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

Executive Summary and Recommendations

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.

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, 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.

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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.

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 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.

* 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.

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.

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For further information please contact:

Health Information and Quality Authority
Dublin Regional Office
George's Court
George's Lane
Smithfield
Dublin 7

Phone: +353 (0) 1 814 7400
URL: www.hiqa.ie