia for women who require Caesarean delivery and other theatre care.

They are also required to assist with the resuscitation and care of pregnant women who become seriously ill as a result of haemorrhage (severe bleeding), pre-eclampsia* and other major complications.

National and international medical literature concludes that a duty anaesthetist should be immediately available for the delivery suite 24-hours-per-day and that there should be a clear line of communication from the duty anaesthetist to the supervising consultant at all times.

Recent professional guidelines published in 2013 state that there should be a nominated consultant in charge of the obstetric anaesthesia service and as a basic minimum there should be 12 consultant anaesthetist sessions allocated for every maternity unit. These guidelines also recommend that an agreed system for the antenatal assessment of high-risk mothers should be in place to ensure that the obstetric anaesthetist is given sufficient advance notice of all potential high-risk patients.

The HSE must review its workforce arrangements for maternity services nationally to ensure maternity teams are made up of sufficient numbers of staff with the right mix of skills and deployed effectively both during core and on-call hours. This review should be conducted in line with advice from the Obstetrics and Gynaecology Clinical Care Programme.

As a result of a range of these findings the Authority is recommending that the HSE must, as a priority, conduct a review of the national maternity services and agree and implement standard, consistent models for the delivery of a national maternity service and to ensure that all pregnant women have appropriate choice, access to the right level of safe care and support on a 24 hour basis. This review must establish the relevant structures to ensure consistency in the provision of maternity services as they transition as a core component of Hospital trusts.

The Authority has made recommendations in respect of these findings.

* A medical condition pregnant women may develop resulting in high blood pressure and protein in the urine. This condition can lead to the development of eclampsia which may be life threatening.

11 Findings in relation to use of information

11.1 Introduction

In order to effectively manage and deliver healthcare services, and be assured that they are providing high quality, timely and safe care, it is fundamental that appropriate information is collated, analysed and action taken as necessary. The importance of information to the Irish healthcare system has been highlighted by a number of State and external organisations. Data about health and social care services is formally collected on a regular basis in Ireland both by the health service and a number of other national organisations, groups and bodies. This data is potentially used for many important purposes such as informing decision making, planning of services, measuring patient safety outcomes, improving the health of the population and for international reporting purposes.

Based on international best practice, four key overarching objectives relating to health information based on maximising health gain for the individual and the population have been identified, these are:

1. Information is used to deliver and monitor safe and high quality care for everyone.
2. Information should be of the highest quality and where appropriate collected as close as possible to the point of care.
3. Information should be collected once and used many times, where possible.
4. Data collection should be 'fit for purpose' and cost-effective.

The delivery of safe and effective healthcare depends on access to, and use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. The primary purpose of collecting this data should be to improve and manage the quality and safety of health and social care services.

This chapter describes the Authority's findings at local and national level in relation to the use of information for the collection and reporting of maternal morbidity and mortality data. The Investigation Team also identified opportunities for improvement in the use of information to inform patient outcome measures and service development and these findings are also reported below.

11.2 Performance monitoring of maternity services

Performance monitoring is a continuous process that involves collecting accurate up-to-date information to determine if a service is meeting the desired standards and targets. It is then incumbent on healthcare professionals and other managers to ensure that any variation from normal is routinely considered, acted upon and managed in a supportive and constructive way in order to continually improve the service as a whole, and the care provided by teams and individuals. Nationally and locally, organisations should have systems in place to assure themselves that the monitoring of performance is actively and routinely taking place across the organisation.

In order that the data collected can be compared between individuals and organisations, a systematic process to ensure that validated data is collected consistently, both within and across organisations, is required. Key performance indicators, also known as KPIs, help an organisation define and measure progress towards meeting pre-identified and agreed critical quality and safety success factors. To ensure its reliability, data used to support KPIs should be standardised, with uniform definitions, to ensure that it is collected consistently and facilitates meaningful comparisons between services[57].

In order to provide assurances that pregnant women are receiving safe, high quality and reliable care during and after their pregnancy, maternity services must collect and analyse quality and safety performance measures to evaluate the performance of their clinicians and their service. These measures should be primarily focused on assessing quality and safety outcomes for patients.

While maternal morbidity and mortality data is being collected by a number of national groups/organisations*, the HSE confirmed at interview that at the time of the investigation there was no agreed national dataset for the collection of quality and safety measures for maternity services in Ireland. It also confirmed that while maternity services in Ireland have traditionally collected certain service and activity data, up until recently, this information has largely not been acted on. More recently, in 2011, the Obstetrics and Gynaecology Clinical Care Programme within the HSE had for the first time provided maternity units with their individual perinatal reports produced by the Economic and Social Research Institute (ESRI) and had also sent their Caesarean section rates back to individual units for local review.

The Lourdes Hospital Inquiry (into peripartum hysterectomy at Our Lady of Lourdes Hospital, Drogheda) in 2006 recommended that annual clinical reports of activity and clinical outcomes should be prepared and published within nine months of the previous year's end[58]. Although this recommendation was directed at Our Lady of Lourdes Hospital, the production of a timely annual clinical report containing relevant statistics should, at the time, have been viewed as a necessity for monitoring clinical care in any modern day maternity unit in Ireland.

* These groups include the National Perinatal Epidemiology Centre, The Hospital Inpatient Enquiry System, and the Economic and Social Research Institute.

As part of the investigation, the Authority asked each of the 19 public maternity hospitals/units whether they produced an annual clinical report and requested them to provide their annual reports for 2011 and 2012. It was reported that 8 of the 19 maternity units do not produce any form of annual clinical report. The remaining 11 units reported that they do produce an annual report and they provided the Authority with their 2011 reports. Reports for 2012 were not yet available for the majority of maternity hospitals/units at the time of the investigation.

On examination of the 11 clinical reports provided, the Authority found that the majority of reports included details of Caesarean section rates, the incidence and severity of perineal tears, induction-of-labour rates, and instrumental intervention rates. The Authority acknowledges the practice of three Dublin maternity hospitals who collect and aggregate the same key activity data, which allows for comparison and benchmarking of performance between the three hospitals. However, the remaining eight reports varied significantly in style, format and degree of detail. For example, some of the reports contained commentary of individual cases of maternal morbidity and mortality while others provided statistical summary data only.

The Authority was concerned at the absence of a national overview and structured assurance arrangements to monitor the safety and quality of maternity services in Ireland. Consequently, the Authority recommends that the HSE must develop, publish and implement a suite of national performance measures for maternity services with a clear focus on patient outcomes. These indicators would form the basis of a national maternity 'dashboard'[59] which should be collected, analysed and appropriate action taken where variance exists locally. They should be published and reported on nationally on a regular basis. As part of this dashboard development, appropriate national benchmarks for performance must be developed and implemented.

In line with the Terms of Reference of this investigation, the Authority explored the arrangements in place within the maternity services nationally for the review and reporting of patient outcome data with particular relevance to maternal mortality, maternal morbidity and also maternal morbidity related to sepsis. These findings are reported below. The Authority also explored the national data collection sources for mortality and morbidity data in Ireland and a more detailed outline of these sources is provided in Appendix 10.

11.2.1 Maternal mortality data

The Investigation Team explored the number of cases of maternal death in Ireland and how these deaths were being reviewed in order to inform the quality and safety of maternity services. The Confidential Maternal Death Enquiry (MDE) in Ireland is the primary organisation for collecting and reporting on maternal deaths in this country. It was established in 2009 to investigate why some women die during or shortly after pregnancy, and to learn how such tragedies can be avoided

in the future. This was set up following the establishment of a Joint Working Group on Maternal Mortality between the HSE and the Institute of Obstetricians and Gynaecologists in Ireland, with the objective of linking Ireland in with the UK-based Confidential Enquiries into Maternal and Child Health (CEMACH*).

The Maternal Death Enquiry (MDE) Ireland is situated as a 'stand-alone' office within the National Perinatal Epidemiology Centre, which is funded by the HSE and supported by the Department of Health and the State Claims Agency. The HSE reported that assurance mechanisms are in place to ensure accurate and consistent reporting of maternal deaths across the HSE through:

- MDE Ireland
- implementation of the National HSE Incident Management Policy and Procedure
- a toolkit of documentation supporting the National HSE Policy and Procedure requiring all incidents to be reported to the Clinical Indemnity Scheme (CIS).

In August 2012, MDE Ireland reported that the total number of maternal deaths for the three-year period 2009 to 2011 was 25[45]. This equated to six direct maternal deaths, 13 indirect maternal deaths and six maternal deaths attributed to coincidental causes. A maternal mortality rate of 8.0 per 100,000 maternities for the combined years of 2009 and 2010 was reported by MDE Ireland[45]. MDE Ireland concluded that this rate compares favourably with the Confidential Enquiries into Maternal and Child Health in the UK, which reported a maternal mortality rate of 11.39 per 100,000 maternities for the period 2006 to 2008.

The *Saving Mothers' Lives* report, (published 2011), identified that mortality due to severe maternal sepsis had increased in the UK and is now the leading cause of direct maternal death in the UK[60]. The MDE Ireland report in 2012 reported that there were no maternal deaths due to sepsis reported in Ireland between 2009 and 2011. As part of the investigation, the Authority requested maternal mortality data from the 19 maternity hospitals/units for 2011 and 2012. The hospitals reported a total of 10 maternal deaths for 2011 and sepsis was not a contributory factor in any of these deaths. However, the data received from 2012 indicated a total of 11 maternal deaths and reported that sepsis had been a contributing factor in three of these 11 deaths.

MDE Ireland publishes its findings every three years. However, at the time of this Report, the governance arrangements for the UK's Confidential Enquiries into Maternal and Child Health were being transferred to the National Perinatal Epidemiology Unit (NPEU) at the University of Oxford and it was reported that MDE Ireland expects that this Group will develop a more streamlined enquiry process with annual reporting.

Investigating the causes of maternal death and implementing lessons learned from

* A series of reviews of maternal deaths undertaken since 1952 to save mothers' lives and more generally to improve maternity services overall.

these tragic deaths is crucial to improving maternity services and it was reported by the HSE that a formal process for the implementation of recommendations of the MDE are in development. Thankfully, maternal deaths are relatively rare and therefore it is increasingly important that maternity services also measure maternal morbidity outcomes.

11.2.2 Maternal morbidity data

While the Hospital In-Patient Enquiry (HIPE†) system is the only source of maternal morbidity data available nationally for maternity services in Ireland, the National Perinatal Epidemiology Centre (NPEC), based in Cork University Maternity Hospital, collects data and conducts annual audits of severe maternal morbidity in Ireland[46].

The NPEC was set up in response to the recommendations of the Lourdes Hospital Inquiry (2006) and is funded by the HSE. The NPEC aims to provide the Irish maternity services with a facility to undertake in-depth reviews of their own medical practices, through monitoring outcomes and regular audit. Maternity hospitals/units voluntarily participate in this audit and at the time of its first audit in 2011, 18 out of 19 public maternity hospitals/units and the single private maternity hospital were providing data to the NPEC. At the time of the investigation, all 19 maternity hospitals/units were participating in the audit.

There is a designated midwife, obstetric consultant or specialist registrar at each maternity hospital/unit responsible for the completion of the Severe Maternal Morbidity Notification Form for submission to the NPEC audit. To ensure accuracy, missing or incomplete data is sought from respective maternity units by the NPEC. It was reported that the data collected through the severe maternal morbidity audit (NPEC) is more clinically orientated and detailed in comparison with maternal morbidity data collected through HIPE.

The national morbidity rate reported by the NPEC was 3.8 cases per 1,000 maternities or 1 in 263 maternities. It was reported that maternity hospitals/units were provided with an individual report on the audit results for their own unit which enables them to observe their performance in comparison with other maternity hospitals/units.

In comparison, Scotland reported its national morbidity rate as 7.3 per 1,000 births or 1 in every 137 births[61]. This morbidity rate is reported in terms of births rather than maternities.

The Authority is of the view that there is an opportunity to further standardise the reporting of maternal morbidity rates in Ireland, both locally, through the annual clinical reports of each maternity hospital/unit and nationally, through their participation in the National NPEC audit. There are a number of data collection

† HIPE collects demographic, clinical and administrative data on discharges and deaths from all public acute hospitals.

sources involved in the collection of maternal morbidity and mortality data in Ireland and the Authority is of the opinion that these sources should be reviewed to explore the potential for a centralised and consistent approach to reporting on maternal morbidity and mortality.

11.2.3 Sepsis

Mortality due to severe maternal sepsis has increased in the UK and is now the leading cause of direct maternal death in the UK[60]. Substandard clinical care was identified in many of the cases of maternal death from sepsis[60].

Savita Halappanavar died as a result of sepsis which progressed to severe sepsis and eventually septic shock*. The Authority examined the evidence available for the recording of maternal morbidity related to sepsis nationally. The Authority reviewed information received from the NPEC, HIPE, the 19 maternity hospitals/units in Ireland, annual clinical reports of 11 maternity hospitals/units and information gathered through interview.

As part of the investigation, the HSE was asked to provide the Authority with figures for the 19 maternity hospitals/units in relation to severe maternal morbidity related to sepsis for 2011 and 2012. In total, the 19 units reported 25 cases of severe maternal morbidity related to sepsis in 2011 and 41 cases in 2012. The Authority did not provide the HSE with a definition of what constitutes severe maternal sepsis and it was apparent from documentation received that there was no national standardised definition for severe maternal morbidity related to sepsis.

The Authority observed that there were large variations in the numbers of cases reported between maternity units even when the respective birth rates of each of the units were taken into consideration. For example, one maternity unit reported 30 morbidity cases associated with sepsis which was almost 10 times greater than the number of cases reported by the other maternity hospitals/units. This led the Authority to conclude that it is likely that the quality of data being collected varies among the maternity units and that the definitions for the reporting of severe maternal sepsis are not standardised across the maternity units.

This finding was further validated by the HSE's National Clinical Care Programme for Obstetrics and Gynaecology that had performed an audit on maternal sepsis in November 2012. The Programme had asked all maternity hospitals/units to complete a standardised questionnaire detailing their figures for cases of maternal sepsis.

* The Surviving Sepsis Guidelines define sepsis as infection plus systemic manifestations of infection. They define severe sepsis as sepsis plus sepsis-induced organ dysfunction or tissue hypoperfusion. Finally they define septic shock as severe sepsis plus persistent hypotension despite adequate fluid replacement therapy. The Royal College of Obstetrics in the UK has adopted these definitions in its bacterial sepsis in pregnancy guidelines[13].

It was subsequently reported at interview that results for this audit were not available as it was reported that the quality of information that was returned was variable and overall not interpretable.

The Authority obtained data for cases of maternal sepsis in public HIPE-reporting hospitals from 2009 to 2012. For a total of 128,996 discharges with any diagnosis from Pregnancy, Childbirth and the Puerperium† in 2011, 45 discharges with a diagnosis of sepsis‡ were recorded. For 2012, there were 127,002 discharges and 39 discharges with a diagnosis of sepsis.

The National Perinatal Epidemiology Centre (NPEC) audit on severe maternal morbidity in Ireland collects data on septicaemic shock. The audit includes a clear definition of septicaemic shock (systolic blood pressure less than 80mmHg in association with infection with no other cause for decreased blood pressure, and a heart rate of 120 beats per minute or more)[46]. Septicaemic shock was reported by the NPEC at a rate of 0.06 per 1,000 for 2011, reporting four cases in total in 2011[46]. The Authority acknowledges the introduction of a standardised definition and the collection of figures for septicaemic shock by the National Perinatal Epidemiology Centre. However, further review and standardisation of definitions for both sepsis and severe sepsis are required nationally and need to be established promptly.

While aware that the Saving Mothers' Lives report in 2011 identified that mortality due to maternal sepsis was the leading cause of direct maternal death in the UK, and also that there are reported increases in maternal sepsis in Ireland, it is of concern to the Authority that the Investigation Team was unable to obtain a definitive figure for the number of cases of maternal morbidity related to sepsis for a given year.

Where information is not based on quality data, it does not provide an accurate picture of the quality and safety of services. Therefore, opportunities for learning and improvement are missed. The Authority found that the quality of data being collected varied among the maternity units and the definitions for the reporting of maternal sepsis are not standardised across the maternity units. This lack of standardisation of definitions across the service poses a potential significant shortcoming to the management of the service and learning within the national maternity service, and to improving the quality and safety of services for pregnant women. In addition, it suggests that other maternal morbidity data may not be clearly defined and has the potential to restrict the ability of the service to compare both regionally, nationally and internationally for improved learning and safety within maternity services.

† (ICD-10 O00-O99 [International Classification of Diseases (ICD), World Health Organization])

‡ (ICD-10 A40-41)

The Authority is of the view that arrangements should be put in place nationally to build on the existing approaches to the collection, analysing and reporting of maternal morbidity and mortality data at a local and national level, to improve coordination, consistency and integration of all approaches, including national data collection sources, to inform service delivery, improve efficiencies within the service and ensure patient safety nationally. The Authority is of the opinion that the HSE should review its current arrangements to ensure harmonisation and increase usability of existing health information data sources and systems.

11.3 Summary of findings in relation to use of information

In order to provide assurances that pregnant women are receiving safe, high quality and reliable care during and after their pregnancy, maternity services must collect and analyse quality and safety performance measures to evaluate the performance of their clinicians and their service. These measures should be primarily focused on assessing quality and safety outcomes for patients.

The Lourdes Hospital Inquiry (into peripartum hysterectomy at Our Lady of Lourdes Hospital, Drogheda) in 2006 recommended that annual clinical reports of activity and clinical outcomes should be prepared and published within nine months of the previous year's end.[58] The Authority found that 8 of the 19 maternity units do not produce any form of annual clinical report.

There are a number of data collection sources involved in the collection of maternal morbidity and mortality data in Ireland. However, there is no centralised and consistent approach to reporting on maternal morbidity and mortality.

Savita Halappanavar died as a result of sepsis which progressed to severe sepsis and eventually septic shock. *Saving Mothers' Lives 2011* identified that mortality due to severe maternal sepsis is now the leading cause of direct maternal death in the UK, and also that there are reported increases in maternal sepsis in Ireland. The Authority examined the evidence available for recording of maternal morbidity related to sepsis nationally and found no national agreed definition of maternal sepsis, and inconsistencies in recording and reporting maternal sepsis.

At the time of the investigation, there was no agreed national dataset of quality and safety measures for maternity services in Ireland and no consistent approach to reporting clinical outcomes. The Authority was significantly concerned about the absence of a national overview and structured assurance arrangements to monitor the safety and quality of maternity services in Ireland.

The Authority has made recommendations in respect of these findings.

Part 6

Findings in relation to Antimicrobial surveillance

12 Antimicrobial surveillance

12.1 Introduction

Gram-negative organisms are a large group of bacteria that can cause a wide range of infections in both community and hospital settings, including urinary tract infection, surgical wound infection and bloodstream infection. *Escherichia coli*, better known as *E. coli*, is the commonest cause of infections due to Gram-negative organisms. Many bacteria, including some strains of *E. coli*, are becoming increasingly resistant to antibiotics. The European Centre for Disease Prevention and Control (ECDC) estimate that infections dues to antibiotic-resistant bacteria account for 25,000 deaths in Europe per year.

The Investigation Team reviewed the healthcare record of Savita Halappanavar which indicated that the results of blood tests taken identified a particular strain of *E. coli* called ESBL (Extended-Spectrum Beta-Lactamase) producing *E. coli*. ESBL-producing *E. coli* are antibiotic resistant and consequently make the infections harder to treat. ESBLs are enzymes, produced by some strains of bacteria, that break down penicillin-based antibiotics thereby rendering the bacteria resistant to certain types of antibiotics. ESBL-producing bacteria may also be resistant to multiple antibiotics and thus limit options for effective antibiotic therapy.

Infections caused by ESBL-producing bacteria are associated with an increased morbidity and mortality rate. This is coupled with the fact that prevalence rates are rising globally including in non-hospital settings, and the diminishing options for effective antimicrobial therapy, antimicrobial resistance, including resistance due to ESBL-producing bacteria, has been identified as a global threat to public health. Therefore it is imperative that the risk associated with antimicrobial resistance is given a high priority at national and local levels. This risk can be controlled by prudent antimicrobial prescribing, antimicrobial stewardship and national alert systems.

12.2 Microbiology services

Effective and responsive microbiological services are required to support effective clinical management of infections and support the infection, prevention

and control. In addition, studies have found that microbiology services with comprehensive surveillance programmes which feedback to clinical staff contribute to more effective programmes for preventing and controlling infections.

At a local level all hospitals should have 24-hour seven-days-a-week (24/7) access to an accredited microbiology laboratory, with 24/7 access to expert medical microbiological advice. At the time of the Investigation, some hospitals had 24/7 access to accredited microbiology laboratory services and expert advice. However, it was reported by microbiology experts that there were significant gaps in these arrangements. In addition, at the time of the investigation not all hospital microbiology laboratories were accredited, which is a non-compliance with the nationally-mandated *National Standards for the Prevention and Control of Healthcare Associated Infections*[62].

Early detection of resistant pathogens and timely result communication accompanied by expert medical microbiological advice forms the basis of a good microbiology service.

Good quality infectious disease surveillance is dependent on the availability of detailed, comparable and timely information on pathogenic isolates and knowledge of a pathogen that may pose a substantial threat to public health is paramount. Trend analysis, communication and dissemination of such information forms the basis of good practice in this area.

Surveillance of infectious diseases in Ireland is coordinated by the Health Protection Surveillance Centre (HPSC), which monitors trends in relevant infectious diseases. The HPSC Annual Reports, along with annual reports from existing reference laboratories, provide a comprehensive overview of human infectious disease epidemiology in Ireland. Current microbiological reference laboratory services contribute to the collection of data for Ireland as part of EARS-Net and Ireland's international obligations to European surveillance programmes. However, despite the availability of such data, there remain significant gaps with regard to infectious disease epidemiology in Ireland, particularly for pathogens for which no national reference laboratory services currently exist.

At the time of the investigation, there were five formal (nominated by the Minister for Health) microbiological reference laboratories in place in Ireland and seven informally designated laboratories. Although functioning as reference laboratories, there was no formal governance structure in place. The HSE Microbiological Reference Laboratory Group (MRLG) in Ireland developed national recommendations for the provision of high quality clinical microbiological reference laboratory services to build on current arrangements and to strengthen the work undertaken by front-line microbiological laboratories in Ireland. The group has recommended a national governance structure for microbiological reference laboratories to be established and linked to the National Review of Public Health Services[63].

The Authority is of the view that all diagnostic laboratories should have a designated surveillance scientist, with sufficient protected time to deliver surveillance requirements.

Diagnostic microbiology laboratories and national services should be supported by a network of appropriately resourced and accredited reference laboratory services that meet the European Centre for Disease Control (ECDC) definitions for reference laboratory functions[64].

12.3 National alert systems

Standardised surveillance systems are essential components in the control and prevention of antimicrobial resistance and infection. It was reported by microbiology experts that nationally and locally there is good informal inter-collegial communication in place for early communication of new or emerging antimicrobial resistance/infection trends, or early detection of outbreaks, in place in Ireland. Emerging threats have been recognised through infectious disease notification data and data generated by reference laboratories. However, this is a disjointed approach and dependent on the recognition of patterns by the individuals involved.

The Authority is concerned about these arrangements and the sustainability of any informal communication system and recommends that there should be a national laboratory-based alert system that allows real-time analysis of data from local laboratory information systems, or from other healthcare information systems (such as the national Computerised Infectious Disease Reporting (CIDR) system for notifiable infectious diseases) that allows timely recognition of emerging national microbial threats, including antimicrobial resistance. Such systems have been put in place in a number of European countries, including France ('e-SIN'), Sweden ('SVEBAR') and the Netherlands ('ISIS-AR'), and have been reported as proven useful in the early detection of new antimicrobial resistance/HCAI threats and outbreaks.

There should be a clear mechanism for the communication of findings from the alert system, and clear lines of accountability for acting on such findings. The alert system should be integrated with national surveillance, public health and laboratory governance structures. There should be a clear mechanism for the communication of findings from the alert system and clear lines of accountability for acting on such findings.

12.4 Summary of findings in relation to antimicrobial surveillance

Gram-negative organisms are a large group of bacteria that can cause a wide range of infections in both community and hospital settings, including urinary tract infection, surgical wound infection and bloodstream infection. The Investigation Team reviewed the healthcare record of Savita Halappanavar which indicated that the results of blood tests taken identified a particular strain of *E. coli* called ESBL- (Extended-Spectrum Beta-Lactamase) producing *E. coli*. ESBL-producing *E. coli* are antibiotic resistant and consequently make the infections harder to treat.

Surveillance of infectious diseases in Ireland is coordinated by the Health Protection Surveillance Centre (HPSC) which monitors trends in relevant infectious diseases. However, the Authority identified significant gaps in relation to infectious disease epidemiology in Ireland, particularly for pathogens for which no national reference laboratory services currently exist. In addition a national governance structure for microbiological reference laboratories was not in place.

The Authority found that there was no national laboratory-based alert system that enabled real-time analysis of data from local laboratory information systems, or from other healthcare information systems (such as the national Computerised Infectious Disease Reporting (CIDR) system for notifiable infectious diseases), thereby facilitating timely recognition of emerging national microbial threats, including antimicrobial resistance.

The Authority has made recommendations in respect of these findings.

Part 7

Findings in relation to National Incident Management and Learning

13 Findings in relation to national incident management and learning

13.1 Introduction

International evidence shows that the delivery of healthcare services will always include some element of risk and that in every healthcare system errors can and will happen. Learning when things go wrong is crucial in order to improve patient safety and reduce the risk of similar events occurring again. This learning should be applied both in the organisation where the error occurred and elsewhere in the wider health service when there is the opportunity for national learning. This would allow the HSE to nationally prioritise the development and implementation of learning, for example through safety programmes, to reduce the risk of recurrence of a similar event in the future.

Individuals and organisations that provide a high quality, safe and reliable service should also learn from other information relevant to the provision of safe services. Such information must be accurate, valid, reliable, timely, relevant, and complete and comes from a variety of sources including:

- lessons from adverse events and near misses, complaints and claims within their service
- learning from clinical audit
- performance against key quality and safety indicators
- findings from national and international inquiries into major patient safety incidents
- service-user and patient feedback
- local and national analysis of patient safety incidents
- monitoring performance and compliance with standards and/or guidelines
- coroners' inquests.

It is important that such information is actively used to inform and improve the safety of health services within each healthcare facility and, through its integration into evidence-based practice, national policy and national clinical care programmes.

Failure to implement learning in this way has potential for errors to be repeated in the future, resulting in further patient harm.

The Terms of Reference of this investigation required the Authority to investigate the arrangements that the HSE has in place to assure the delivery of high quality, safe and reliable services, including the arrangements relating to the reporting and management of patient safety incidents. This included the arrangements for the implementation of the National Clinical Care Programmes, which are a joint initiative between the HSE and the Forum of Irish Postgraduate Medical Training Bodies with the shared objective of improving the quality of care the HSE delivers to all users of HSE services.

While reviewing these arrangements the Authority identified opportunities for improving how information from patient safety incidents is used, and how recommendations of national reviews and investigations into these incidents and the clinical care programmes are implemented. This chapter outlines these findings and associated recommendations.

13.2 National Systems for incident reporting

The national systems for clinical incident reporting in place in Ireland at the time of the investigation consisted of:

- STARS Web – the information system through which hospitals funded by the HSE report clinical and non-clinical incidents and near misses. The system is run by the Clinical Indemnity Scheme (CIS).
- The National Incident Management Team of the HSE to whom all hospitals funded by the HSE escalate high-risk serious clinical incidents in line with HSE policy[65].

13.2.1 STARS Web and the Clinical Indemnity Scheme

The Clinical Indemnity Scheme (CIS) was established in 2002 to rationalise medical indemnity arrangements by transferring to the State, via the HSE, hospitals and other health agencies, responsibility for managing clinical negligence claims and associated risks.

One of its objectives is to provide risk management advisory services to State authorities, including the HSE, with the aim of reducing the frequency and severity of adverse events and in so doing, also reducing subsequent claims.

In 2004, the introduction of the CIS's STARS Web system provided organisations with a central point for the recording of non-clinical and clinical incidents and near misses. It is a confidential and highly secure web-based information technology (IT) system. The system links hospitals and other healthcare enterprises to the Clinical Indemnity Scheme's core database. Each enterprise has access only to its own data; however, the State Claims Agency can access all data in order to identify emerging trends.

Indemnity for the specialty of obstetrics is provided by the State Claims Agency and represents a significant volume and cost of all medico-legal claims in Ireland. In 2011 the State Claims Agency reported that active obstetrics-related claims accounted for almost a quarter (23%) of all claims submitted for that year[66]. These cases represented 59% of the total cost of all medico-legal claims for 2011.

However, at interview it was reported that the HSE Clinical Care Programmes, at both Director and Clinical lead level, do not currently have formal links with the CIS. It was subsequently reported by the HSE in September 2013 that links do exist through the annual publication of analyses of incidents reported by the HSE to the CIS and through regular meetings between the HSE and CIS. This disparity in perception between those interviewed and information submitted by the HSE indicates potential gaps in the context of sharing learning and enabling the effective prioritisation of quality and safety programmes resulting from reported adverse events across the maternity services nationally.

13.2.2 National Incident Management Team

The HSE's National Incident Management Team (NIMT) has functioned through the pre-existing HSE Serious Incident Management Team since 2010. The function of the National Incident Management Team is to promote and support improvements in the management and investigation of incidents, including a standardised approach to incident management with supporting policies, procedures and guidelines. It was reported that a Quality and Patient Safety Incident Information Management System (QPS IIMS) was in development to support the NIMT, with Phase 1 of the system having been rolled out in February 2012 to facilitate the communication of information from the RDO to the NIMT.

It was clarified at interview that it is not the role of the National Incident Management Team to provide national oversight to all incidents which occur in the Irish healthcare system. Rather, it was reported that there are set criteria in place for the escalation to the National Incident Management Team of certain incidents with a potential national impact (for example, the case of Savita Halappanavar).

At the time of the investigation, there were two co-chairpersons of the National Incident Management Team. One representing the Quality and Patient Safety Directorate (QPSD) of the HSE and the other representing the Integrated Service Directorate (ISD) of the HSE. The Authority explored the rationale behind the appointment of two chairpersons and it was described at interview as a shared accountability arrangement, with each co-chair reporting to their respective National Directors, who both hold overall shared accountability for the NIMT. However, in separate documentation provided by the HSE, it was confirmed in September 2013, that the National Director for Quality and Patient Safety has overall accountability for the NIMT.

13.3 National governance structures for incident management and escalation

As part of the investigation, the HSE provided the Authority with details of the local, regional and national governance structures for the escalation and management of risks and incidents. Analysis of these structures indicated that identifying and managing risks and incidents is primarily the responsibility of the local manager. In accordance with the principle of regional accountability, the regional directors of operations (RDOs) were responsible for the management of risks and incidents in their area of responsibility. However, as part of HSE organisational restructuring, at the time of the investigation, it was reported that the new role of Regional Directors for Performance and Integration (RDPI) (July 2013) have taken over the role of RDO.

The documentation submitted by the HSE at the time of the investigation, did not identify the planned interim governance arrangements that were to be put in place during the organisational restructuring process towards the establishment of Hospital Groups to support effective incident management. In addition, the HSE documentation did not identify the formal structures in place for escalation and management of incidents by the hospital groups/shadow trust structures to which a regional governance structure does not apply, such as the Galway and Roscommon University Hospitals Group and Mid-Western Hospital Group, both formed in 2012.

The HSE clarified at interview and through documentation that the chief executive of a hospital group/shadow trust is accountable for the management of risks and incidents and engages regularly with both the National Director for Integrated Service Delivery and the National Director for Quality and Patient Safety through a performance review process.

Following the death of Savita Halappanavar on 28 October 2012, the Hospital notified the NIMT on 1 November 2012. A local UHG Investigation Team was established on 13 November in line with HSE practice for the review of serious incidents. However, on Monday 19 November, the HSE announced that the NIMT was to conduct an incident investigation, led by an external chair and as a result, the local UHG Investigation Team was stood down. It was reported by staff at the Hospital that an additional local, internal review was not undertaken in parallel to the HSE's incident investigation.

13.4 Improving incident management processes

In addition to learning from the incident itself, there is also an opportunity to learn from how the incident is managed and reviewed to ensure that any potential areas for improvement can be identified. It was reported at interview that the National Incident Management Team had developed a tool to assess compliance with the HSE guidelines for systems analysis investigation of incidents and complaints for investigators at local level to monitor their own compliance with this guideline[67].

This tool was published by the HSE in November 2012.

At a national level, it was reported that the National Incident Management Team planned to arrange for audits in line with the published guidelines (November, 2012) and this was to be conducted through the HSE Healthcare Audit function. However, up to that point, there was no reported established and standardised audit practice across the system; this included an absence of an automatic audit of incident reviews where the incident management/review process had not achieved optimum results.

13.4.1 Involvement of patients and family members in incident management

On exploration at interview with the HSE, it was clarified that the membership of the HSE incident investigation team had been established in line with HSE policy, which was reflective of international best practice and advice. Regret was also expressed by the National Incident Management Team and the Quality and Patient Safety Directorate that the family had chosen not to participate in the incident investigation into the death of Savita Halappanavar.

The involvement of patients, and/or their family, is a key component of reviewing a clinical incident. When a patient is receiving care, more often than not, no one is closer to the patient than a family member or care giver. They are often a consistent presence throughout each stage of a patient's care, for example, from attending at an emergency department, to an inpatient ward, to surgery, on transfer to another ward and so on. Inclusion of the patient, and/or their family, can also increase the credibility of the process and validity of the overall findings and lessons learned. HSE incident management policies provided to the Authority outlined the approach to be taken by staff to involve families in the review of an incident.

13.4.2 Supporting staff

It is recognised that healthcare staff do not set out to harm patients in their care and healthcare staff are deeply upset by adverse events which result in harm to patients. As such, when an adverse incident occurs, the staff involved in the patient's care may also be significantly impacted, both emotionally and functionally.

Staff who have been involved in an adverse event have been described as the unrecognised 'second victim'[68]. Incident management structures should include staff and promote learning and healing, as opposed to excluding staff which can promote blame.

It was reported at interview that the HSE Incident Management Policies and Guidelines state that managers must ensure that employees receive the appropriate support during an incident management process. This includes access to an employee assistance programme and occupational health services. The HSE

provided a Policy for Preventing and Managing Critical Incident Stress (2012) which indicated the arrangements in place for the prevention and management of stress following exposure to a critical incident or traumatic stressor, a critical incident being defined as "an event out of the range of normal experience – one which is sudden and unexpected, makes you lose control, involves the perception of a threat to life and can include elements of physical or emotional loss"[69]. However, this policy did not make any particular reference to support for staff throughout an incident management or an investigation process nor was there a national audit mechanism in place to ensure that the support for staff is occurring consistently and to a satisfactory standard within the system, during an incident management or incident investigation process.

While there is public consultation on policies pertaining to incident management, there was no specific national policy or mechanism in place to facilitate staff feedback on how an incident is managed. In promoting an open and just culture of patient safety and quality, it is important to be proactive in identifying opportunities for improvement and to involve staff in identifying new mechanisms to ensure open disclosure becomes an established norm in our healthcare system.

Importantly, an open and just culture is not a 'blame-free' culture but a culture that requires full disclosure of mistakes, errors, near misses and patient safety concerns in order that system-based analysis can take place to identify learning. It equally balances this with the holding to account of those whose competencies and performance has fallen below what might reasonably be expected of them.

13.5 Learning from a national patient safety inquiry

In exploring the national learning from national investigations and inquiries, the Authority reviewed the implementation status of the following HSE inquiry:

- The HSE's Report into the circumstances pertaining to the death of Tania McCabe and her infant son Zach at Our Lady of Lourdes Hospital, Drogheda on 9 March 2007[47].

The report into the circumstances pertaining to the death of Tania McCabe and her infant son Zach was of particular relevance to this investigation given that Tania McCabe died after developing septic shock following premature rupture of the membranes. The HSE reported in January 2013 that 25 of the report's 27 recommendations have been implemented in full in Our Lady of Lourdes Hospital, Drogheda.

While most of the 27 recommendations in the HSE report were specifically directed for implementation at a local level, the Authority believes that the report had and continues to have wider application to all maternity units in Ireland and learning from this should have been implemented nationally. In reviewing the recommendations of the HSE report into the death of Tania McCabe, the Authority noted that many of the recommendations had particular relevance in the care of Savita Halappanavar.

For example:

> *The HSE should adopt the international Surviving Sepsis Campaign which encompasses awareness, early recognition and standardised treatments of sepsis. This would encourage the implementation of these standards nationally.*
>
> *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 [the HSE review team of the Tania McCabe report] strongly recommend that the ICSI [Intensive Care Society Ireland] and the Institute of Obstetricians and Gynaecologists should formulate a strategy for the care of the critically ill woman in pregnancy for all hospitals in Ireland.*
>
> *The primary consultant and his/her team should ensure timely follow up of all tests ordered.*
>
> *The immediate care a patient receives must be dictated by their needs and this should commence upon the recognition of their estimated required Intensive Care Society Ireland Level of Care. The HSE should embrace this approach and ensure adequate training and resources to support this new concept.*

The HSE reported that at the time of the publication of the Tania McCabe report in 2007, the governance arrangements for implementation of the recommendations were at a local HSE level with regional HSE oversight. A formal status report was then sent by the Regional HSE Network Manager to the Director of the HSE National Hospitals Office for dissemination to the public maternity hospitals/units. The Investigation Team explored the national implementation status of all 27 recommendations. However, the HSE reported that the current procedures for ensuring national implementation and learning from major reports were not in place at the time of the Tania McCabe report.

As part of the investigation, the Authority requested the HSE to provide details of how the recommendations of the report into the circumstances pertaining to the death of Tania McCabe and her infant son Zach at Our Lady of Lourdes Hospital had been implemented at each of the 19 public maternity units/hospitals (as applicable to their hospital). According to information received from the HSE, five of the 19 hospitals/units provided a detailed status update for all 27 recommendations, with one hospital/unit reporting that 24 out of 27 recommendations were implemented. Six of the 19 maternity hospitals/units reported their status against a different investigation, had no comment, or reported that evidence for implementation was not in existence. This is unsatisfactory and concerning. The remaining hospitals/units reported a number of local guidelines and/or training programmes that were put in place in response to the recommendations, for example, sepsis guidelines and guidelines for pre-labour rupture of membranes. Others reported that recommendations were reported on and followed up and actioned through the minutes of meetings.

The responses from the hospitals/units in the HSE Dublin North East and Dublin Mid Leinster tended to be more informative than those from elsewhere in Ireland in terms of status updates for each recommendation. This suggests a regionalised rather than national approach to implementation of the recommendations.

The lack of a coordinated approach to the implementation of the recommendations of the HSE inquiry into the death of Tania McCabe again raises a fundamental and worrying deficit in our health system – namely the ability to implement and apply system-wide learning from adverse events across the system in a timely and appropriate manner in order to prevent the recurrence of patient safety events that may cause harm, or worse, to future patients.

13.6 Implementation of HIQA reports

Since 2007, the Authority has conducted six investigations, with this investigation included, and one statutory inquiry into the quality and safety of services provided by the HSE and other service providers. The Authority has made a number of recommendations for implementation and it is apparent that the HSE has implemented many of these recommendations. However, the pace of implementation has been slow.

This section of the Report provides an overview of the particular recommendations made by the Authority in previous investigations, where the timely and effective implementation of them nationally may potentially have influenced the provision of care provided to Savita Halappanavar. These recommendations primarily relate to early warning systems and critical care services.

It was reported at interview that the HSE developed a policy, approved in December, 2011, for supporting major investigations, receipt of subsequent reports and managing the implementation of report recommendations[70]. This policy applies to reports received from the Authority and other statutory regulators, commissioned by the Minister for Health or Government, commissioned by the National Incident Management Team, received from the Office of the Ombudsman and other reports as determined by the HSE's National Director for Quality and Patient Safety.

The above policy outlines that a HSE implementation team, under the governance of its Quality and Patient Safety Directorate, is set up to support the implementation of recommendations of investigation reports. It states that implementing recommendations from the specified investigation reports is the responsibility of the service area to which they apply. It was reported by the HSE that this process follows the principles of the HSE Toolkit of Documentation to Support the Health Services Executive Incident Management (2009)[71] in relation to the implementation of recommendations.

The HSE has established a Steering Group for advising and overseeing the implementation of recommendations of the HSE incident investigation into

the death of Savita Halappanavar, to incorporate the recommendations of the Coroner's inquest and the recommendations of this HIQA Investigation.

It was reported in the terms of reference for this Steering Group provided by the HSE, that the Chair of the Steering Group was the Assistant National Director for Quality and Patient Safety (QPS), the post-holder having a dual reporting arrangement in place to the National Director for Quality and Patient Safety and the National Director, Integrated Services Directorate (ISD). It is noteworthy that the Steering Group, as per the terms of reference, is an advisory and oversight role rather than a formal role in the implementation of recommendations.

The HSE's action plan for implementing the recommendations of the HSE incident investigation, was submitted to the Authority in July 2013. This action plan identified the named accountable person for overall implementation of the recommendations as the HSE's Director General. At a local and regional level, accountability for implementation of the recommendations was reported as resting with the role of Regional Directors for Performance and Integration (RDPI). It was reported that implementation was taking place through national clinical leads for particular service areas.

Although the action plan submitted by the HSE identifies the Director General of the HSE as the accountable person, with individual national clinical leads responsible for their specialty areas, the plan did not identify who is the delegated named individual who holds overall responsibility for the implementation and ongoing monitoring of the recommendations at a national level.

This is of significant concern to the Authority, particularly when implementation of previous recommendations from national investigations has been historically slow and inconsistent.

In addition, and as indicated earlier in this report in Chapter 8, the findings of the three investigative processes, including this HIQA investigation, have highlighted a number of issues of non-compliance with the *National Standards for Safer better Healthcare* both at local and national level. (See Appendices 14 and 15). In parallel with any action plan for the implementation of these recommendations, the HSE, together with the Galway and Roscommon University Hospital Group and all providers of maternity services, should assure itself of the actions needed to bring the maternity services into compliance with those National Standards.

13.6.1 National Early Warning Score

In 2011, the Authority, in its investigation report into Mallow General Hospital,5 and again in its 2012 report into the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (Tallaght Hospital)[4], recommended that the HSE should, as a priority, agree and implement a National Early Warning Score (NEWS) to ensure that there is a system of care in place for the prompt identification and management of clinically deteriorating patients. A National Early Warning Score was developed and rolled out to all acute hospitals in 2012.

However, the scope of the NEWS did not extend to obstetric patients due to the difference in physiological parameters between obstetric and general patients for the early recognition and management of deterioration in clinical condition. Since this investigation started, all HSE maternity hospitals/units had commenced the implementation of the Irish Maternity Early Warning System (I-MEWS), a maternity EWS chart.

13.6.2 Critical care services

The Authority, in its Mallow Hospital report (2011),[5] made a number of recommendations relating to the quality and safety of arrangements in place for the provision of critical care services both regionally and nationally. These included recommendations that the:

HSE and all healthcare service providers must ensure that ICS [Intensive Care Society] Level 2/3 critical care is delivered to patients at a unit where there are on-site senior clinical decision makers with the required competencies available.

HSE must take immediate action to put arrangements in place for the implementation of national mandatory patient transfer and acceptance protocols to ensure the immediate and safe transfer of critically ill patients to a unit providing ICS Level 2/3 critical care. It also included that consideration should be given to a nationally-managed critical care network to optimise critical care capacity regionally and nationally.

HSE must put in place arrangements for the routine collection and evaluation of critical care services demand and capacity information to inform any planned clinical service change.

At the time of this investigation, the Authority was not assured by the HSE that the above recommendations had been effectively implemented to include the maternity services. The Authority further determined that the arrangements in place for the provision of critical care services to maternity patients varied nationally.

Data submitted by the 19 maternity hospitals as part of this investigation indicated that the majority of maternity hospitals/units accessed the general critical care unit of the main hospital on site where the maternity hospital/unit was co-located on the same campus. In the case of stand-alone maternity hospitals, patients requiring critical care were transferred by ambulance to the closest general hospital providing critical care services. Some maternity hospitals/units had arrangements in place for the provision of high dependency care on the labour ward/delivery suite while awaiting transfer to an appropriate high dependency unit or intensive care unit (ICU).

However, it was reported at interview that there were challenges associated with the timely transfer and admission of maternity patients from a maternity hospital/unit to a general ICU and it was also reported that there were no national pathways for initiating critical care in maternity units before transfer of care to the ICU.

At the time of the investigation, the HSE's National Clinical Care Programme for Obstetrics and Gynaecology was developing a patient pathway for the critically ill mother in collaboration with the HSE's National Clinical Care Programmes for Anaesthesia and Critical Care for implementation nationally in the 19 maternity units. The development of this pathway for the care of the critically ill obstetric patient was reported as completed and was scheduled to be signed off by the end of September 2013, to be implemented immediately afterwards.

In addition to this, the National Clinical Care Programme for Critical Care had developed a Critical Care Model that was reported as being in line with HIQA investigation reports from 2011[5] and 2012[4], the Report on the Establishment of Hospital Groups as a Transition to Independent Hospital Trusts[72] and the report on securing the future of smaller hospitals framework document[73].

Despite these initiatives, the Authority received evidence that at the time of the investigation (during 2013), the maternity hospitals/units were not routinely collecting and reporting information on the length of time that obstetric patients were waiting to be admitted to critical care from the time of request for transfer.

It was reported at interview that there was no system in place at the time of the investigation for recording the numbers of maternity patients who require Level 3 critical care nationally each year. The Authority was of the view that this type of information would be integral to any demand and capacity analysis of critical care services aimed at improving quality and safety.

As with the implementation of recommendations of the Authority's previous investigations, the impact of these initiatives was slow to emerge. The Authority was of the view that the current arrangements at the time of this Report for the provision of critical care gives rise to potential risks for maternity patients who may be at risk of clinical deterioration and/or developing sepsis.

In recognising the significance of this step in the patient journey, as reported in previous investigations, and the potential risk that this poses to the safety and welfare of ill maternity patients, the Authority wrote the Director General of the HSE on 5 July 2013 requesting assurances in relation to the provision of care for clinically deteriorating obstetric patients in a safe, timely manner and that associated risks had been identified and managed effectively (see Appendix 11).

Following receipt of information from the HSE, the Authority sought further assurances from the HSE regarding the availability of high dependency and critical care support for clinically deteriorating obstetric patients. (See Appendix 12).

The Director General responded to the Authority outlining the current arrangements in place to ensure clinically deteriorating obstetric patients are being managed appropriately in a safe and timely manner. This included an overview of the arrangements in place in the 19 maternity hospitals/units in Ireland relating to the implementation and audit of I-MEWS, 24/7 access to senior clinical decision making, operational policies for transfer and clinical handover of care to high dependency/critical care units and mandatory acceptance policies in place at alternative sites where ICU beds are not available on-site (See Appendix 13).

These arrangements are reported in detail in Table 8 on the following pages. Assurances relating to the governance arrangements in place to ensure that clinically deteriorating patients are transferred within and between services safely with continuity of care provision are also indicated in Table 8.

Table 8: Assurances provided by the HSE to HIQA in August 2013 in relation to the quality and safety of critical care services

Assurance 1 **Robust arrangements to ensure clinically deteriorating obstetric patients are being managed appropriately in a safe environment in a timely manner as indicated by maternity services**		
Arrangements in place at hospitals/ maternity units	Percentage compliance	Exceptions
I-MEWS implemented in maternity hospital/unit	100%	
Defined governance structures for auditing implementation and responding to findings from I-MEWS	100%	
Training programme for staff on I-MEWS	100%	
On-call roster that ensures competent consultant cover on a 24/7 basis	100%	
24/7 access to on-site diagnostics	79%	Limerick, Rotunda and the National Maternity Hospital have access to off-site diagnostics. Portlaoise reported no access on a 24/7 basis.
24/7 access to on-site ICU/HDU beds	79%	Limerick, Rotunda, the National Maternity Hospital and The Coombe have access to off-site critical care beds.
24/7 access to anaesthesia	100%	

Assurance 2 **Governance arrangements in place to ensure that clinically deteriorating patients are transferred within and between services safely and there is continuity of care provision as indicated by maternity services**		
Arrangements in place at hospitals / maternity units	Percentage compliance	Exceptions
Operational transfer policies for access to ICU/HDU within the hospital	74%	Kerry, Mayo, Waterford, CUH and The Coombe
Operational policies for the clinical handover of care to ICU/HDU	74%	Kerry, Mayo, Waterford, CUH and Letterkenny General Hospital
Where ICU beds are not available on-site, there are acceptance policies in place with an alternative site for access to an ICU bed	63%	Kerry, Mayo, Wexford, Cavan, Sligo, Portlaoise, Mullingar

Assurance 3 **Processes in place to identify all risks relating to the current arrangements for the provision of care to clinically deteriorating obstetric patients with actions in place to mitigate risks as indicated by maternity services**		
Arrangements in place at hospitals / maternity units	Compliance	Exceptions
A process for assessing and managing risks relating to the provision of obstetric care, and if required risks are placed on a Directorate's/Hospital's risk register	100%	
A review of any identified risks and mitigating actions by a clinical governance committee in the hospital including follow-up on actions from the reviews	100%	
A review of incidents/complaints or adverse events by a clinical governance committee in the hospital including follow-up on actions for the reviews	100%	

Where hospitals/maternity units do not have the arrangements in place, it was reported that hospitals were directed to immediately ensure that the required policies were completed and implemented in full with a timeline for completion of mid September 2013. An independent audit was scheduled to take place at these sites during the final three months of 2013.

The development of the pathway for the care of the critically ill obstetric patient was reported as completed and was scheduled to be signed off by the end of September 2013, to be implemented immediately afterwards.

The HSE reported that it will continue to monitor the introduction of I-MEWS through the regional and national performance review processes, feedback from the Maternity Hospital Programme Implementation Boards and through Clinical Governance Committees at hospital level.

Further details of the assurances provided by the HSE are included in appendix 13.

Following review of the HSE response received on 27 August 2013, the Authority, while noting the response on assurances in respect of the safety of services in a number of hospitals, remained concerned that such assurances were not in place for every hospital providing maternity services. The Director General gave a commitment in his letter that assurance would be in place by September 2013. With this in mind the Authority will require further progress updates in respect of safety over the coming months.

13.7 Learning from coroners' recommendations

Certain deaths of patients within the healthcare services must be reported to the coroner who will decide if an inquest to further examine the cause of death needs to be held. On conclusion of this inquest, the coroner will usually make recommendations based on the learning from the case, which are aimed at improving safety for future patients.

In Ireland, the coronial process sits within the legal system and is entirely separate to the quality improvement process in the healthcare system. The recommendations made by the coroner are usually only directly communicated to the organisation where the death occurred. The HSE reported that the implementation of the Coroner's recommendations arising from the inquest of Savita Halappanavar was incorporated into the overall HSE implementation plan for the recommendations of the HSE incident investigation and the HIQA Investigation.

However, there was no centralised national database for collating, disseminating and implementing learning and recommendations gathered from these inquests nationally to all relevant healthcare services.

The Authority considers this to be a significant deficit given the invaluable source of learning that the coronial process brings to improving the quality and safety of patient services.

13.8 Learning from the service user

Actively seeking feedback from service users and patients and learning from complaints, concerns, claims and compliments is critical in the development and implementation of initiatives to improve the safety and quality of patient care.

As part of the investigation, the HSE provided the Authority with an analysis of complaint letters received from pregnant women following their discharge from HSE-funded maternity services. It was reported by the HSE that this analysis was carried out to inform the development of the National Healthcare Charter for Maternity Services, which is due for public consultation in October 2013. The Authority found that while this analysis document quantified and categorised complaints, it did not reach any specific conclusions, nor did it detail recommendations to address the analysis' findings. The HSE reported that the patient sample size was small and not representative of the experiences of all women who have used the maternity services.

The HSE should review their processes for carrying out complaints analysis to ensure that the information gathered is valid, reliable and representative of the experience of maternity service users. In addition, the Investigation Team found that there was limited communication within the HSE in relation to this complaints analysis. The Authority was concerned that this showed a missed opportunity to address and disseminate information gathered from learning within the HSE.

It was reported that the role of the HSE Director of the National Advocacy Unit is not an operational role – rather it is to provide advice, policy and support. The Authority is concerned that there is a lack of ownership for the implementation of findings from national learning from service-user and patient feedback and this can lead to an inability to learn from service users' and patients' negative experiences and put steps in place to minimise their risk of recurrence.

13.9 Learning from international evidence and best practice

Safe, effective and reliable care for service users is achieved by using best available national and international evidence and standards. Clinical guidelines for healthcare professionals are a key intervention to support evidence-based practice. It is important that clinical guidelines are developed through a systematic approach and are linked to service delivery priorities, many of which may result from learning from adverse events.

13.9.1 Learning from international evidence

In Building a Culture of Patient Safety – Report of the Commission on Patient Safety and Quality Assurance (2008), the importance of learning from the findings and recommendations of both national and international patient safety events was emphasised and the report stated that it is essential that the lessons learned in one healthcare setting are communicated regionally, nationally and internationally[9].

The Commission advised that this required consideration of improved mechanisms for deliberate communication between other jurisdictions in relation to patient safety issues, rather than relying on constantly scanning all horizons.

It was reported by the HSE that the Quality and Patient Safety Directorate has prioritised learning from national incidents and complaints. However, at the time of the investigation, there were limited systems and resources assigned in the Quality and Patient Safety Directorate to conduct international reviews to identify relevant reports for learning which may be applicable in the Irish setting. The Authority is of the view that this is a significant opportunity lost and recommends that a formal coordinated response by the HSE to reviewing international evidence and acting on relevant learning and recommendations is required in order to consider valuable lessons learned in other jurisdictions which may applied by the HSE to improve the outcomes for patients in Ireland.

13.9.2 Clinical guidelines in Ireland

The development and use of clinical guidelines is not a new concept within the Irish healthcare system. There are many examples of clinical guidelines that have been developed for use at local and national level by various organisations and professional groups including the Irish College of General Practitioners, Royal College of Physicians of Ireland, Royal College of Surgeons in Ireland and the HSE's National Clinical Care Programmes.

Building a Culture of Patient Safety – Report of the Commission on Patient Safety and Quality Assurance (2008) highlighted that there was no formal system in place at national level in Ireland which sets quality assurance standards for evidence-based guidelines, and that the implementation of guidelines was not being systematically monitored or incorporated into routine health service management processes[9]. The National Clinical Effectiveness Committee (NCEC) was established in September 2010 as part of the Department of Health's Patient Safety First initiative to respond to the recommendations made by Building a Culture of Patient Safety. The role of the NCEC is to prioritise and quality assure clinical guidelines and clinical audits so as to recommend them to the Minister for Health for endorsement to become part of a suite of national clinical guidelines and national clinical audits. Local and national guideline development groups can submit clinical guidelines to the NCEC for consideration to be included in this process.

Importantly, the NCEC identifies that not all clinical guidelines need to be submitted for national endorsement, stating that guideline development groups should continue to develop clinical guidelines in response to the needs of their own organisations. However, once a national clinical guideline is endorsed it will supersede any other guidelines on that topic.

The National Early Warning Score became the first guideline to be recommended by the NCEC and endorsed by the Minister for Health in February 2013. This is

an important development. However, it is of concern that four years since the inception of the National Clinical Care Programmes, no further national guidelines and no national clinical audits had been recommended for national endorsement by the NCEC.

The HSE Clinical Care Programmes are tasked with developing what represents evidence-based practice within its programme, and producing guidelines and integrated care pathways for patients in its specific area. However, it is imperative that the arrangements to support the national endorsement of key national guidelines have sufficient capacity and capabilities to review the guidelines produced by the Clinical Care Programmes and recommend them for endorsement as appropriate. The Authority recommends that the Department of Health immediately reviews the current arrangements to ensure the NCEC is adequately resourced to meet this requirement.

13.9.3 The HSE's National Clinical Care Programmes

The National Clinical Care Programmes were established in 2010 and are a joint initiative between the HSE and the Forum of Irish Postgraduate Medical Training Bodies with a shared objective of improving the quality of care the HSE delivers to all users of HSE services.

This national programme has an important role which is identified in the Department of Health's publication entitled Department of Health Statement of Strategy 2011 – 2014[74]. This identifies the requirement to reform the acute hospitals and highlights the development of the National Clinical Care Programmes to promote service integration. In addition, the Department of Health's report on the Establishment of Hospital Groups as a transition to independent hospital trusts (2013) identifies that the hospital groups will adhere to the principles of the National Clinical Care Programmes[72]. In this context, it is imperative that the National Clinical Care Programmes must be effectively structured and resourced to ensure that they can work in parallel to and meet the objectives of the national strategy.

The Authority previously highlighted in its report of the Tallaght Hospital investigation (2012) that there should be a nationally integrated programme-managed approach to the implementation of the National Clinical Care Programmes, both at national level across the health service and at local hospital level. The Authority also recommended that it should be effectively led, governed, managed, implemented and monitored in order for such initiatives to bring about the improvements required.

The next section of the Report reviews the current governance arrangements in place to ensure effective implementation of the Clinical Care Programmes, which includes the National Clinical Care Programme for Obstetrics and Gynaecology.

13.10 Governance arrangements for the National Clinical Care Programmes

Governance for the Clinical Care Programme sits with the Director of the Clinical Strategy and Programmes Directorate of the HSE, who was newly appointed in November 2012. There were 37 Clinical Care Programmes in existence, each governed by a clinical advisory group and a multidisciplinary working group. These groups are tasked with developing what represents evidence-based practice within their programme, producing guidelines, standards and integrated care pathways for patients in their specific area.

In line with the Authority's Tallaght Hospital recommendations in May 2012, the governance arrangements for these National Clinical Care Programmes had changed with the appointment of the Director of the Clinical Strategy and Programmes Directorate of the HSE in November 2012. It was reported by the HSE that the 37 existing Clinical Care Programmes had been restructured into six groupings to ensure better integration of the Clinical Care Programmes. The six groupings identified are as follows:

- unscheduled care group
- long-term conditions group
- cardiovascular and cerebrovascular diseases group
- diagnostics and support group
- primary and continuing care group
- women's and children's group.

In general, the Authority found that movement towards an integrated approach to programme management and delivery were at an early stage of development with many of the key features of the clinical programmes under review.

However, at the time of the investigation, the Authority was not sufficiently assured as to the strength of the HSE's governance arrangements to implement this work. For example, it was reported that the:

- work of the Clinical Care Programmes and all lead positions were to be reviewed
- group leads were to be appointed to each of the groups listed above to ensure the programmes were integrated
- clear individual roles and responsibilities for group leads, clinical leads and programme managers had not been defined
- clinical leads across the programmes had different levels of understanding of their roles
- sessions allocated to each clinical lead for clinical programme work varied across the clinical programmes
- programme management arrangements were reported as being variable.

Funding for the programmes and resource allocation was also being reviewed. In addition, while there were arrangements in place for the identification of key result areas for programme delivery, it was reported that a standardised process for selecting key performance indicators was going to be developed.

The HSE reported that the National Clinical Care Programmes have a strategic focus only and that implementation takes place through the HSE's Integrated Services Directorate. The Care Programmes have an advisory role rather than an operational role.

The Authority is concerned that there is no clear pathway to provide assurance that the arrangements for programme implementation within the HSE are developed and clear and this represents a significant missed opportunity to develop and embed best practice across a range of clinical services. For example, it was reported by the HSE that the clinical pathway for the critically ill pregnant woman is progressing and will be completed by the end of Quarter 3, 2013. However, it is not clear based on the findings of this investigation how this will be nationally delivered across the 19 maternity hospitals/units and who is ultimately accountable and responsible for its implementation. It is imperative that this approach is developed, published and implemented without delay in order to ensure opportunities are maximised in bringing about this patient safety improvement for critically ill maternity patients.

In addition, the HSE reported that it was not the responsibility of the National Clinical Care Programmes to respond to recommendations of national reviews and investigations. It is imperative that the strategy for implementation of each care programme is aligned with the HSE's strategy for implementation of evidence-based recommendations of national investigations and reviews as they relate to the objectives of each Clinical Care Programme and the quality and safety of HSE clinical services in order to ensure that learning is incorporated into future practice where applicable.

13.11 Summary of findings in relation to national incident management and learning

Healthcare will never be without risk. Therefore, sometimes things may go wrong for patients. This may happen despite the best efforts of staff providing the services. What is essential is that the health services at a national and local level ensure that there are robust arrangements in place to mitigate risk and if an adverse event happens to a patient that they then investigate, analyse and learn from any mistakes that may have occurred.

In saying this, the Authority advises that organisations balance the concept of (a) having an open and just culture that requires full disclosure of mistakes, errors, near misses and patient safety concerns, in order that system-based analysis can take place to identify learning against (b) the importance of holding to account those whose competencies and performance has fallen below what reasonably might be expected of them.

The Authority reviewed the national governance arrangements in relation to incident management. At the time of the Investigation, the Authority was unable to establish who had the overall accountability for, and governance of, the National Incident Management Team. This arrangement indicated that there was potential for confused accountability in respect of the reporting, management and learning from national incidents. However, it was subsequently reported to the Authority in September 2013 that the National Director for Quality and Patient Safety has overall accountability for the NIMT.

The National Clinical Care Programmes are a joint initiative between the HSE and the Forum of Irish Postgraduate Medical Training Bodies with a shared objective of improving the quality of care the HSE delivers to all users of HSE services. However, the HSE reported that each Clinical Care Programme has a strategic focus only and that the implementation of the programmes takes place through the HSE's Integrated Services Directorate. In addition, the HSE reported that it was not the responsibility of the National Clinical Care Programme Leads to respond to recommendations of national reviews and investigations. It is imperative that the strategy for implementation of each Clinical Care Programme is aligned with the HSE's strategy for implementation of evidence-based recommendations of national investigations and reviews as they relate to the objectives of each Clinical Care Programme and the quality and safety of HSE clinical services.

In looking at the process to ensure that there is national learning from national investigations and enquiries, the Authority reviewed the implementation status of the recommendations of the HSE enquiry into the death of Tania McCabe and her infant son Zach at Our Lady of Lourdes Hospital in 2007. The HSE reported that these recommendations were implemented at a local HSE level with regional HSE oversight. However, on enquiry the Authority notes that only five of the 19 maternity hospitals/units were able to provide a detailed status update.

The lack of a nationally-coordinated approach to the implementation of the recommendations of the HSE inquiry into the death of Tania McCabe, the lack of local governance arrangements to ensure that recommendations as applicable to their particular service are implemented and the ambiguity regarding who has the overall ownership of and responsibility for implementing the National Clinical Care Programmes again raises a fundamental and worrying deficit in our health system – namely the inability to implement change and apply system-wide learning from adverse events across the system in a timely and appropriate manner in order to prevent the recurrence of patient safety events that may cause harm, or worse, to future patients. This again emphasises the urgent need for 'ownership', accountability and responsibility within the health service's national and local structures for implementation of critically important recommendations made by various review bodies and organisations.

The Authority received evidence that at the time of the investigation (during 2013), maternity hospitals/units were not routinely collecting and reporting information on the length of time that obstetric patients were waiting to be admitted to intensive care from the time of request for transfer. It was reported at interview that there was no system in place at the time of the investigation for recording the numbers of maternity patients who require Level 3 critical care nationally each year. In recognising the significance of this step in the patient journey, as reported in previous investigations, and the potential risk that this poses to the safety and welfare of ill maternity patients, the Authority wrote to the Director General of the HSE on 5 July 2013 requesting assurances in relation to the provision of care for clinically deteriorating obstetric patients in a safe, timely manner and that associated risks had been identified and managed effectively.

Following review of the HSE response received on 27 August 2013, the Authority, while noting the response on assurances in respect of the safety of services in a number of hospitals, remained concerned that such assurances were not in place for every hospital providing maternity services. The Director General gave a commitment in his letter that assurance would be in place by September 2013. With this in mind the Authority will require further progress updates in respect of safety over the coming months.

The Authority has made recommendations in respect of these findings.

Part 8

Conclusions

14 Conclusions

This investigation arose as a result of the tragic death of Savita Halappanavar on 28 October 2012. At the point of the decision to instigate the investigation, and considering the information available to the Authority at that time, it was felt it was essential to not only look at the quality and safety of care for pregnant women receiving maternity services at University Hospital Galway, as reflected in the care of Savita Halappanavar, but also to look at the quality and safety of services provided to clinically deteriorating patients in UHG and the wider national service issues for the delivery of safe and reliable maternity services in Ireland.

While reviewing the evidence that reflected the care provided to Savita Halappanavar, it became apparent to the Investigation Team that there were a considerable number of missed opportunities to intervene in her care which may potentially have resulted in a different outcome for her – these are covered below. The clinical care themes that were reflected by these missed opportunities further informed the Authority's assessment of the quality and safety of services provided to pregnant women across the 19 public maternity hospitals. This was done to identify similar and/or further risks that may be present in these services in order to further improve them and also to prevent any similar recurrence of the circumstances that led to the death of Savita Halappanavar.

The investigation has also identified a number of strategic opportunities for improvement in maternity services nationally. These represent essential components of any modern day, reliable, integrated maternity service that is consistent with best available national and international evidence.

The following sections outline the key concluding findings of this investigation.

14.1 Care provided to Savita Halappanavar

The Authority identified, through a review of Savita Halappanavar's healthcare record, a number of missed opportunities which, had they been identified and acted upon, may have potentially changed the outcome of her care. For example, following the rupture of her membranes, four-hourly observations including temperature, heart rate, respiration and blood pressure did not appear to have been carried out at the required intervals. At the various stages when these observations were carried out, the consultant obstetrician, non-consultant hospital doctors (NCHDs) and midwives/nurses caring for Savita Halappanavar

did not appear to act in a timely way in response to the indications of her clinical deterioration.

In summary, of the care provided there was a:

- general lack of provision of basic, fundamental care, for example, not following up on blood tests as identified in the case of Savita Halappanavar
- failure to recognise that Savita Halappanavar was at risk of clinical deterioration
- failure to act or escalate concerns to an appropriately qualified clinician when Savita Halappanavar was showing the signs of clinical deterioration.

In essence, Savita Halappanavar did not receive the right care at the right time prior to being admitted to the critical care unit – at which point it was too late for clinicians' intervention in her care that would change her outcome.

14.2 The clinically deteriorating pregnant patient

Timely and effective care and treatment depend on regular monitoring and recording of a patient's clinical observations by clinical staff competent in recognising and understanding their significance, communicating and escalating their concerns to include consultation to and by a senior clinical decision maker regarding abnormal patient observations, and the subsequent triggering of appropriate intervention. The Authority found that, at the time of the investigation, this did not happen on St Monica's Ward.

The Hospital maternity early warning score chart was not used and hospital guidelines to include the management of 'Suspected sepsis and sepsis in obstetric care' were not referred to or implemented. In addition, clinical staff had not received specific sepsis training in relation to the application of this policy and/or the specific management of a maternity patient with sepsis. Also, the arrangements for the handover of patient care between the maternity clinical teams were not always effective and were not in line with best available evidence. The physical environment of St Monica's Ward was not designed to effectively identify, monitor and treat patients at risk of clinical deterioration.

The clinical governance arrangements in place in the Hospital failed to recognise that vital Hospital policies and guidance were not in use and the Hospital did not appear at that time to have robust arrangements in place to ensure the staff caring for Savita Halappanavar were fully trained and competent in identifying and managing maternity patients at risk of clinical deterioration.

14.3 Maternity services at University Hospital Galway

The Authority found that the care pathway for patients who required routine access during core hours to maternity services, including access to ultrasound, was not always timely or appropriate. Best practice guidelines for antenatal care

recommend that all antenatal patients should be seen at 10 weeks and have an ultrasound scan carried out to determine gestational age and detect multiple pregnancies between 10 and 14 weeks' gestation. The Authority was unable to clarify if antenatal patients were receiving timely access to maternity services in line with best available evidence. The care pathway for patients who required emergency access to maternity services outside core hours, including access to assessment in the Emergency Department, ultrasound and clinical examination, was not always appropriate or effective. In addition, there was no formal clinical pathway in place to refer high risk obstetric patients to the antenatal high risk service operated by an obstetric anaesthetist.

The National Maternity Healthcare Record was not in use in UHG and maternity patients did not carry their own records. Patient healthcare records were not managed in line with the HSE's Standards and Recommended Practices for Healthcare Records Management. In particular, there was evidence of retrospective entry of information and, in the case of Savita Halappanavar, retrospective notes were entered two weeks following her death.

The labour ward is a critical location for the pregnant patient and best practice is that patients being cared for on the labour ward have direct supervision and care by consultant obstetric staff with 24-hours seven-days-a-week senior midwifery cover. The Authority found that consultants on call for the labour ward were not present on the labour ward but rather were engaged in other clinical activities. In addition, the Authority found that there were no guidelines or clear pathway of referral to ensure patients were seen by a senior clinical decision maker in a timely manner. While anaesthetic availability for the labour ward during core hours was reported as being essentially immediate – in that the location of the gynaecology theatre was in very close proximity to the labour ward – there was no consultant anaesthetist dedicated solely to the labour ward either during core working hours or on call periods. The Authority found that the arrangements to redeploy anaesthetic consultant cover, particularly to obstetric care, were not always effective.

The Investigation Team found that St Monica's Ward, the gynaecology ward where Savita Halappanavar was cared for, was also used as the overflow ward to accommodate ante- and postnatal patients when the wards were full. Consequently, both the casemix of patients accommodated on St Monica's Ward, and their care needs, were significantly diverse. In addition, this included the unscheduled patient presentations out-of-hours of patients with gynaecological and obstetric emergencies. There was no evidence that at the time of Savita Halappanavar's care the Hospital workforce arrangements took account of the complexity and diversity of the patient casemix being cared for on St Monica's Ward.

14.4 Clinically deteriorating general adult patient

The Investigation Team found that UHG was implementing a National Early Warning Score (NEWS) guideline and ISBAR communication tool, as per the national guidelines. However, the Authority was concerned that the early implementation of these initiatives at UHG had lacked multidisciplinary input and involvement and has made recommendations accordingly.

The absence of clear hospital-wide sepsis guidelines could potentially result in inconsistencies in the provision of care. Furthermore, the absence of clear hospital wide definitions for sepsis can result in inconsistencies in the recording, collection and reporting of sepsis-related morbidity data posing a potential shortcoming to improving the quality and safety of services for pregnant women, management of the service and the implementation of learning.

Severe sepsis and septic shock are major healthcare problems, affecting millions of people around the world each year, leading to a mortality rate of one in four (and often more), and is increasing in incidence worldwide[33,34]. Studies have found that survival rates following sepsis are related to early recognition and initiation of treatment. Therefore, it is essential that healthcare organisations have effective systems to recognise and treat patients who may be at risk or be developing sepsis.

14.5 Governance of Galway and Roscommon University Hospitals Group and University Hospital Galway

Since the inception of the Group on 9 January 2012, a significant reorganisation of its corporate and clinical governance structure and quality assurance processes had been undertaken. This reorganisation – as identified in the 2012 Group Annual Report – placed the clinical directorate structure at the heart of this reorganisation, with one of its key priorities to improve the quality of care provided.

The Hospital Group Board was not configured in line with the recommendations of the Tallaght report in that Executive Officers of the Hospital Group were members of the Board. The Quality and Safety Executive Group was primarily responsible for the safety and quality of patient services throughout the Group, and at the time of the investigation was a recent development which would take a period of time to become fully established.

Corporately and at Directorate level, the Group monitored its performance monthly against key performance indicators. However, at the time of the investigation there were few specific-patient-outcome and standard-of-care metrics currently being measured and the Authority has made recommendations in relation to this.

While acknowledging the work that has been undertaken by the Group to establish their governance arrangements and assurance mechanisms, the Authority is concerned at the complexity of these structures and the large number of committees in place, with a number of these involving the same members,

many of whom also have full-time clinical responsibilities. While the Authority is aware of the dependency of the Group's corporate and clinical governance committees on the involvement of these clinical staff, it will be important that strong arrangements are in place to ensure sustainability for that level of contribution while also ensuring that the provision of their clinical services are not compromised. It is equally important that all clinical leaders are supported in developing the composite management competencies to lead and manage their respective clinical directorates in achieving the Group's strategic plan with the principal emphasis being on the quality and safety of patient services. In addition, it is imperative that an effective communication system is in place to ensure buy-in by all front-line staff. Therefore, it is incumbent on the Executive to ensure that the appropriate supporting and monitoring arrangements through the Group's clinical directorate structures are effective and that the organisational structures to support these are less complex.

Patients and members of the public are entitled to expect the highest level of healthcare quality. When the delivery of care falls below that level, they are entitled to ask why and be assured that measures have been taken to protect them and future patients from harm. The HSE with the Hospital Group Board and Executive, must ensure that the recommendations of this investigation and the HSE incident investigation into the death of Savita Halappanavar are implemented.

In addition, the Chief Executive of the Hospital Group, as the HSE delegated officer, should consider the actions, omissions and practices of the professional's involved in the care of Savita Halappanavar, and make appropriate referral(s) to the relevant professional regulatory body/bodies.

14.6 Current profile and governance arrangements for the provision of maternity services in Ireland

At a national level, the HSE's National Director of Integrated Services is responsible for the delivery of maternity services in Ireland. However, there is wide variation in the local clinical corporate governance arrangements across the 19 maternity hospitals/units nationally. Where such inconsistencies in governance structures exist, and given the Authority's concerns in relation to the lack of accessible, consistent and reproducible data relating to the quality of the service, it is impossible at this time to assess the performance and quality of the maternity service nationally.

The predominant model of maternity care throughout Ireland is the hospital-based

consultant-led model of service which was defined by the 1954 Maternity and infant care scheme, in place some 59 years at the time of the investigation. There has been no national review, or national population-based needs assessment, undertaken to identify the appropriate allocation of resources including multidisciplinary workforce arrangements, or the models of care required to ensure that all pregnant women have appropriate choices and access to the right level of care and support at the right time in Ireland.

14.7 Workforce – national maternity services

High quality maternity services rely on having an appropriate workforce with the leadership, skill-mix and competencies to provide proactive, excellent and safe care at the point of delivery on a 24-hour basis.

There have been a number of national and international reports and recommendations in relation to maternity services that have explored the workforce requirements and arrangements for the delivery of safe care. A published Position Paper 2012-2022, produced by the HSE's Obstetrics and Gynaecology Clinical Care Programme, reported that there are a relatively low number of consultant obstetricians and gynaecologists in Ireland and that action should be taken to increase the numbers of trainees into the national system. The Position Paper highlighted that failure to address this issue could potentially lead to serious adverse consequences for the provision of healthcare services in the medium and long term which could be associated with poorer outcomes for women and children.

There is a small variation in the consultant obstetrician-to-live birth ratios in the existing four HSE regions. However, the regions fall significantly short of the one consultant per 350 births as recommended by *The Future of Maternity and Gynaecology Services in Ireland 2006 – 2016* report as being necessary for the provision of dedicated consultant cover on the labour ward for 40 hours per week, a figure supported by international evidence.

In respect of midwifery staff, the Authority reviewed a range of reports, produced by or on behalf of the HSE that had been conducted either nationally or regionally between 2008 and 2012. The most recent report highlighted that future analysis would need to take place after models of care for maternity services are agreed for implementation by the HSE.

Obstetric anaesthetists play an important role in the maternity team. Successive confidential enquiries into maternal deaths in the UK have stressed the importance of a dedicated obstetric anaesthesia service and the timely involvement of the anaesthetic team in the management of the sick obstetric patient. National and international medical literature conclude that a duty anaesthetist should be immediately available for the delivery suite 24-hours-per-day and there should be a clear line of communication from the duty anaesthetist to the supervising consultant at all times.

The Authority is of the view that the findings of these reviews should be considered and incorporated in to a national review of the maternity services as recommended by the Authority.

14.8 Use of Information

In order to provide assurances that pregnant women are receiving safe, high quality and reliable care during and after their pregnancy, maternity services

must collect and analyse quality and safety performance measures to evaluate the performance of their clinicians and their service. These measures should be primarily focused on assessing quality and safety outcomes for patients.

At the time of the investigation, there was no agreed national dataset of quality and safety measures for maternity services in Ireland, and no consistent approach to reporting clinical outcomes. There are a number of data collection sources involved in the collection of maternal morbidity and mortality data in Ireland. However, there is no centralised and consistent approach to reporting on maternal morbidity and mortality.

Savita Halappanavar died as a result of sepsis which progressed to severe sepsis and eventually septic shock. Saving Mothers' Lives, 2011, identified that mortality due to severe maternal sepsis is now the leading cause of direct maternal death in the UK, and also that there are reported increases in maternal sepsis in Ireland. The Authority examined the evidence available for recording of maternal morbidity related to sepsis nationally and found no national agreed definition of maternal sepsis, and inconsistencies in recording and reporting maternal sepsis.

The Lourdes Hospital Inquiry (into peripartum hysterectomy at Our Lady of Lourdes Hospital, Drogheda) in 2006 recommended that annual clinical reports of activity and clinical outcomes should be prepared and published within nine months of the previous year's end[74]. The Authority found that 8 of the 19 maternity units do not produce any form of annual clinical report.

14.9 Antimicrobial surveillance

The results of blood tests taken from Savita Halappanavar identified a particular strain of *E. coli* called Extended-Spectrum Beta-Lactamase (ESBL). ESBL-producing *E. coli* are antibiotic resistant and consequently make the infections harder to treat. Gram-negative organisms including ESBL are a large group of bacteria that can cause a wide range of infections in both community and hospital settings. Effective surveillance of infectious diseases is critical. The Authority identified significant gaps in relation to infectious disease epidemiology in Ireland, particularly for pathogens for which no national reference laboratory services currently exist. In addition, a national governance structure for microbiological reference laboratories was not in place.

Similarly, there was no national laboratory-based alert system that allowed real-time analysis of data from local laboratory information systems, or from other healthcare information systems for notifiable infectious diseases, that allowed timely recognition of emerging national microbial threats including antimicrobial resistance.

14.10 National Incident Management and Learning

At the time of the investigation (during 2013), maternity hospitals/units were not routinely collecting and reporting information on the length of time that obstetric patients were waiting to be admitted to intensive care from the time of request for transfer.

Following the review of the HSE response received on 27 August 2013, the Authority, while noting the response on assurances in respect of the safety of services in a number of hospitals, remained concerned that such assurances were not in place for every hospital providing maternity services. The Director General of the HSE gave a commitment in his letter that assurance would be in place by September 2013. With this in mind, the Authority will be seeking further progress updates in respect of safety issues over the coming months.

It is essential that the health services at a national and local level ensure that there are robust arrangements in place to mitigate risk and if an adverse event happens to a patient that they then investigate, analyse and learn from any mistakes that may have occurred.

In saying this, the Authority advises that organisations balance the concept of (a) having an open and just culture that requires full disclosure of mistakes, errors, near misses and patient safety concerns, in order that system-based analysis can take place to identify learning against (b) the importance of holding to account those whose competencies and performance has fallen below what reasonably might be expected of them.

The lack of a nationally-coordinated approach to the implementation of the recommendations of the HSE inquiry into the death of Tania McCabe, the lack of local governance arrangements to ensure that recommendations are implemented as they apply to services across the country and the ambiguity regarding who has the overall ownership and responsibility in implementing the National Clinical Care Programme raises a fundamental and worrying deficit in our health system – namely the inability to implement change in a connected way and apply system-wide learning from adverse events across the system in a timely and appropriate manner in order to prevent the recurrence of patient safety events that may cause harm, or worse, to future patients. This emphasises the urgent need for 'ownership', accountability and responsibility within the health service's national and local structures for implementation of critically important recommendations made by various review bodies and organisations.

14.11 Concluding remarks

The findings of this investigation reflect a failure in the provision of the most basic elements of patient care to Savita Halappanavar and also the failure to recognise and act upon signs of her clinical deterioration in a timely and appropriate manner. The missed opportunities to intervene in her care that have been identified in this investigation, if acted upon, may have resulted in a different outcome for Savita Halappanavar.

Patients and members of the public are entitled to expect healthcare services that are at the very least safe and free from harm. Cognisant of this fundamental entitlement, and the responsibility of any service provider to provide safe health services, the Chief Executive of the Hospital Group, as the HSE delegated officer, should consider the actions, omissions and practices of the professional's involved in the care of Savita Halappanavar, and make appropriate referral(s) to the relevant professional regulatory body/bodies.

Every day there are patients who receive good, safe care at the Hospital Group and also at other maternity hospitals across Ireland. This investigation has identified that the provision of materity services, on occasion, may not be as safe as they should be or of sufficient quality. Where this is the case, this must be addressed as a matter of urgency.

Every health system must ensure that, both nationally and at a local level, there exists the ability to learn. To learn when things go wrong and ensure that errors are not repeated wherever possible, and also to learn from the best available evidence nationally and internationally to ensure that clinical practice and models of care are safe, effective and up-to-date. This includes learning from incidents within a healthcare setting and also learning from the findings and recommendations of relevant investigations, inquiries, and inquests nationally and also internationally. The responsibility to ensure that this happens sits locally with the Boards and Executives (or equivalent) of healthcare facilities and nationally with the HSE and other corporate bodies providing health services.

The investigation found concerning deficits in how learning, particularly in the areas of maternity services and clinically deteriorating patients, has been adopted and implemented following previous investigations and inquiries. These deficits include an inability to apply system–wide learning to minimise clinical risk for all patients from adverse findings in one part of the system for the benefit of all service users. At the heart of this ability to learn is the culture and leadership within an organisation that actively seeks out ways to continually improve the quality and safety of services for their population in an open and transparent way with clear accountability and responsibility arrangements to do so. The achievement of this must be an aim for all healthcare providers.

Finally, the sequence of events that led to the death of Savita Halappanavar will constitute a difficult read for Praveen Halappanavar, his wider family, the public and healthcare staff across the country. What is critically important is that we must learn from this tragic event and ensure that the findings, learning and recommendations of this investigation, and that of the HSE inquiry, are effectively implemented across the health service. This investigation clearly shows that where responsibility for implementation of learning is not clearly owned, then learning nationally does not happen, as demonstrated in the findings relating to the HSE enquiry into the death Tania McCabe and her son Zach in 2007, the circumstances of which have a disturbing resemblance to the case of Savita Halappanavar.

As a result of the findings of the investigation, the Authority makes a series of

recommendations that focus on the improvements required in University Hospital Galway and across all maternity hospitals/units nationally. These changes include the need to review and improve maternity services in respect of the management of sepsis, clinically deteriorating pregnant women, patient choice, models of care and providing a suitably skilled and competent workforce that can deliver safe and effective care at any given time.

Instrumental to the further development of our maternity services nationally is the recommendation requiring an urgent review of maternity services to ensure that the services purchased and provided on behalf of the State are safe and meet international best practice standards. This review should take account of the outcomes of this investigation and the other investigative processes initiated as a result of Savita Halappanavar's death. The review should inform the development and implementation of a National Maternity Services Strategy.

Moving forward

This investigation includes local and national recommendations for improvement that are specific to the Hospital and also apply nationally. The HSE governance arrangements to support the execution of these national recommendations must be clear, with a named accountable person with overall delegated responsibility for implementation – the implementation plans should include clear timelines and identified individuals with responsibility for each recommendation and action.

The HSE must ensure that every hospital should self-assess itself against the local recommendations within this report and national recommendations where applicable, and develop and implement a Quality Improvement Plan within the context of the National Standards for Safer Better Healthcare where shortcomings exist. The implementation of this Plan should be overseen by the HSE as part of its performance management arrangements and it will be considered as a high priority in the Authority's monitoring programme against the National Standards for Safer Better Healthcare where such services are provided.

These recommendations are grouped together in accordance with the themes of the *National Standards for Safer Better Healthcare* and are reported on the following pages.

Based on the findings of this investigation the Authority will submit this report to the relevant professional regulatory bodies for their consideration.

Recommendations

Local Recommendations **(L=Local, N=National)**

Leadership, Governance and Management	
L1	The Hospital Group must ensure that the recommendations of this investigation, and the HSE incident investigation, are implemented in full through the development of an implementation plan with clear timelines and identified individuals with responsibility for each recommendation.
L2	In accordance with recommendation N6, the Chief Executive of the Hospital Group, as the HSE delegated officer, should consider the actions, omissions and practices of the professional's involved in the care of Savita Halappanavar, and make appropriate referral(s) to the relevant professional regulatory body/bodies.
L3	The Chief Executive must be assured and provide assurance to the Hospital Group Board and the HSE about the quality, safety, timeliness and standards of care provided by the Hospital. These assurances should be provided through regular reviews of key performance indicators (KPIs), patient outcome measures and self assessments against National Standards. KPIs that measure the outcomes and experiences of women using the maternity services should be developed as a priority.
L4	The Hospital Group should review its current governance structures and arrangements, including cross committee membership, in order to ensure that these are in line with the principles of good governance and the recommendations of the HIQA Tallaght investigation.
L5	The Hospital Group should develop a clear action plan to implement the improvements necessary to comply with the *National Standards for Safer Better Healthcare* with a particular and urgent focus on aspects of non-compliance identified within this investigation.
Effective Care	
L6	The Hospital Group should review and amend where required, the models and pathways of care for pregnant women at UHG to include those who require emergency access to maternity services. Following the review, the Group should provide clear and accessible information to pregnant women/ their families and GPs in relation to these.
L7	The Hospital Group should continually review the arrangements to ensure that patients are cared for in a suitable clinical environment that facilitates the delivery of effective and safe care to patients.

L8	The Hospital Group should establish arrangements to ensure and demonstrate that all patient information including a plan of care, clinical observations, diagnostic tests and progress notes are actively followed up on and contemporaneously recorded by the relevant healthcare professional in an agreed format within an agreed patient healthcare record.
L9	The Hospital Group should urgently review the current arrangements for the referral of high-risk antenatal pregnant women to a consultant obstetric anaesthetist and develop a clear referral pathway.
L10	The Hospital Group should review its clinical governance arrangements to ensure that all clinical areas are appropriately implementing local and national policies, procedures and protocols and put in place an assurance mechanism to monitor their effective implementation.
L11	The Hospital Group, as a priority, should review the arrangements in relation to the roll-out of NEWS ensuring that all relevant clinical staff are immediately involved and trained in its use and all other similar patient safety initiatives. The Group should develop a programme of mandatory induction and refresher training for maintaining competency in NEWS.
Workforce	
L12	The Hospital Group should ensure that all medical and midwifery staff involved in the care of antenatal and post natal women regularly maintain their professional knowledge, skills and competence in line with best practice and the needs of the patient group being cared for while fulfilling the requirements of professional regulation.
L13	The HSE and the Hospital Group must put in place arrangements to ensure that the clinical directors have the necessary competencies, as well as adequate time and support, to effectively meet the leadership and managerial requirements of the role.
Safe Care	
L14	The Hospital Group must ensure that arrangements are put in place to support and train all staff responsible for managing risk, adverse incidents, near misses, claims and complaints. The Group should ensure that the review, implementation and monitoring of actions, trend analysis and implementation of learning from such incidents are disseminated to staff and incorporated within the clinical governance arrangements in the Group.
Use of Information	
L15	The Hospital Group should ensure, as a matter of priority, that it reviews and addresses any shortfall in the storage and management of healthcare records in line with the HSE national policy.

National Recommendations

Leadership, Governance and Management	
N1	The HSE must ensure that every hospital providing maternity services self-assess's itself against the local recommendations within this report and national recommendations where applicable, and develop and implement a Quality Improvement Plan within the context of the *National Standards for Safer Better Healthcare* where shortcomings exist. The implementation of this Plan should be overseen by the HSE as part of its performance management arrangements and will be considered as a priority in the Authority's monitoring programme against the *National Standards for Safer Better Healthcare* where such services are provided.
N2	The HSE must put in place effective governance structures and accountability arrangements to assure the delivery of high quality safe health services, including maternity services. These corporate and clinical governance arrangements must include unambiguous lines of accountability for assuring, performance managing and improving the quality and safety of services at a national, regional, local and clinical level.
N3	The HSE must demonstrate that it has the governance structures and mechanisms in place to ensure that the findings, learning and performance management of relevant healthcare organisations, in respect of implementing safety and quality issues emanating from serious adverse incidents, near misses and their investigations, are implemented.
N4	The HSE must ensure that there are clear mechanisms that provide assurance for the implementation and monitoring of the National Clinical Care Programmes, to include clear descriptors of the accountability arrangements at a national, regional, local and clinical unit level. This should include a programme of audit and evaluation to ensure that programmes are consistently implemented by each service provider.
N5	The HSE, as the national agency accountable for the planning, delivery and commissioning of health services, should develop a robust system to ensure that all service providers can demonstrate compliance with the *National Standards for Safer Better Healthcare* and, where shortfalls are identified, apply mechanisms by which it can assure itself that proactive and corrective action is being taken by any given provider.

N6	The Department of Health should develop a 'Code of Conduct' for employers that clearly sets out employers' responsibilities in relation to achieving an optimal safety culture, governance and performance of the organisation. The Code should include the expected attributes, behaviours and responsibilities of all managers as representatives of the employer, and underpin their role and responsibility in achieving these aims. It should also clearly articulate the duties and responsibilities on them in the regulation of health and social care professionals in their organisation including referral of professionals to the appropriate regulatory body/bodies. The Code of Conduct should be incorporated into the recruitment, appointment, job descriptions and performance review of managers in health and social care services. The Chief Executive (or equivalent) of all health and social care organisations will be accountable for the implementation of this Code. HIQA will monitor compliance with this Code as part of its monitoring of National Standards.
Effective Care	
N7	The Department of Health and the HSE must, as a priority, conduct a review of the maternity services nationally and develop and implement a National Maternity Services Strategy. The purpose for the Strategy should be to implement standard, consistent models for the delivery of a national maternity service that reflects best available evidence to ensure that all pregnant women have appropriate and informed choice and access to the right level of safe care and support 24 hours a day. The National Strategy should include the following elements: ■ a population-based needs assessment with a review of current and future demand and activity to inform the models of care, workforce planning and clinical governance arrangements ■ the development of models of care that reflect modern day, reliable and integrated maternity services both in-hospital and in the out-of-hospital setting ■ consideration of core medical and midwifery workforce needs, skills and competencies in line with national and international recommendations and standards ■ the corporate clinical leadership, governance, management and measurement arrangements necessary at a local and national level to ensure the delivery of safe, high quality and reliable maternity services. ■ the development of integrated care pathways for pregnant women within different settings. This should include pathways for women at risk of clinical deterioration with agreed, safe and effective arrangements for escalation and access to critical care ■ monitoring and assurance arrangements at a local and national level ■ an implementation plan with timelines and a clear implementation structure that identifies national and local responsibilities ■ the relevant structures to ensure consistency in the provision of maternity services as they transition as a core component of Hospital trusts.

N8	The HSE must implement actions to mitigate risks identifed in the current model of materity services.
N9	The HSE should develop, and ensure the implementation of, a national guideline for the effective communication and clinical handover of information relating to the care of a patient both within and between clinical teams. This should be based on best available evidence and provide for effective handover in any clinical situation. Additional guidance should be provided to tailor this for the clinical handover of patients for different clinical settings with maternity services being the first setting to be prioritised.
N10	The HSE should develop a national clinical guideline on the management of sepsis and ensure that all hospitals put in place arrangements for formal staff training on the recognition and management of sepsis and on the clinically deteriorating patients, including pregnant women in line with the guideline. This guideline should incorporate an escalation/referral pathway that includes clinical, legal and ethical guidance for staff at critical clinical points and contain key elements of patient consultation and consent in respect of their treatment and associated interventions.
N11	The Department of Health should immediately review the current arrangements in place to ensure the National Clinical Effectiveness Committee is adequately resourced to support the national endorsement of key national guidelines.
N12	The HSE should ensure that nationally all diagnostic microbiology laboratory services are compliant with the *National Standards for the Prevention and Control of Healthcare Associated Infections* and include a designated surveillance scientist and surveillance pharmacist.
N13	The HSE should ensure that diagnostic microbiology laboratory services are supported by a network of appropriately resourced and accredited reference laboratory services that meet the European Centre for Disease Control (ECDC) definitions for reference laboratory services.
N14	The HSE should ensure, as a priority, that national early warning systems to include a mandatory education programme for the prompt identification and management of all patient groups at risk of clinical deterioration including maternity and paediatric patients, are agreed and rolled out. This should include clear descriptors of accountability for the implementation and audit at a national, local and clinical unit level.

Safe Care	
N15	The HSE should put in place arrangements to collate and review information from national and international inquiries, reviews, investigations and coroner's inquests and, where relevant, act on learning and recommendations so that valuable lessons learned can be applied by each service provider in order to improve the outcomes for patients in Ireland.
Use of Information	
N16	The HSE and key stakeholders should agree and implement effective arrangements for consistent, comprehensive national data collection for maternity services in order to provide assurance about the quality and safety of maternity services. This should include the development of an agreed and defined dataset and standardised data definitions to support performance monitoring, evaluation and management of key patient outcome and experience indicators.
N17	The arrangements for collecting, reviewing and reporting maternal morbidity and mortality should be reviewed by the HSE to facilitate national and international benchmarking for improved learning and safety in the provision of maternity services. This should include a formal process for the implementation of recommendations of the Confidential Maternal Death Enquiries.
N18	The HSE should develop a national laboratory alert system that allows for real time analysis of data from local laboratory information systems, or from other relevant healthcare information systems, to allow for timely recognition of emerging national microbial threats including antimicrobial resistance. These arrangements should also allow for a clear mechanism for communication of findings from the alert system, and clear lines of accountability for acting on such findings.
N19	The HSE, in line with the Department of Health's strategy, *Future Health*, should develop a more formal communication with the Clinical Indemnity Scheme in order to share information and learning on safety incidents within healthcare services and enable the effective prioritisation and development of tailored quality and safety programmes across services nationally. This learning should actively inform the respective Clinical Care Programmes and relevant guidelines and guidance.

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Glossary of terms and abbreviations

Accountability: being answerable to another person or organisation for decisions, behaviour and any consequences.

Adverse event: an incident that results in harm to a patient.

Advocacy: the practice of an individual acting independently of the service provider, on behalf of, and in the interests of a patient, who may feel unable to represent themselves.

An Bord Altranais: the Irish Nursing Board which is the regulatory body for the nursing profession in Ireland.

Antenatal care: care provided to a pregnant woman during her pregnancy.

Antimicrobial stewardship: this involves selecting an appropriate drug and optimising its dose and duration to cure an infection while minimising toxicity and conditions for selection of resistant bacterial strains.

Benchmarking: a continuous process of measuring and comparing care and services with similar service providers.

Best available evidence: the consistent and systematic identification, analysis and selection of data and information to evaluate options and make decisions in relation to a specific question.

Care pathway: a multidisciplinary care plan that outlines the main clinical interventions undertaken by different healthcare professionals in the care of patients with a specific condition or set of symptoms.

Casemix: the types of patients and complexity of their condition treated within a healthcare service, including diagnosis, treatments given and resources required for care.

CIS: Clinical Indemnity Scheme. The Clinical Indemnity Scheme (CIS) was established in 2002 to rationalise medical indemnity arrangements by transferring to the State, via the HSE, hospitals and other health agencies, responsibility for managing clinical negligence claims and associated risks.

Clinical audit: a quality improvement process that seeks to improve patients' care and outcomes through systematic review of care against explicit criteria and the implementation of change.

Clinical director: the senior clinical leader with delegated responsibility and accountability for patient safety and quality throughout a healthcare organisation.

Clinical directorate: a team of healthcare professionals within a specialty, or group of specialties.

Clinical governance: a system through which service providers are accountable for continuously improving the quality of their clinical practice and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. This includes mechanisms for monitoring clinical quality and safety through structured programmes, for example, clinical audit.

Clinical guidelines: systematically developed statements to assist healthcare professionals and patients' decisions about appropriate healthcare for specific circumstances.

Clinical nurse manager (CNM): a nurse more senior than a staff nurse but more junior than an assistant director of nursing. A CNM 2 is more senior than a CNM 1.

COMPASS©: an education programme for the early detection and management of deteriorating patients.

Competence: the knowledge, skills, abilities, behaviours and expertise sufficient to be able to perform a particular task and activity.

Complaint: an expression of dissatisfaction with any aspect of service provision.

Concern: a safety or quality issue regarding any aspect of service provision raised by a patient, service provider, member of the workforce or general public.

Consultant: a consultant is a registered medical practitioner in hospital practice who, by reason of his/her training, skill and experience in a designated specialty, is consulted by other registered medical practitioners and undertakes full clinical responsibility for patients in his/her care, or that aspect of care on which he/she has been consulted, without supervision in professional matters by any other person. Consultants include surgeons, physicians, anaesthetists, pathologists, radiologists, oncologists and others.

Core hours: core working hours can be classified as the working hours of 9am to 5pm, Monday to Friday.

Corporate governance: the system by which services direct and control their functions in order to achieve organisational objectives, manage their business processes, meet required standards of accountability, integrity and propriety and relate to external stakeholders.

Critical care services: service for the provision of medical care for a critically ill or critically injured patient.

Culture: the shared attitudes, beliefs and values that define a group or groups of people and shape and influence perceptions and behaviours.

Day unit: a ward in an acute hospital for day patients to stay in to recover from their treatment.

Dilatation and curettage (D and C): surgical procedure to remove tissue from the endometrium (lining of the womb).

DoH: Department of Health.

DOMINO (Domiciliary Care In and Out of Hospital scheme): this scheme enables women who are deemed at 'low risk of complications' to see members of a dedicated midwives' team for their antenatal visits and to have a member of this team deliver their baby, either in hospital (DOMINO Scheme) or at home.

Early warning score (EWS): EWS is a physiologically-based system of scoring a patient's condition to help determine severity of illness and predict patient outcomes.

ED: emergency department.

Effective: a measure of the extent to which a specific intervention, procedure, treatment, or service, when delivered, does what it is intended to do for a specified population.

Elective: an elective procedure is one that is chosen (elected) by the patient or is planned by the physician that is advantageous to the patient but is not urgent.

Emergency care: the branch of medicine that deals with evaluation and initial treatment of medical conditions caused by trauma or sudden illness.

Emergency response system: a generic name given to the emergency assistance provided as a response to patient deterioration in acute hospitals. The emergency response system should form part of an organisation's escalation protocol.

ESRI: Economic and Social Research Institute.

Evaluation: a formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved.

Evidence: data and information used to make decisions. Evidence can be derived from research, experiential learning, indicator data and evaluations.

Evidence-based practice: practice which incorporates the use of best available and appropriate evidence arising from research and other sources.

Executive board member: a member of the board of an organisation who also holds or has held a position within the organisation itself.

First trimester: from week 1 to the end of week 12 of pregnancy.

Governance: in healthcare, an integration of corporate and clinical governance; the systems, processes and behaviours by which services lead, direct and control their functions in order to achieve their objectives, including the quality and safety of services for patients. See also 'Clinical governance' and 'Corporate governance' above.

GP: general practitioner. A doctor who has completed a recognised training programme in general practice and provides personal and continuing care to individuals and to families in the community.

GRUHG: Galway and Roscommon University Hospitals Group, in this Report referred to as 'the Hospital Group'.

Gynaecology: the branch of medicine particularly concerned with the health of the female organs of reproduction and diseases thereof.

Healthcare Associated Infections: infections that are acquired as a result of healthcare interventions.

Healthcare professional: a person who exercises skill or judgment in diagnosing, treating or caring for service users, preserving or improving the health of service users.

Healthcare record: all information in both paper and electronic formats relating to the care of a service user.

High dependency unit (HDU): a unit in a hospital that offers specialist nursing care and monitoring to ill patients. It provides greater care than is available on general wards but less than is given to patients in intensive care.

Hospital In-Patient Enquiry (HIPE): an information technology system used to collect information on inpatients at Irish acute hospitals. Information is provided by the hospitals to the central system administered by the Economic and Social Research Institute (ESRI).

HSE: Health Service Executive.

Hysterectomy: surgical removal of the uterus (womb).

ICS: Intensive Care Society, the representative body in the UK for intensive care professionals and patients.

ICS Level 0 (Ward): patients' needs can be met through normal ward care in an acute hospital.

ICS Level 1 (Ward at-risk): patients at risk of their condition deteriorating, or those recently relocated from higher levels of care, whose needs can be met on an acute ward with additional advice and support from the critical care team.

ICS Level 2 (HDU): patients requiring more detailed observation or intervention including support for a single failing organ system or postoperative care and those stepping down from higher level care.

ICS Level 3 (ICU): patients requiring advanced respiratory support alone or basic respiratory support together with at least two organ systems. This level includes all complex patients requiring support for multi-organ failure.

ICSI: Intensive Care Society of Ireland.

Infection control: the discipline and practice of preventing and controlling Healthcare Associated Infections and infectious diseases in a healthcare organisation.

Inpatient: a patient who remains in hospital while receiving medical or surgical treatment.

Intensive care unit (ICU): a unit in a hospital providing complex support for multi-organ failure and or advanced respiratory support.

Intrapartum care: care provided during labour and delivery.

Irish Maternal Early Warning System (I-MEWS): a system for the early detection of illness during pregnancy and after a woman has had a baby.

Key performance indicator (KPI): specific and measurable elements of practice that can be used to assess quality and safety of care.

Laparoscopy (laparoscopies): a surgical procedure that allows a surgeon to access the inside of the abdomen and pelvis without having to make large incisions in the skin. It is also known as keyhole surgery.

Locum: a healthcare professional, with the required competencies, who is employed to temporarily cover the duties of another healthcare professional who is on leave.

Methodology: a system of methods, rules and procedures used for the delivery of a project.

Microbiologist: a specialist in microbiology.

Microbiology: the branch of biology that deals with micro-organisms and their effects on other living organisms.

Model of service: the way a health service is delivered and can be applied to a single service unit, to an organisation or a national service.

MOEWS: Modified Obstetric Early Warning Score. An early warning score that has been modified for applicability to pregnant women and the difference in physiological parameters between obstetric and general patients.

Morbidity rate: refers to the incidence or the prevalence of a disease or medical condition in a given population.

Mortality rate: refers to the measure of the number of deaths in a given population.

Multidisciplinary: an approach to the planning of treatment and the delivery of care for a service user by a team of healthcare professionals who work together to provide integrated care.

NEWS: National Early Warning Score. This is a nationally agreed early warning score for the early recognition and management of acutely ill adult patients.

NIMT: National Incident Management Team within the Health Service Executive (HSE). Its function is to promote and support improvements in the management and investigation of incidents, including a standardised approach to incident management with supporting policies, procedures and guidelines.

Non-consultant hospital doctor (NCHD): terminology used in Ireland to describe doctors that have not yet reached hospital consultant grade. NCHDs include specialist registrars, registrars, senior house officers and interns.

Non-executive board member: a member of the board of an organisation who does not form part of the executive management team, nor are they an employee of the organisation.

Obstetrics: the branch of medicine concerned with pregnancy and childbirth.

On call: the provision or availability of clinical advice in addition to or outside of core working hours.

Oncology: branch of medicine concerned with treatment of cancer.

Open disclosure: a comprehensive and clear discussion of an incident that resulted or may have resulted in harm to a service user while receiving healthcare. Open disclosure is an ongoing communication process with service users and their families or carers following an adverse event.

Out of hours: outside the core working hours of 9am to 5pm, Monday to Friday.

Outpatient department (OPD): a hospital department which is primarily designed to enable consultants and members of their teams to see patients at clinics for scheduled care. Patients attending the outpatient department may be a new patient referral or patients who are attending for review following discharge from **hospital or had previously attending the OPD.**

Ovarian cystectomy (cystectomies): surgical removal of a cyst from an ovary.

Ovarian debulking: surgical removal of as much of the tumour as possible from a patient with ovarian cancer.

Paediatrics: the branch of medicine concerned with the treatment of infants and children.

Patient safety incident /event: an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient. Patient safety incidents include an incident which reached the patient and caused harm (adverse event); an incident which did not reach the patient (near miss); and an incident which reached the patient, but resulted in no discernable harm to the patient (no harm event).

Person-centred care: the behaviours, practices and protocols which ensure that the patient is at the centre of the delivery of coordinated and integrated care which, in turn, should ensure the best possible outcomes for the patient in terms of health and welfare.

Policies, procedures, protocols and guidelines (PPPGs): a set of statements or commitments to pursue courses of action aimed at achieving defined goals.

Policy: a written operational statement of intent which helps staff make appropriate
decisions and take actions, consistent with the aims of the service provider, and in the best interests of service users.

Postnatal care: care delivered during the period from delivery to the first six weeks after birth.

Primary care: an approach to care that includes a range of services designed to keep people well. These services range from promotion of health and screening for disease, to assessment, diagnosis, treatment and rehabilitation as well as personal social services.

PROMPT: PRactical Obstetric Multi-Professional Training (PROMPT).

Protocol: a detailed plan of a medical treatment or procedure.

Quality assurance: the systematic process of checking to see whether a product or service is consistently meeting a desired level of quality.

Quality information: data that has been processed or analysed to produce something useful and is accurate, valid, reliable, timely, relevant, legible and complete.

Qualsec: Quality and Executive Group at Galway and Roscommon University Hospitals Group.

RDO: Regional Director of Operations, HSE.

Risk management: the systematic identification, evaluation and management of risk. It is a continuous process with the aim of reducing risk to an organisation and individuals.

Risk register: a risk register is a risk management tool. It acts as a central repository for all risks identified by an organisation and, for each risk, includes information such as risk probability, impact, controls and risk owner.

Risk: in healthcare, the likelihood of an adverse event or outcome.

Second trimester: from week 13 to the end of week 26 of pregnancy.

Serum lactate: a blood test to determine the amount of lactic acid in the blood. It can be used to determine the severity of sepsis.

Service level agreement (SLA): a framework for the provision of services, including details of quality and governance requirements.

Service provider: any person, organisation, or part of an organisation delivering healthcare services [as described in the Health Act 2007 section 8(1)(b)(i)–(ii)] on behalf of the HSE.

Service user: the term service user includes people who use healthcare services (this does not include service providers who use other services on behalf of their patients and service users, such as general practitioners [GPs] commissioning hospital laboratory services); parents, guardians, carers and family and potential users of healthcare services. The term service user is used throughout this document, but occasionally the term patient is also used where it is more appropriate.

Service: anywhere health or social care is provided. Examples include, but are not limited to, acute hospitals, community hospitals, district hospitals, health centres, dental clinics, general practitioner (GP) surgeries, homecare, etc..

Skill-mix: the combination of competencies including skills needed in the workforce to accomplish the specific tasks or perform the given functions required for safe high quality care.

SOP: standard operating procedure.

Stakeholder: a person, group or organisation that affects or can be affected by the actions of, or has an interest in, the services provided.

STARSWeb: a national database established and maintained by the Clinical Indemnity Scheme of the State Claims Agency to record adverse clinical incidents and 'near misses' reported by hospitals.

Symphyis pubis dysfunction: also called pregnancy-related pelvic girdle pain. A collection of uncomfortable symptoms or pain caused by a misalignment or stiffness of the pelvic joints at either the back or front of the pelvis.

Terms of reference: a set of terms that describe the purpose and structure of a project, committee or meeting.

The Authority: the Health Information and Quality Authority.

The Hospital Group: Galway and Roscommon University Hospitals Group (GRUHG).

Third trimester: is from week 27 to the end of the pregnancy

Triage: the process in which patients are sorted according to their need for care. The process is governed by the kind of illness or injury, the severity of the problem, and the facilities available.

UHG: University Hospital Galway, referred to in this report as 'the Hospital'.

Ultrasound: a procedure in which high-energy sound waves are bounced off internal tissues or organs and make echoes. The echo patterns are shown on the screen of an ultrasound machine, forming a picture of body tissues called a sonogram.

Un-differentiated patients: all types of patients with any degree of seriousness or severity.

Urinary Tract Infection (UTI): an infection of one or more structures in the urinary system.

Whole-time equivalent (WTE): the total number of hours that staff are contracted to work.

Workforce: the people who work in, for or with the service provider. This includes individuals that are employed, self-employed, temporary, volunteers, contracted or anyone who is responsible or accountable to the organisation when providing a service to the service user.

Appendix 1

Letter to HIQA from Director General Designate, Health Service Executive, 22 November 2012

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Oifig an Phríomhfheidhmeannaigh
Feidhmeannacht na Seirbhíse Sláinte
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Dr. Tracey Cooper
Chief Executive Officer
Health Information and Quality Authority
Head Office
Unit 1310
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CEO Ref: 226973

22 November 2012

Dear Tracey

I wish to confirm our discussion earlier today and request HIQA to consider undertaking an investigation in accordance with section 9(1)(a) of the Health Act 2007 into the death of Ms. Savita Halappanavar at Galway University Hospital.

In light of the death of Ms. Halappanavar at the hospital, I believe there may be circumstances which give rise to a potential serious risk to the safety, quality and standards of services provided such that it would be appropriate for HIQA to conduct an investigation. The HSE will cooperate fully with any such investigation.

In the meantime you will be aware that the HSE has initiated its own clinical investigation of this incident which will continue and be concluded as quickly as possible.

Yours sincerely

HIQA
Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte
26 NOV 2012
Head Office
RECEIVED

Tony O'Brien
Director General Designate

Tús Áite do Shábháilteacht Othar
Patient Safety First

Appendix 2

Recommendations of the HSE incident investigation report following the death of Savita Halappanavar

All recommendations listed here are reproduced directly from the incident investigation report published by the Health Service Executive (HSE) in June 2013, entitled 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.

HSE 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 multidisciplinary response.

HSE 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.

HSE 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.

HSE 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 that 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.

HSE Recommendation 4b.

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

HSE 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 6 (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.

HSE 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.

HSE 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 safety systems and interventions before a catastrophe happens.

Monthly workloads, 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).

HSE 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.

HSE 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.

Appendix 3

Recommendations of the West Galway Coroner, Dr Ciaran MacLoughlin, County Hall, 19 April 2013, following the inquest into the death of Savita Halappanavar

1. You may recommend that the Medical Council lay out exactly when a doctor can intervene to save the life of the mother in similar circumstances, which will remove doubt and fear from the doctor and also reassure the public. An Bord Altranais should have similar directives for midwives so that the two professions always complement one another.
2. That blood samples are properly followed up and proper procedures are put in place to ensure errors don't occur. That would be a national recommendation.
3. Protocols are followed in the management of sepsis and there is proper training and guidelines for all medical and nursing personnel. And that would be a national recommendation.
4. Proper and effective communication to occur between staff on-call and a team coming on duty and a dedicated handover time is set aside for such communications. That should be applied nationally.
5. A protocol for sepsis written by the department of microbiology for each hospital and each hospital directorate. And that should be applied nationally.
6. That a modified early warning score chart should be adopted by all hospitals in the State as soon as practicable.
7. Early and effective communications with patients and/or their relatives to ensure that a treatment plan is readily explained and understood. And this should be applied nationally.
8. That the medical notes and nursing notes should be separate documents and kept separate. And that should be applied nationally.
9. No additions are made to the medical records of a deceased whose death is the subject of a coroner's inquiry. Additions may inhibit the inquiry and prohibit the making of recommendations which may prevent further fatalities. And that should be applied nationally.

Appendix 4

HIQA Investigation Team of Authorised Persons*

Name	Role
Paul Fogarty	Consultant Obstetrician and Gynaecologist, Ulster Hospital, Belfast, Northern Ireland
Nuala Lucas	Consultant Anaesthetist, Northwick Park, England
Denise Boulter	Midwife Consultant, Public Health Agency, Northern Ireland
Bharat Patel	Consultant Medical Microbiologist, Public Health England (formerly Health Protection Agency, UK)
Robert Cunney	Consultant Microbiologist, Health Protection Surveillance Centre and Children's University Hospital, Temple Street, Dublin
Gavin Lavery	Consultant in Intensive Care Medicine, Clinical Director, Health and Social Care (HSC) Safety Forum, Northern Ireland
Loretta Evans	Patient Safety Champion

* Internal HIQA staff were also Authorised members of the Invistigation Team.

Appendix 5

Membership of Advisory Panel

Postgraduate Training Body	Name	Role
The College of Anaesthetists	John Loughrey	Consultant Anaesthetist
The Joint Faculty of Intensive Care Medicine of Ireland	Jeanne Moriarty	Consultant in Anaesthesia and Intensive Care
The Royal College of Physicians of Ireland	Peter McParland	Consultant Obstetrician/ Gynaecologist
The Royal College of Surgeons in Ireland	John Hyland	Consultant Colorectal Surgeon
Trinity College Dublin	Deirdre Daly	Lecturer in Midwifery

Appendix 6

Request for data

From HSE and public providers of maternity services

- Number of maternity inpatient beds, day beds, high dependency beds/ intensive care beds.
- Number of live births (2011 and 2012).
- Number of maternal deaths (2011 and 2012).
- Number of maternal deaths where sepsis was a contributing factor (2011 and 2012).
- Number of severe maternal morbidity cases related to sepsis (2011 and 2012).
- Number of pregnant women/recently pregnant women who required high dependency unit/intensive care unit (HDU/ICU) care as a result of sepsis (2011 and 2012).

From University Hospital Galway

Number of beds in the following categories:

- inpatient and day case
- intensive care beds for Level 1, 2 and 3 intensive care
- critical care beds
- High Dependency Unit beds.

In University Hospital Galway for the years 2011 and 2012:

- Number of inpatient discharges (2011 and 2012)
- Number of deaths (2011 and 2012).
- Number of deaths where sepsis was a contributing factor (2011 and 2012).
- Number of morbidity cases related to sepsis (2011 and 2012).
- Number of patients who required HDU/ICU care as a result of sepsis (2011 and 2012).

Appendix 7

Request for documentation

HSE nationally

Report (draft or otherwise) of the clinical review into the death of Savita Halappanavar at University Hospital Galway and status and timelines for publication.

Governance

Organogram to describe the national governance structures of public maternity services in Ireland.

Copies of signed service level agreements (SLA) in place between the HSE and any of public providers of maternity services in Ireland.

Agenda and minutes of the last three meetings pertaining to the SLA which took place between the HSE and public providers of maternity services in Ireland.

National Clinical Care Programmes

Copy (draft or otherwise) of the Obstetrics and Gynaecology Clinical Care Programme and status and timelines for implementation and persons responsible.

Risk Management

Organogram which describes the national governance structures for the management of risks pertaining to the provision of public maternity services in Ireland.

Details of serious incidents reported nationally pertaining to the provision of public maternity services for 2011 and 2012.

Findings of each review undertaken for each serious incident reported and evidence of how the learning from each serious incident is disseminated system wide.

Status of the implementation of the local and national recommendations of the HSE Report into the circumstances pertaining to the death of Mrs. Tanya McCabe and her infant son Zach at Our Lady of Lourdes Hospital, Drogheda on Friday, 9 March, 2007. Evidence of how the learning from the report was disseminated system wide.

Incident Management

Copy of the report (final or most recent version) of the learnings identified by the HSE Risk Committee from the review of the incident management approach taken in the case of the death of Savita Halappanavar.

Infectious disease

Organogram which describes the national governance structures for the reporting and management of maternal sepsis in public maternity hospitals.

Details of all notifiable maternal sepsis reported in 2011 and 2012 by all public maternity hospitals and details of all root cause analysis (RCA) undertaken in response to the reported maternal sepsis. Evidence of how learning from the above RCAs was disseminated system wide.

Copy of the most recent version of the report of the Microbiological Reference Laboratory Group relating to the Development of Clinical Microbiological Reference Laboratory.

Early Warning Score

Status, and timelines, of the implementation of the Modified Early Obstetric Warning Score, including details of the training programme for each public provider of maternity services.

Implementation of recommendations

Schedule and minutes of all meetings of the Health Service Executive (HSE) Steering Group for advising and overseeing recommendations for the Investigation of incident 50278 from time of patient's self-referral to hospital on 21 October 2012 to the patient's death on 28 October 2012.

Status of implementation of the recommendations of (1) the Investigation of incident 50278 from time of the patient's self-referral to hospital on 21 October 2012 to the patient's death on 28 October, 2012, and (2) recommendations of the Coroner, following the inquest of Savita Halappanavar, to include identified accountable person for implementation, timeline for implementation and evaluation and audit mechanisms in place to ensure implementation.

Workforce

Copy of the report of the review of Consultant Workforce Planning for obstetrics and gynaecology in the Republic of Ireland 2012–2022, and/or any reports of national reviews of obstetrics and gynaecology consultant workforce planning carried out by, or on behalf of the HSE, for the HSE.

Details and/or copies of the reports of any national reviews of midwifery workforce planning carried out by or on behalf of the HSE, for the HSE.

Use of Information

Copies of published Annual Clinical Reports of the 19 public providers of maternity services (2011 and 2012).

Details of the criteria used by the HSE, to define/classify and report a maternal death occurring in general hospitals, maternity hospitals/units and/or the community.

Description of the assurance mechanisms in place to ensure that the reporting of maternal deaths is accurate and consistent across all service providers in the HSE.

HSE: public providers of maternity services including University Hospital Galway

Governance

Organogram to reflect the corporate and clinical governance arrangements for the provision of maternity services.

Terms of reference (ToR), membership, agendas and minutes of meetings of:

- University Hospital Galway's senior/executive management team
- maternity related meetings/forums at University Hospital Galway.

Risk Management

Organogram of the risk management structure in place.

Role of Risk Manager is in place.

Details of reported incidents relating to the diagnosis and/or management of sepsis in maternity cases.

Details of arrangements in place for morbidity and mortality meetings for maternity services to include agenda and minutes of the last six meetings.

List of all root cause analyses (RCAs), and details of resultant actions, conducted by the maternity/midwifery department where there has been an incident for the years 2011 and 2012.

Details of the process to ensure learning is disseminated from locally reported incidents and adverse events.

Details of the process to ensure learning is disseminated and implemented from national and international publications pertaining to the management of maternity cases and sepsis and maternity cases.

Evidence of how the recommendations (as applicable to your hospital) of the 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.

List of the high risks identified in the risk register (or elsewhere) relating to maternity.

Access to clinical services

Questions in relation to whether there was 24/7 on-site access to clinical services related to:

- anaesthetic/intensivist expertise at consultant level
- radiology services
- laboratory services
- consultant microbiologist
- senior clinical decision making at specialist registrar or consultant level
- alternative arrangements for access to clinical services in the case when clinical expertise is not available on site 24/7.

Questions in relation to microbiology services related to:

- accreditation of the microbiology laboratory
- hospital-wide policy in place for the reporting of significant/urgent laboratory results
- microbiologist ward rounds to visit septic patients
- audit of laboratory turnaround times.

Person-centred Care

Copy of hospital policy in place for communicating with patients, if available.

The arrangements in place to ensure service-users' complaints and concerns are responded to and supported in this process to include audit results of these arrangements if available.

List of maternity patient safety initiatives undertaken by the service in 2011/2012.

Workforce

The staff allocation for maternity services.

List of training programmes in place/and provided at induction to ensure that all healthcare professionals are 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.

Evidence of the attendance rate per discipline for the above training programmes.

Effective and safe care

Use of the Modified Early Obstetric Warning Score.

Details of the controls in place to ensure that all healthcare professionals are 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.

List of guidelines/policy/standard operating procedures in place pertaining to:

- the prompt recognition of sepsis
- appropriate investigations when sepsis is suspected
- indications for transfer to critical care facilities (HDU/ICU)
- timely administration of the appropriate antimicrobial therapy for suspected sepsis
- appropriate fetal monitoring and delivery in the case of suspected/confirmed maternal sepsis
- the appropriate administration of prophylactic antibiotics to the neonate, family members and healthcare workers
- infection control guidelines used in the management of maternal sepsis.

Arrangements in place to support the timely and safe transfer of clinically deteriorating patients for critical care in the case of suspected significant sepsis.

Local: Galway and Roscommon University Hospitals Group

Implementation of recommendations

Copy of the action plan(s) for implementation of the local and national recommendations of the draft final report of the HSE's National Incident Management Team (NIMT) Investigation of the Incident 50278, (March 2013), to include status of implementation, timelines, key milestones and accountability for implementation.

Copy of the terms of reference of the group responsible for implementation of the national recommendations of the draft final report of the HSE's National Incident Management Team (NIMT) investigation of the incident 50278, (March, 2013).

Terms of reference, membership, schedule and minutes of all meetings of the local group/committee responsible for implementation of the recommendations for the investigation of incident 50278 from time of patient's self-referral to hospital on the 21 October 2012 to the patient's death on 28 October 2012 at Galway and Roscommon University Hospitals Group.

Template of action taken by Galway and Roscommon University Hospitals Group in response to the recommendations of

(1) the investigation of incident 50278 from time of the patient's self-referral to hospital on 21 October 2012 to the patient's death on 28 October 2012, and

(2) the recommendations of the Coroner West Galway, following the inquest of Savita Halappanavar, to include the identified accountable person for implementation at local level, associated timelines for implementation of action and evaluation and audit mechanisms in place to ensure implementation.

Governance arrangements

Terms of reference, membership, schedule, agendas and minutes of meetings (2013) of the

- Group Board of Directors
- Group Executive Council
- Women and Children's Directorate
- Clinical Directors' Forum
- Group Management Team
- Board Group Quality and Patient Safety Committee
- Group Quality and Patient Safety Committee
- Nursing Professional Council
- Local Incident Management Team
- Clinical Governance Group
- Women and Children's Directorate Core Group
- Women and Children's Directorate Paediatricians and Obstetricians Groups.

Copies of the reports of the Clinical Directors of the Women and Children's Directorate and the Theatre, Anaesthetics and Critical Care (TACC) Directorate to the Executive Management Council meetings (2013).

Copies of the reports (to include the directorate risk reports) of the Women and Children's Directorate to the Clinical Directors' Forum (2013).

Copies of the risk register for the Women and Children's Directorate for December 2012 to July 2013.

Draft copy or otherwise of the Annual Clinical Report for the Women and Children's Directorate for 2012.

Copy of the Guidelines on 'Pre-term Pre-labour Rupture of Membranes (PPROM)'. Revision 3.

Microbiological service activity

Details of the volume of specimens processed by the microbiological service at University Hospital Galway (UHG) and Portiuncula Hospital for the year 2012.

Copy of the reports of audits of turnaround times for specimens processed at UHG and Portiuncula Hospital for the year 2012.

National Reference Laboratory Services (NSSLRL) (Galway University Hospitals)

Copy of report of activity data for the National Salmonella Shigella and Listeria Reference Laboratory at UHG for the years 2012 and 2013.

List of all services provided by the National Reference Laboratory relating to national surveillance in 2012 and 2013, to include details of the commissioner of those services and associated duration of contracts.

Local: University Hospital Galway

Safe and Effective Care

Evidence of the implementation of recommendations in University Hospital Galway of:

- the 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
- the Eighth Report of the Confidential Enquiries into Maternal Deaths in the United Kingdom – Saving Mother's Lives, Reviewing maternal deaths to make motherhood safer: 2006-2008, March 2011
- the Confidential Maternal Death Enquiry in Ireland: The report for the Triennium 2009-2011.

Copies of the clinical management guidelines for obstetrics and gynaecology for the:

- management of miscarriage (first trimester spontaneous miscarriage)
- management of late miscarriage; stillbirths and neonatal deaths
- management of postpartum haemorrhage (PPH) plus early warning score and maternity observation chart.

Copy of the Flow Chart on the Management of Sepsis – as per the Guideline on the Management of Suspected Sepsis and Sepsis in Obstetric Care.

Copies of the clinical management guideline for the management of suspected sepsis and sepsis (for all patients).

Evidence of the implementation at University Hospital Galway (UHG) of recommendations of the Royal College of Obstetricians and Gynaecologists (RCOG) Good Practice Guide No. 12 - Improving Patient Handover, December 2010.

Copy of University Hospital Galway (UHG) condition-specific patient information leaflet pertaining to threatened miscarriage (draft) and medical and surgical management of miscarriage.

Copy of the early warning score guideline/policy/standard operating procedure in use on St Monica's Ward in 2012.

Details of the arrangements in place for the pathway for (1) booked and non-booked pregnant women, presenting as an emergency during working hours and out of hours; and (2) non-booked pregnant women, in labour and not in labour, presenting as an emergency during working hours and out of hours.

Details of how the governance structure at University Hospital Galway (UHG) has

been established to support the implementation and ongoing evaluation of the

National Early Warning Score (NEWS) System of the HSE (2011) Guiding Framework and Policy for the National Early Warning Score System to Recognise and Respond to Clinical Deterioration.

Details of the arrangements in place at University Hospital Galway to ensure development of local policy to support the implementation of the National Early Warning Score (NEWS) System, management of the clinically deteriorating patient, and associated audit and evaluation of the HSE (2011) Guiding Framework and Policy for the National Early Warning Score System to Recognise and Respond to Clinical Deterioration.

Details of the arrangements in place at University Hospital Galway to ensure staff undertake the COMPASS© education programme as per the HSE (2011) Guiding Framework and Policy for the National Early Warning Score System to Recognise and Respond to Clinical Deterioration.

Details of the arrangements in place at University Hospital Galway for the emergency response system (ERS) and critical care outreach for patients whose condition is deteriorating as per the HSE (2011) Guiding Framework and Policy for the National Early Warning Score System to Recognise and Respond to Clinical Deterioration.

Patient healthcare record

Copy of the complete healthcare record of Savita Halappanavar.

Incident management

Copy of the transcription of the proceedings of the Coroner's inquest into the death of Savita Halappanavar.

Copy of the draft final report of the HSE's National Incident Management Team (NIMT) investigation of the incident 50278, relating to the death of Savita Halappanavar, as provided to Praveen Halappanavar during the week of 25 March 2013.

Prevention and Control of Healthcare Associated Infection (PCHCAI)

Copy of the agendas and minutes of meetings of the Infection Prevention and Control Committee (IPCC) and the Antimicrobial Stewardship Committee (2013).

Copy of the Antimicrobial Stewardship Programme for 2012.

Copy of the Work Programme for the Prevention and Control of HCAIs developed by the IPCC for 2012 and 2013.

Copy of the PCHCAI (prevention and control of Healthcare Associated Infection) related surveillance programme for 2012 and 2013.

Copies of the blood-stream infection rate and trend analysis reports for 2011 and 2012.

Analysis detail and any resultant actions of blood-stream infection related adverse events, incidents and complaints for 2011 and 2012.

Audit results and any resultant actions of the use of antimicrobials and achievements with specific targets related to the antimicrobial stewardship programme, at the Hospital for 2011 and 2012.

Arrangements in place to review and act on Infection Surveillance Reports published by the Health Protection Surveillance Centre (HPSC).

Antimicrobial management

Copy of the Antimicrobial Consumption report to the HPSC, to include Quarter 1 to Quarter 4 for 2012.

Copy of reports of the quarterly monitoring of antimicrobial use and spend for 2012.

Copy of the report of any audits/root cause analyses undertaken in response to the identified ESBL/e coli bacteraemia at UHG in 2011 and 2012.

Copy of report or details of the action taken to alert other local/regional hospitals and care facilities with regard to the identification of ESBL/E coli bacteraemia in UHG 2011 and 2012.

Copy of report of action taken by antimicrobial management in response to rising levels of antimicrobial resistance for 2012 and 2013.

Copy of audits/evaluation of the actual frequency of antimicrobial stewardship rounds at UHG for 2012 and 2013.

Workforce

Details of the infection prevention and control staff whole-time equivalent (WTE) (to include antimicrobial management/stewardship staff) for 2012 and 2013.

Copy of the guideline/policy/standard operating procedure and/or arrangements in place to support staff after an adverse event.

Percentage of clinical staff who had attended the COMPASS© education programme training as per the HSE (2011) Guiding Framework and Policy for the National Early Warning Score System to Recognise and Respond to Clinical Deterioration by the end of 2012.

Appendix 8

Letter from HIQA to Chief Executive, Galway and Roscommon University Hospitals Group, 16 July 2013

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

PERSONAL PRIVATE AND CONFIDENTIAL

Bill Maher
Chief Executive Officer
Galway Roscommon University Hospital Group
Merlin Park
Galway
bill.maher@hse.ie

16 July 2013

Ref: HOSL\INVi6\127

Re: Investigation (Investigation) into the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration and as reflected in the care and treatment provided to Savita Halappanavar

Dear Bill,

As you are aware, the Health Information and Quality Authority (the Authority) is currently undertaking an investigation in to the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration and as reflected in the care and treatment provided to Savita Halappanavar. I am writing to you as an authorised person, authorised pursuant to Section 70 of the Health Act 2007 as amended (the "Act") for the purpose of the Investigation, which was instigated under Section 9(1) of the Act.

In the course of the investigation, issues have been identified that the Authority believes may have the potential to pose serious risks to the health and welfare of persons receiving maternity and gynaecological services at University Hospital Galway.

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e-mail: info@hiqa.ie **www.hiqa.ie**

Letter from HIQA to Chief Executive, Galway and Roscommon University Hospitals Group, 16 July 2013 continued

Specifically, issues have been identified in relation to

1. **A nurse staffing shortage of 8.5 Whole Time Equivalents (WTE) in the gynaecology ward (St Monica's ward) at University Hospital Galway in June 2013.**

It is of significant concern to the Authority, whether the Hospital has the arrangements in place to ensure that St. Monica's ward can sustain the delivery of care at their current level of in-patient service provision and ensuring the provision of safe, quality patient services while awaiting a return to normal staffing levels.

Can you please, as a matter of urgency, review these arrangements and provide information, to the Authority **by 2pm on Friday, 19 July, 2013** to rdi6@hiqa.ie; to demonstrate assurances that there are interim arrangements in place to ensure that safe, quality care is currently being provided to patients of St Monica's ward. These assurances should include an identification of the risks associated with the shortage of staffing levels and the aligned mitigating actions.

If in the course of this investigation, further potential serious issues relating to the health and welfare of patients receiving services at University Hospital Galway are identified, the Authority will bring these to your attention.

Should you have any queries in relation to the above, please don't hesitate in contacting me at rdi6@hiqa.ie.

Yours sincerely,

Mary Dunnion

MARY DUNNION
Authorised Person

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Appendix 9

Letter to HIQA from Chief Operating Officer, Galway and Roscommon University Hospitals Group, 19 July 2013

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

University Hospital Galway
Ospidéal na h-Ollscoile, Gaillimh
GALWAY UNIVERSITY HOSPITALS

Our Ref. COO/AC/

19th July 2013

Mary Dunnion,
HIQA,
Georges Court,
Georges Lane,
Smithfield,
Dublin 7

A Chara,

I refer to your correspondence of 16th July to Mr Bill Maher, in respect of June 2013 Nurse Staffing levels on the gynaecology ward (St Monicas) in University Hospital Galway. I am responding as Bills deputy while he is on annual leave.

The allocation of nursing staff to St Monicas ward in June 2013 was 17.97wte
Nursing allocations are subdivided into 5/4 staff on morning shift, 4/3 staff on evening shift & 2 staff on night shift. There was also a Health Care Assistant on each day shift.
The actual nurse staffing level was 14.97 plus a HCA daily.

During this period the nurse staffing levels were :

- Monitored daily by the Assistant Director of Nursing & the Director of Nursing.
- When service demand required additional support, the following measures were taken,
  - redeployment from other areas in the hospital to St Monica's,
  - engagement of agency staff &
  - overtime was sanctioned to supplement staffing needs as required
- Directorate team meeting monitored situation on a weekly basis.

Every effort was made to ensure that safe quality care was provided to the patients on St Monicas ward during June 2013 and continues to be a priority for the Management team and staff in University Hospital Galway.

If you require anything further I am happy to assist. You can reach me at my office on 091 893800, or by email (tony.canavan@hse.ie).

Is mise le meas,

Tony Canavan,
Chief Operating Officer,
Galway & Roscommon University Hospitals Group

University Hospital Galway, Ospidéal na h-Ollscoile, Gaillimh,
Galway, Ireland. Tel: 00 353 (0)91 524222 / 544544
www.guh.hse.ie

Appendix 10

National data collection sources for mortality and morbidity data in Ireland

Source	Purpose	Date established	Scope	Governance
Hospital In-Patient Enquiry (HIPE)	To collect data on discharges from, and deaths in, acute hospitals nationally.	Established in 1971; management transferred to Economic and Social Research Institute (ESRI) in 1990.	Covers public hospitals.	ESRI manages this system on behalf of the Department of Health and the Health Service Executive (HSE).
National Perinatal Reporting System (NPRS)	To provide national statistics on perinatal events in Ireland.	Commenced in the 1980s; management transferred to ESRI in 1999.	All live births and stillbirths are covered.	ESRI manages this system on behalf of the Department of Health and the HSE.
National Perinatal Epidemiology Centre (NPEC)	To collaborate with Irish maternity hospitals to translate clinical audit data and epidemiological evidence into improved maternity services in Ireland.	2007	Voluntary reporting from all maternity units in Ireland to NPEC.	Funding from the Department of Health and some research funding.
Maternal Death Enquiry (MDE) – Ireland	To promote safer pregnancy by conducting confidential reviews into maternal deaths, identifying learning, and using findings to disseminate recommendations.	MDE was initiated in England and Wales in 1952 and became UK-wide in the 1980s. Ireland joined in 2009.	MDE Ireland aims to report on all cases of maternal death occurring during or within one year of the pregnancy.	Funded and endorsed by the HSE. Is a stand-alone office within the NPEC.

Source	Purpose	Date established	Scope	Governance
Central Statistics Office (CSO) – Deaths Registration	To collect data on all deaths (including place and cause of death) in Ireland.	Deaths registration from 2003	Since 2003, all death data from the General Register Office (GRO) is sent electronically to the CSO.	Statutory body responsible for compiling Irish official statistics.
General Register Office	Central civil repository for records relating to births, deaths and marriages in Ireland.	1864	All deaths, other than those referred to a coroner must be registered within three months.	Central civil repository for records relating to births, deaths and marriages in Ireland, Department of Social Protection.
Coroner Service	To investigate sudden and unexplained deaths so that a death certificate can be issued.	Coroners (Ireland) Act, 1846.	All deaths, other than those referred to a coroner must be registered within three months.	Coroners are qualified doctors or lawyers, independently appointed by local authorities who fund the Service.

Appendix 11

Letter from HIQA to Director General Designate, Health Service Executive, 5 July 2013

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

PERSONAL PRIVATE AND CONFIDENTIAL

Tony O' Brien
Director General Designate
Health Service Executive
Dr. Steevens' Hospital
Dublin 8
ceopa@hse.ie

05 July 2013

Ref: HOSL\INVi6\126

Re: Investigation (Investigation) into the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration and as reflected in the care and treatment provided to Savita Halappanavar

Dear Tony,

As you are aware the Health Information and Quality Authority is currently undertaking an investigation into the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration and as reflected in the care and treatment provided to Savita Halappanavar. I am writing to you as an authorised person, authorised pursuant to Section 70 of the Health Act 2007 as amended (the "Act") for the purpose of the Investigation, which was instigated under Section 9(1) of the Act.

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Letter from HIQA to Director General Designate, Health Service Executive, 5 July 2013 continued

In the course of this investigation, issues have been identified that the Authority believes may have the potential to pose serious risks to the health and welfare of persons, particularly, clinically deteriorating obstetric patients, using those services. These include:

1. **The availability of on-site maternity High Dependency beds**

Thirteen of the 19 maternity hospitals /units reported having no maternity high dependency beds.

2. **The availability of on-site maternity Intensive Care beds**

None of the 19 maternity hospitals/units reported having maternity critical care beds.

3. **The accessibility of and timely access to off –site critical care beds**

Information received identified limitations in the capacity of the maternity hospitals/units, particularly in the HSE Dublin North East, for the provision of critical care services to obstetric patients through neighbouring acute general hospitals.

Consequently, the Authority is not assured that the maternity service, nationally, has the arrangements in place to appropriately care for and treat clinically deteriorating obstetric patients in a safe, timely manner. Can you please, as a matter of urgency, review these arrangements and provide information, to the Authority **by 2pm on Friday, 12 July 2013** to rdi6@hiqa.ie; to demonstrate assurances that the HSE and local providers of maternity services have

- robust arrangements in place to ensure clinically deteriorating obstetric patients are being managed appropriately, in a safe environment and in a timely manner.
- robust governance arrangements in place to ensure clinically deteriorating obstetric patients are transferred within and between services safely and that there is continuity of care provision
- identified the risks relating to the current arrangements for the provision of care to clinically deteriorating obstetric patients and have put action in place to mitigate these risks and any other risks identified by national audits or reviews (for example, the National ICU Audit of the National Office for Clinical Audit)

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Letter from HIQA to Director General Designate, Health Service Executive, 5 July 2013 continued

If in the course of this investigation, further potential serious issues relating to the health and welfare of patients receiving services in the HSE are identified, the Authority will bring these to your attention.

Should you have any queries in relation to the above, please don't hesitate in contacting me at rdi6@hiqa.ie.

Yours sincerely,

PHELIM QUINN
Authorised Person

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Appendix 12

Letter from HIQA to Director General, Health Service Executive, 20 August, 2013

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

PERSONAL PRIVATE AND CONFIDENTIAL

Tony O' Brien
Director General Designate
Health Service Executive
Dr. Steevens' Hospital
Dublin 8
ceopa@hse.ie

20 August 2013

Ref: HOSL\INVi6\129

Re: Investigation (Investigation) into the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration and as reflected in the care and treatment provided to Savita Halappanavar

Dear Tony,

As you are aware the Health Information and Quality Authority (Authority) is currently undertaking an investigation into the safety, quality and standards of services provided by the Health Service Executive (HSE) to patients, including pregnant women, at risk of clinical deterioration and as reflected in the care and treatment provided to Savita Halappanavar.

In correspondence of 05 July 2013, reference number HOSL\INVi6\126, (Appendix 1), the Authority sought assurances from the HSE, that the maternity service nationally has the arrangements in place to appropriately care for and treat clinically deteriorating obstetric patients in a safe, timely manner, to be returned to the Authority on 12 July, 2013.

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Letter from HIQA to Director General, Health Service Executive, 20 August, 2013 continued

Following a request for an extension on the date of return of these assurances, the Authority received some information on 22 July 2013 and additional information on 13 August 2013, on your behalf, from the Director of Quality and Patient Safety, HSE.

Through the information provided, the HSE has indicated that opportunities for improvement relating to a review of maternity services have not yet been identified and a critical care capacity and requirements review of the acute services is in progress. No timelines for completion have been provided to the Authority.

The Authority acknowledges that a series of initiatives have been delivered, or are in progress including the implementation of the National Irish Maternity Early Warning Score (IMEWS) to detect and initiate action on clinical deterioration. However, IMEWS is in the early stages of implementation since April 2013 with an audit of its practice planned for April 2014, therefore, knowledge of the effectiveness of its implementation will not be available until after the audit has taken place.

While awaiting formal implementation and roll out of a clinical pathway for the critically ill woman, the HSE has not provided information as to the interim arrangements that are in place to mitigate risks to current and future obstetric patients that may be at risk of clinical deterioration.

Consequently, the Authority is of the opinion that the HSE, currently, does not have access to timely, relevant information to assure itself that there are arrangements in place to appropriately care for and treat clinically deteriorating obstetric patients in a safe, timely manner and that risks to the safety of current and future obstetric patients have been identified and mitigated.

Can you please, as a matter of urgency, review the concerns of the Authority as indicated in earlier correspondence (HOSL\INVi6\126).

Can you please provide the Authority with assurances that the HSE has an action plan in place for the timely identification and mitigation of risks associated with the care and treatment of current and future obstetric patients at risk of clinical deterioration.

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Letter from HIQA to Director General, Health Service Executive, 20 August, 2013 continued

Please include a timeline for completion of the HSE reviews of maternity services and critical care capacity and requirements that are reported as being in progress, to include a timeline for implementation of required action of these reviews and roll out of the clinical pathway for the critically ill woman. All actions should include a named accountable person for implementation.

Please provide the Authority with this information, by email to rdi6@hiqa.ie before 2pm on Tuesday 27 August, 2013.

Should you have any queries in relation to the above, please don't hesitate in contacting me at rdi6@hiqa.ie.

Yours sincerely,

PHELIM QUINN
Authorised Person

CC: Philip Crowley, National Director, Quality and Patient Safety

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Appendix 13

Letter to HIQA from Director General, Health Service Executive, 27 August 2013

Oifig Stiúrthóir Ginearálta na Seirbhíse Sláinte
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Tel: (01) 635 2000
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27 August 2013

Your Ref: HOSL/INVi6/129
Our Ref: 255686

Mr Phelim Quinn
Director of Regulation
Health and Information & Quality Authority
George's Court
George's Lane
Dublin 7

Dear Phelim,

Thank you for your correspondence dated 20th August 2013 regarding your *Investigation into the safety, quality and standards of services provided by the Health Services executive to patients, including pregnant women, at risk of clinical deterioration and as reflected in the care and treatment provided to Savita Halappanavar*.

I have set out below the HSE response in relation to the issues that the Authority has raised.

Firstly in relation to the overall concern the Authority has expressed regarding access to critical care services for critically ill maternity patients; the National Director for Quality and Patient safety met with the clinical leads for the clinical programme in intensive care and in obstetrics and the experience of them and their colleagues is that a critically ill maternity patient is given priority in accessing a critical care bed when it is required an that with the exception of a case of a woman transferred to Northern Ireland from Sligo that access has not been a problem.

Equally the National Critical Care Programme has indicated that it *''does not support stand-alone Level 2 High Dependency Unit (HDU) and Level 3 Intensive Care Units (ICU) in maternity units. Rather the Critical Care Model requires detection, recognition, intervention and timely mandatory transfer access for the critically ill pregnant woman to high-volume multi-specialty Level 2 HDUs and Level3 ICUs either on-site or off-site with Critical Care Retrieval. At the same time each Maternity Unit should have an Observation Unit which also is competent to provide Level 2 HDU care to a critically ill patient.*

The specific issues that you raise:

1. ***That each maternity unit can demonstrate that they have robust arrangements in place to ensure clinically deteriorating obstetric patients are being managed appropriately in a safe environment and in a timely manner***

   All maternity sites have provided assurance that the following are in place.
   - I-MEWS has been introduced along with training programmes completed to develop staff competencies in its use (further details on implementation is set out under point 5 below).
   - Sites have indicated that a multidisciplinary team approach to the provision of obstetric care is in place in all units with regular meetings and handover arrangements at shift change times. In addition, a national group is currently being established to improve communication specifically in the handover of critically ill patients.

Tús Áite do Shábháilteacht Othar
Patient Safety First

Letter to HIQA from Director General, Health Service Executive, 27 August 2013 continued

- 24/7 consultant obstetric 'on-call' is available in all units
- 24/7 access to Hospital emergency response teams is available in all units.
- 24/7 access to Anaesthesia

In addition, the majority (see below) of hospitals have indicated that they have:

- 24/7 access to on site diagnostics
- 24/7 access to on site ICU/HDU beds (4 hospitals have indicated that they have access to off site critical care beds)

The majority of hospitals have reported that guidelines are in place for the management of obstetric emergencies.

Does your service have:	% Compliance	Exceptions
I-MEWS implemented in your hospital.	100%	-
Defined governance structures for auditing implementation and responding to findings from I-MEWS	100%	-
Training programme for staff on I-MEWS	100%	-
On-call roster that ensures competent consultant cover on a 24/7 basis	100%	-
24/7 access to on site Diagnostics	79%	Limerick, Rotunda and the National Maternity Hospital indicate that they have access to 'off site' diagnostics. Portlaoise indicate that they have no access on a 24/7 basis.
24/7 access to on site ICU/HDU beds	79%	Limerick, Rotunda, National Maternity Hospital and The Coombe indicate that they have access to 'off site' critical care beds.
24/7 access to Anaesthesia	100%	

We believe that this places Ireland at the forefront internationally in implementing on a national basis a system for identifying the deteriorating maternity patient. We also believe that while the clinical programme in obstetrics maintains contact with the maternity units that 2014 is an appropriate timeframe to **fully** validate and audit the implementation of IMEWS.

2. ***Improving the governance arrangements that are in place to ensure that clinically deteriorating patients are transferred within and between services safely and that there is continuity of care provision.***

All Maternity units have indicated that if a patient clinically deteriorates, the obstetric team in consultation with the Anaesthetic team and other specialties will make the decision regarding the future clinical management of the patient and the environment which may be required to continue the care.

Each maternity unit was specifically asked if they had policies in place with regard to the following

- Operational transfers for access to ICU/HDU within the hospital
- Operational policies for the clinical handover of care to ICU/HDU
- Where a bed is not available on site there are mandatory acceptance policies with an alternative site for access to an ICU bed

Letter to HIQA from Director General, Health Service Executive, 27 August 2013 continued

Does your service have:	% COMPLIANCE	Exceptions
Operational transfer policies for access to ICU/HDU within the hospital	74%	Kerry, Mayo, Waterford, CUH, Coombe
Operational policies for the clinical handover of care to ICU/HDU	74%	Kerry, Mayo, Waterford, CUH, Letterkenny
Where ICU bed is not available on site there mandatory acceptance policies with an alternative site for access to an ICU bed	63%	Kerry, Mayo, Wexford, Cavan, Sligo, Portlaoise, Mullingar

Most hospitals have indicated that they have policies in place in this regard.

The HSE has requested that where policies are not fully in place, hospitals should immediately ensure that the required policies are completed and implemented in full. These sites have been directed to have this work completed by mid September 2013. An independent audit will be undertaken at these sites in Q4 2013.

In addition, the implementation of these policies will be monitored through National, Regional and local safety and performance review processes.

3. ***Seek further assurance that maternity hospitals have processes in place to iidentify all risks relating to the current arrangements for the provision of care to clinically deteriorating obstetric patients and have actions in place to mitigate these risks and any other risks identified by national audits or reviews.***

All maternity units indicated that they have governance and good practice arrangements in place for the provision of care to clinically deteriorating patients as follows:

- A process for assessing and managing risks relating to the provision of obstetric care, and if required risks are placed on a Directorate's/Hospitals risk register
- A process for review of any risks/mitigating actions by a clinical governance committee in the hospital including follow up actions from the reviews
- A review of incidents/complaints or adverse events by a clinical governance committee in the hospital including follow up actions from the reviews

The processes described by the maternity units include:

- Clinical Governance Committees
- Quality and Safety Committees
- Clinical Incident Reporting and Review systems
- Risk Registers
- IMEWS audits
- Up to date Clinical Practice Guidelines
- Case Presentations
- Training and Education Sessions

The HSE will undertake an independent Audit in Q4 2013 to obtain assurance that the above processes are in place.

Letter to HIQA from Director General, Health Service Executive, 27 August 2013 continued

Does your service have:	% COMPLIANCE	Exceptions
A process for assessing and managing risks relating to the provision of obstetric care, and if required risks are placed on a Directorate's/Hospitals risk register	100%	-
A review of any identified risks and mitigating actions by a clinical governance committee in the hospital including follow up on actions from the reviews.	100%	-
A review of incidents/complaints or adverse events by a clinical governance committee in the hospital including follow up on actions from the reviews	100%	-

4. ***Sign off and implementation of the Care Pathway for the critically ill obstetric patient***

   The development of the pathway for the care of the critically ill obstetric patient is completed and is awaiting sign off by the Critical Care Programme. It is expected that this pathway will be signed off by end of September 2013 and implemented immediately afterwards.

5. ***Monitor ongoing implementation of Irish Maternity Early Warning System (IMEWS) in maternity hospitals and validation of its in Irish Maternity hospitals***

   The Irish Maternity Early Warning System (I-MEWS) was introduced nationally by the HSE to all 19 maternity units on April 2nd 2013 as a standardised system to support the identification of deteriorating obstetric patients. I-MEWS was developed by a multidisciplinary design team with a reference group to oversee the development of the tool. The development of I-MEWS involved significant public consultation and a review period after one month to check the effectiveness of the implementation and the functionality of the tool.

   The introduction of I-MEWS was supported by a multidisciplinary educational programme that was rolled out in all 19 maternity units. Education and support on the use of I-MEWS is still provided by a named local I-MEWS lead for each maternity unit. The continuous roll out and monitoring is also the responsibility of the Programme Implementation Boards for each maternity unit. All 19 maternity units have reported that they have fully implemented the I-MEWS tool and defined governance structures exist for auditing implementation of, and responding to findings from its use.

   Throughout the introduction of I-MEWS it has been made clear that although a very valuable tool, it is not intended to replace clinical judgment but rather to assist with identifying the clinically deteriorating pregnant patient. The next step in the development of I-MEWS will be to validate the tool in the context of its use in the Irish health services. A Specialist Registrar will be appointed to carry out this validation process. This post has been advertised.

   The HSE will continue to monitor the introduction of I-MEWS through the regional and national performance review processes, feedback from Maternity Hospital Programme Implementation Boards and through Clinical Governance committees at hospital level pending the completion of the validation process.

Letter to HIQA from Director General, Health Service Executive, 27 August 2013 continued

I would be happy to arrange a further interaction between yourselves and the Clinical programme leads and other senior managers should you require further clarification.

Yours sincerely,

Tony O'Brien
Director General

Appendix 14: University Hospital Galway Compliance Failures

NS No	National Standard	UHG Compliance Failures
NS 2.1	***Healthcare reflects national and international evidence of what is known to achieve best outcomes for service users.***	■ There were no formal multidisciplinary arrangements or associated governance structure for the prioritisation, development, dissemination and monitoring of usage of policies, guidelines, protocols and care pathways based on best available evidence. ■ Consultants on call for the labour ward were not present on the labour ward but rather engaged in other clinical activities. This is at variance with national and international best evidence. ■ The Hospital did not have a hospital-wide guideline in place for the management of sepsis in adult patients.

NS 2.2	***Care is planned and delivered to meet the individual service user's initial and ongoing assessed healthcare needs, while taking account of the needs of other service users.***	■ The care pathway for patients, who required routine access to maternity services , including access to ultrasound, was not always timely or appropriate. ■ The care pathway for patients, who required emergency access to maternity services, including access to assessment in the Emergency Department, ultrasound, and clinical examination, was not always appropriate and effective. ■ Patients were not always seen by a senior clinical decision maker in a timely manner. ■ There was no formal guideline in place at the Hospital to direct staff as to when it was appropriate to contact the on-call consultant obstetrician. ■ There were no contingency arrangements in place to support a more junior doctor when a registrar is unavoidably delayed.

NS 2.3	***Service users receive integrated care which is coordinated effectively within and between services.***	■ Active cooperation and a shared sense of common purpose between clinical directorates, to ensure safe and integrated care for patients, was not always evident. ■ The Theatre and Critical Care (TACC) Directorate was not involved in the initial roll-out of the Early Warning Score and had not been involved in local decisions with regard to the appropriate interventions and escalation in response to NEWS scores.
NS 2.4	***An identified healthcare professional has overall responsibility and accountability for a service user's care during an episode of care.***	■ The handover of patient care arrangements between the maternity clinical teams were not always effective and were not in line with best available evidence.
NS 2.5	***All information necessary to support the provision of effective care, including information provided by the service user, is available at the point of clinical decision making.***	■ Relevant patient information, including a plan of care, clinical observation and diagnostic test follow-up, was not recorded, shared and responded to by clinicians in a timely and appropriate manner.

NS 2.6	***Care is provided through a model of service designed to deliver high quality, safe and reliable healthcare.***	■ There was no clear information available to GPs or pregnant women and their families in relation to available models or pathways of maternity care. ■ There was no formal clinical pathway to refer high risk obstetric patients to the obstetric anaesthetist antenatal high risk service.
NS 2.7	***Healthcare is provided in a physical environment which supports the delivery of high quality, safe, reliable care and protects the health and welfare of service users.***	■ The physical layout of St Monica's Ward was not designed to meet the needs of those patients at risk of clinical deterioration and the complexity and diversity of the patient casemix. ■ The physical layout of the Emergency Department was not designed to meet the needs of patients who required clinical examination.
NS 2.8	***The effectiveness of healthcare is systematically monitored, evaluated and continuously improved.***	■ The key performance indicators adopted did not specifically focus on measuring outcomes for patients. ■ There were no definitions of sepsis to facilitate reporting of sepsis-related morbidity data.

NS 3.2	***Service providers monitor and learn from information relevant to the provision of safe services and actively promote learning both internally and externally.***	■ There was no formal structured process in place, to assist in the dissemination of findings and learning from the monthly mortality and morbidity meeting. ■ There were no arrangements to gather, analyse and implement learning from national and international information.
NS 5.11	***Service providers act on standards and alerts, and take into account recommendations and guidance, as formally issued by relevant regulatory bodies as they apply to their service.***	■ The appointment of four executive directors to the Board of Galway and Roscommon University Hospitals Group is not in line with the Authority's recommendations in its 2012 report into the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (Tallaght Hospital) Investigation or best available international evidence.
NS 6.1	***Service providers plan, organise and manage their workforce to achieve the service objectives for high quality, safe and reliable healthcare.***	■ There was no evidence the organisation of the workforce took account of the complexity and diversity of the patient casemix on St Monica's Ward. This included the unscheduled presentations, out-of-hours, of patients with gynaecological and obstetric emergencies. ■ The arrangements to redeploy anaesthetic consultant cover, particularly to obstetric care, were not always effective.

NS 6.3	***Service providers ensure their workforce have the competencies required to deliver high quality, safe and reliable healthcare***	■ There was no evidence that UHG facilitated or had in place arrangements to ensure that medical and nursing staff had the necessary competencies and skills to provide care to patients at risk of clinical deterioration. ■ There was no evidence that UHG facilitated or had in place arrangements, to provide formal staff training on the recognition and management of sepsis and the clinically deteriorating obstetric patient. ■ There was no formal multidisciplinary skills training or simulation programmes in place to assess the clinical, communications, and team-skills competencies.
NS 8.3	***Service providers have effective arrangements in place for the management of healthcare records.***	■ Patient healthcare records were not managed or stored in line with the HSE's Standards and Recommended Practices for Healthcare Records Management. In particular, there was evidence of retrospective entry of information. ■ There were delays in accessing patient healthcare records, particularly outside office hours.

Appendix 15: HSE Compliance Failures

NS No	National Standard	HSE Compliance Failures
NS 2.1	***Healthcare reflects national and international evidence of what is known to achieve best outcomes for service users.***	■ The governance structure for the prioritisation, development, dissemination and monitoring of usage of policies, guidelines, protocols and care pathways based on best available evidence was not effective. ■ There were no arrangements in place to ensure that national care programmes took account of information from sources such as claims, complaints, incidents, confidential enquiries and investigations when developing national guidelines and policies.
NS 2.3	***Service users receive integrated care which is coordinated effectively within and between services.***	■ There was no national system in place, at the time of the investigation, for recording the numbers of maternity patients who require access to level 3 critical care each year. ■ Seven of the 19 maternity service providers did not have effective governance arrangements in place to ensure that clinically deteriorating patients are transferred within and between services safely and there is continuity of care provision.

NS 2.5	***All information necessary to support the provision of effective care, including information provided by the service user, is available at the point of clinical decision making.***	■ There was no national policy for effective communication and handover of patient information. ■ The National Maternity Healthcare Record was in use in 5 of the 19 hospitals providing maternity services.
NS 2.6	***Care is provided through a model of service designed to deliver high quality, safe and reliable healthcare.***	■ There was no national strategy that described the models or pathways of maternity care ■ There was no evidence of a national review of multidisciplinary maternity workforce arrangements, or national population-based needs assessment, undertaken to demonstrate the appropriate allocation of resources for the provision of maternity services in Ireland.
NS 2.8	***The effectiveness of healthcare is systematically monitored, evaluated and continuously improved***	■ There were no national key performance indicators for maternity services in place. ■ There was no national integrated approach to evaluate the safety and effectiveness of the maternity services.

NS 3.1	***Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services.***	■ There was no national integrated approach to collating, disseminating and implementing the learning and recommendations gathered from, amongst other things: - Coroner's Inquests - Claims - Complaints - Patient feedback - Findings and recommendations from local, national and international reviews and investigations. ■ In 2012, there was no formal process for the implementation of recommendations of the Confidential Maternal Death Enquiries. This process is now in development.

NS 3.2	***Service providers monitor and learn from information relevant to the provision of safe services and actively promote learning both internally and externally.***	■ There was no centralised and consistent approach to reporting on maternal morbidity and mortality. ■ There were no arrangements to gather, analyse and implement learning from national and international information. ■ The HSE did not ensure the implementation of the recommendations of The HSE's Report into the circumstances pertaining to the death of Tania McCabe and her infant son Zach at Our Lady of Lourdes Hospital, Drogheda on 9 March 2007. This report and its recommendations had particular relevance in the care of Savita Halappanavar. ■ Five of the 19 hospitals/ units provided a detailed status update for all 27 recommendations of the above Report, with one hospital/unit reporting that 24 out of 27 recommendations were implemented. Six of the 19 maternity hospitals/units reported their status against a different investigation, had no comment, or reported that evidence for implementation was not in existence.
NS 3.3	***Service providers effectively identify, manage, respond to and report on patient-safety incidents.***	■ There was potential for confused accountability in respect of the reporting, management and learning from national incidents.

NS 5.1	***Service providers have clear accountability arrangements to achieve the delivery of high quality, safe and reliable healthcare.***	■ Named accountability and delegated responsibility for the dissemination of learning, the implementation and monitoring of recommendations within defined timelines and the incorporation of national learning into future clinical guidelines, clinical audit activity and health policy was not clear. ■ The roles and responsibilities of the National Clinical Care Programme leads were not widely understood.
NS 5.2	***Service providers have formalised governance arrangements for assuring the delivery of high quality, safe and reliable healthcare.***	■ There were a range of governance structures and oversight arrangements in place for the delivery of public maternity services in Ireland. ■ There were no national governance arrangements in place to assure the safety and quality of care provided in each of the 19 centres providing maternity services in Ireland. ■ There was no national governance structure for microbiological reference laboratories in place.

NS 5.8	***Service providers have systematic monitoring arrangements for identifying and acting on opportunities to continually improve the quality, safety and reliability of healthcare services***	■ The HSE did not have in place arrangements to monitor the performance and quality of the maternity service nationally due to the lack of accessible, consistent and reproducible data ■ The HSE did not have formal arrangements in place to ensure the sharing of information and learning from reported incidents both at a national and local level.
NS 6.4	***Service providers support their workforce in delivering high quality, safe and reliable healthcare***	■ The HSE policy Preventing and Managing Critical Incident Stress (2012) did not make any particular reference to support for staff throughout an incident management or an investigation process. ■ There was no national audit mechanism in place to ensure that the support for staff is occurring consistently and to a satisfactory standard within the system, during an incident management or incident investigation process.

NS 8.1	***Service providers use information as a resource in planning, delivering and improving the quality, safety and reliability of healthcare services***	■ The quality of data being collected varied among the maternity units and the definitions for the reporting of maternal sepsis were not standardised across the maternity units. ■ There was no agreed national dataset of quality and safety measures for maternity services in Ireland. ■ There were no national definitions of sepsis to facilitate reporting of sepsis-related morbidity data. ■ There is no national laboratory-based alert system that allows real-time analysis of data from local or national laboratory information systems, in order to facilitate timely recognition of emerging national microbial threats including antimicrobial resistance.
NS 8.3	***Service providers have effective arrangements in place for the management of healthcare records***	■ There was no standardised practice in relation to healthcare record management in place across all maternity services.

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